Nurofen Express 200mg Liquid Capsules: Each capsule contains Ibuprofen 200 mg. **Indication**: For the symptomatic relief of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness colds and influenza symptoms. **Dosage and Administration**: Adults and children over 12 years: Take one or two capsules, up to three times a day as required. Leave at least 4 hours between doses. Do not take more than 6 capsules in any 24 hour period. Not for use by children under 12 years of age. Do not use for more than 10 days, or if symptoms worsen, without medical advice. **Contraindications:** Known hypersensitivity to ibuprofen or other ingredients. History of bronchospasm, asthma, rhinitis, or urticaria, associated with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). History of, or existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. Severe hepatic failure, severe renal failure or severe heart failure. Concomitant NSAIDs, including COX-2 inhibitors. Last trimester of pregnancy. **Special warnings and precautions:** SLE and mixed connective tissue disease. Gastrointestinal disorders and chronic inflammatory intestinal disease. Hypertension and/or cardiac impairment. Renal impairment. Hepatic dysfunction. Bronchial asthma or allergic disease. GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of GI events. Caution with concomitant medications which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin. Withdraw treatment if GI bleeding or ulceration occurs. Possible reversible effects on fertility. Avoid use during the first 6 months of pregnancy if possible. Patients with rare hereditary problems of fructose intolerance should not take this medicine. **Side effects:** Hypersensitivity reactions including: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea, (c) various skin reactions e.g. pruritus, urticaria, angiodemaand more rarely exfoliative and bullous dermatoses (including epidermal necrolysis anderythema multiforme). Gastrointestinal disturbance including: peptic ulcer, perforation or GI haemorrhage, headache, acute renal failure, liver disorders, haematopoietic disorders including anaemia. **Product Licence Numbers**: GSL: PL 00063/0648 (previously PL 00327/0202) and P: PL 00063/0654 (previously PL 00327/0201) **Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd, SL1 4AQ (previously Crookes Healthcare Limited). **Legal category:** GSL MRRPs: Express Liquid Capsules 10s: £3.12, 16s: £4.09, 30s (pharmacy only): £6.47; **Date of preparation**: August 2011 – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Nuromol 200mg/500mg tablets (film-coated): Active ingredients: Each tablet contains ibuprofen (200mg) and paracetamol (500mg). **Indications:** For the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever. This product is especially suitable for pain which requires stronger analgesia than ibuprofen or paracetamol alone. **Dosage instructions:** *Adults over 18 yrs*: One tablet to be taken up to three times per day with water. If needed, dose may be increased to two tablets three times a day. Leave at least six hours between doses. Maximum of 6 tablets per 24 hours. To minimise side effects it is recommended that patients take Nuromol with food. If symptoms persist, worsen or if the product is required for more than 3 days, the patient should consult a doctor. *Elderly*: The lowest effective dose should be used for the lowest possible duration. The patient should be monitored regularly for gastrointestinal bleeding when using a NSAID. **Contra-indications:** Known hypersensitivity to ibuprofen, paracetamol or any other excipients. History of hypersensitivity reactions associated with acetylsalicylic acid/NSAIDs. History of, or an existing gastrointestinal ulceration/perforation or bleeding, defects in coagulation, severe hepatic failure, severe renal failure or severe heart failure. Do not give : in concomitant use with other paracetamol-containing products, in concomitant use with other NSAID containing products, including cyclo-oxygenase-2 (COX-2) specific inhibitors and doses of acetylsalicylic acid above 75 mg daily, during the last trimester of pregnancy. **Side effects, precautions:** The risk of paracetamol overdose is greater in patients with non-cirrhotic alcoholic liver disease. Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed, serious liver damage. Caution is required in elderly patients and in patients with certain conditions: respiratory disorders, cardiovascular, cerebrovascular, renal and hepatic impairment, gastrointestinal bleeding, ulceration and perforation, SLE and mixed connective tissue disease. Serious skin conditions and impaired female fertility may occur. *Warnings for use:* do not give to patients who have taken ibuprofen or paracetamol in the last 6 hours; do not give in combination with paracetamol or NSAID containing medicine. *Common side effects:* abdominal pain, diarrhoea, dyspepsia, nausea, stomach discomfort and vomiting. Increase in amino-transferase, gammaglutamyltransferase, blood creatine, blood urea, liver disfunction. **Recommended retail price**: (ex. VAT): 3.99 per 12 tabs. **Supply classification:** P **Marketing authorisation holder:** Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 3UH **MA number:** PL 00063/0649 (formerly PL 00063/0579). **Date last revised:** November 2011 – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Nurofen Plus: Each tablet contains 200mg ibuprofen and 12.8mg of Codeine phosphate. **Indications**: For the short term treatment of acute, moderate pain (such as rheumatic and muscular pain, backache, migraine, headache, neuralgia, period pain and dental pain) which is not relieved by paracetamol, ibuprofen or aspirin alone. **Dosage and Administration**: Adults, the elderly and children over 12 years: Take 1 or 2 tablets with water every 4 to 6 hours. Leave at least 4 hours between doses and do not take more than 1200mg of ibuprofen in any 24 hour period. Do not exceed 6 tablets in any 24 hours. Not for use by children under 12 years of age. Do not use for more than 3 days continuously without medical review, or if symptoms persist or worsen. **Contraindications**: Known hypersensitivity to ibuprofen, codeine or other ingredients. History of bronchospasm, asthma, rhinitis, or urticaria, associated with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). History of, or existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. Severe hepatic failure, severe renal failure, severe heart failure, respiratory depression or chronic constipation. Concomitant NSAIDs, including COX-2 inhibitors. Last trimester of pregnancy. **Special warnings and precautions for use**: Caution with concomitant medications which could increase the risk of gastrotoxicity or bleeding. Withdraw treatment if GI bleeding or ulceration occurs. Patient with a deficiency of CYP2D6 may not obtain adequate analgesic effects. Patient which are ultra-rapid metaboliser of CYP2D6 have increased risk of developing side effects of opioid toxicity at low doses. Increased risk of meningitis in patients with SLE and mixed connective tissue disease. Avoid use during the first 6 months of pregnancy if possible. This medicine contains codeine which can cause addiction if taken continuously for more than three days. See SPC for full information. **Side effects**: ibuprofen related side effects; Hypersensitivity reactions which may include: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity (c) skin reactions..Gastrointestinal disturbance, uncommon:, headache, vary rare: acute renal failure, liver disorders, haematopoietic disorders. Codeine related side effects include constipation, respiratory depression, cough suppression, nausea and drowsiness. **Product Licence Number**: PL 00063/0376. **Licence Holder**: Reckitt Benckiser Healthcare (UK) Ltd, SL1 4AQ. **Legal category**: Pharmacy Only **MRRP**: £ 6.99 (32 tablets) **Date**: November 2011 – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Nurofen Express Heat Patches: Non-medicated device. Always read the instructions. Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd, HU8 7DS. **Legal category:** GSL **MRRP:** £3.99 (Regular) £4.99 (Large) (2 patches) **Date**: December 2012.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Nurofen Maximum Strength 10% Gel 10% w/w Ibuprofen gel. **Indications:** For the relief of pain and inflammation associated with backache, rheumatic pain, muscular aches, pains or swellings such as sprains, strains and sports injuries. **Dosage instructions:** Adults, the elderly, and children over 12 years: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel (50mg to 125 mg ibuprofen) from the tube and lightly rub into the affected area until absorbed. Use up to four times daily with individual doses administered at least 4 hours apart. Patients should not apply more than 500mg ibuprofen (approximately 5g gel) in any 24 hour period. Wash hands after each application. Review treatment after 2 weeks, especially if the symptoms worsen or persist. **Contraindications:** Hypersensitivity to any of the constituents. Hypersensitivity to aspirin or other non-steroidal anti-inflammatory drugs, asthma, rhinitis or urticaria. Not to be used during pregnancy or lactation. **Special warnings and precautions:** Apply with gentle massage only. Avoid contact with eyes, mucous membranes and inflamed, broken or damaged skin. Discontinue if rash develops. Hands should be washed immediately after use. Not for use with occlusive dressings. Patients with an active peptic ulcer, a history of kidney problems, asthma or intolerance to aspirin or ibuprofen taken orally should seek medical advice before using Ibuprofen gel. Patients should be advised against excessive exposure to sunlight of area treated in order to avoid possibility of photosensitivity. **Side effects:** Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types. Gastro-intestinal: abdominal pain, dyspepsia. **PL number:** PL 10972/0089. **Licence holder:** Mercury Pharma Group Ltd, CR0 0XT, UK and distributed by Reckitt Benckiser Healthcare (UK) Ltd. **Legal category:** GSL. **MRRP:** £6.99 (40g). **Date of preparation:** February 2013. For full information refer to SPC (http://www.medicines.org.uk/emc/).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Nurofen 5% Gel 5% w/w Ibuprofen gel. **Indications:** Topical analgesic and anti-inflammatory for backache, rheumatic and muscular pain, sprains, strains and sports injuries. **Dosage instructions:** Adults, the elderly and children over 14 years: Squeeze 4 to 10cm of the gel (equivalent to 50 to 125 mg of ibuprofen) from the tube and lightly rub into the affected area until absorbed. The dose should not be repeated more frequently than every four hours and no more than 4 times in any 24 hour period. Wash hands after each application. Do not exceed the stated dose. Review treatment after 2 weeks, especially if the symptoms worsen or persist. Do not use on children under 14 years of age except on the advice of a doctor. **Contraindications:** Hypersensitivity to any of the constituents. Hypersensitivity to aspirin or other non-steroidal anti-inflammatory drugs, asthma, rhinitis or urticaria. Not to be used during pregnancy or lactation. **Special warnings and precautions:** Apply with gentle massage only. Avoid contact with eyes, mucous membranes and inflamed, broken or damaged skin. Discontinue if rash develops. Hands should be washed immediately after use. Not for use with occlusive dressings. Patients with an active peptic ulcer, a history of kidney problems, asthma or intolerance to aspirin or ibuprofen taken orally should seek medical advice before using Ibuprofen gel. Patients should be advised against excessive exposure to sunlight of area treated in order to avoid possibility of photosensitivity. **Side effects:** Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types. Gastro-intestinal: abdominal pain, dyspepsia. **PL number:** PL 10972/0045. **Licence holder:** Mercury Pharma Group Ltd, CR0 0XT, UK and distributed by Reckitt Benckiser Healthcare (UK) Ltd. **Legal category:** GSL. **MRRP:** £4.99 (35g). **Date of preparation:** December 2012. For full information refer to SPC (http://www.medicines.org.uk/emc/).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN ORANGE 3 MONTHS TO 12 YEARS: Suspension of ibuprofen 100mg/5ml. **Indications:** Prescription only: For symptomatic treatment of Juvenile Rheumatoid Arthritis. Prescription and OTC: For the fast and effective reduction of fever, including post immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as a sore throat, teething pain, toothache, earache, headache, minor aches and sprains. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). For post immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult your doctor. Not suitable for children under 3 months of age unless advised by doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0665. **Legal Category:** P **MRRP:** £6.49 (200ml) **Date of preparation:** August 2011 - For full information refer to SPC. (http://www.medicines.org.uk/emc/).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN STRAWBERRY 3 MONTHS TO 12 YEARS: Suspension of ibuprofen 100mg/5ml. **Indications:** Prescription only: For symptomatic treatment of Juvenile Rheumatoid Arthritis. Prescription and OTC: For the fast and effective reduction of fever, including post immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as a sore throat, teething pain, toothache, earache, headache, minor aches and sprains. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). For post immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult your doctor. Not suitable for children under 3 months of age unless advised by doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd. SL1 4AQ **Product Licence Number:** PL 00063/0666 **Legal Category:** P **MRRP:** £6.49 (200ml) **Date of preparation:** August 2011 - For full information refer to SPC. (http://www.medicines.org.uk/emc/).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS ORANGE / NUROFEN FOR CHILDREN ORANGE BABY / NUROFEN FOR CHILDREN ORANGE: Ibuprofen 100mg/5ml (equivalent to 2% w/v). **Indications:** Prescription and OTC: For the fast and effective reduction of fever, including post-immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as sore throat, headache, minor aches and sprains. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). For post immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult a doctor. Not suitable for children under 3 months of age unless advised by the doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing, peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0668 **Legal Category:** GSL **MRRP:** £3.99 (100 ml) **Date of preparation:** September 2011 - For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS STRAWBERRY / NUROFEN FOR CHILDREN STRAWBERRY BABY: Ibuprofen 100mg/5ml (equivalent to 2% w/v). **Indications:** Prescription and OTC: For the fast and effective reduction of fever, including post-immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as sore throat, headache, minor aches and sprains. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). For post immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult a doctor. Not suitable for children under 3 months of age unless advised by the doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing, peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0667 **Legal Category:** GSL **MRRP:** £3.99 (100 ml) **Date of preparation:** September 2011 - For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN Cold, Pain and Fever Strawberry Flavour 100mg/5mL Oral Suspension : Ibuprofen 100mg/5ml (equivalent to 2% w/v). **Indications:** Prescription and OTC: For the fast and effective reduction of fever, including post-immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as sore throat, headache, minor aches and sprains. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). For post immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult a doctor. Not suitable for children under 3 months of age unless advised by the doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing, peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0667 **Legal Category:** GSL **MRRP:** £3.99 (100 ml) **Date of preparation:** November 2012 – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN Cold, Pain and Fever Orange Flavour 100mg/5mL Oral Suspension : Ibuprofen 100mg/5ml (equivalent to 2% w/v). **Indications:** Prescription and OTC: For the fast and effective reduction of fever, including post-immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as sore throat, headache, minor aches and sprains. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). For post immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult a doctor. Not suitable for children under 3 months of age unless advised by the doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing, peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0668 **Legal Category:** GSL **MRRP:** £3.99 (100 ml) **Date of preparation:** November 2012 – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN ORANGE SINGLES: Suspension of ibuprofen 100mg/5ml. **Indications:** For the treatment of rheumatic or muscular pain, headache, dental pain, feverishness, or symptoms of colds and influenza. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). Not suitable for children under 3 months of age unless advised by doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0669 **Legal Category:** GSL **MRRP:** £3.11 (8 sachets of 5 ml), £5.54 (16 sachets of 5 ml) **Date of preparation:** August 2011 - For full information refer to SPC (http://www.medicines.org.uk/emc/).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

NUROFEN FOR CHILDREN STRAWBERRY SINGLES: Suspension of ibuprofen 100mg/5ml. **Indications:** For the treatment of rheumatic or muscular pain, headache, dental pain, feverishness, or symptoms of colds and influenza. **Dosage:** For pain and fever: 20-30mg/kg bodyweight daily in divided doses (see pack for details). Not suitable for children under 3 months of age unless advised by doctor. For oral administration and short term use only. **Contraindications:** Hypersensitivity to constituents in the product. History of, or existing peptic ulceration. History of asthma, rhinitis, urticaria, gastrointestinal bleeding or perforation associated with aspirin or other NSAIDs. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and Warnings:** Do not exceed the stated dose. A doctor should be consulted if symptoms persist for more than 3 days (for a child aged over 6 months); for children under 6 months, seek medical advice if symptoms persist after 24 hours use (3 doses). Do not take if you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding; are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers; are taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult your doctor before use if you are pregnant, a smoker, have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems. **Side Effects:** Hypersensitivity reactions including (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, and (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia. **Product Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd., SL1 4AQ **Product Licence Number:** PL 00063/0670 **Legal Category:** GSL **MRRP:** £3.11 (8 sachets of 5 ml), £5.54 (16 sachets of 5 ml) **Date of preparation:** August 2011 - For full information refer to SPC (http://www.medicines.org.uk/emc/).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

E45 Cream Active Ingredients: White Soft Paraffin 14.5% w/w, Light Liquid Paraffin 12.6% w/w and Anhydrous Lanolin 1.0% w/w. **Indications:** For the symptomatic relief of dry skin conditions, where the use of an emollient is indicated, such as flaking, chapped skin, ichthyosis, traumatic dermatitis, sunburn, the dry stage of eczema and certain dry cases of psoriasis. **Dosage and administration:** Adults, children, infants over 1 month of age and elderly: Apply to the affected part two or three times daily. **Contra-indications:** E45 Cream should not be used by patients who are sensitive to any of the ingredients. **Precautions and Warnings:** For external use only. If symptoms persist, consult your doctor. **Side effects:** Occasionally, hypersensitivity reactions. For further information, consult the SmPC. **Product licence number:** PL 00063/0404 **Product licence holder:** Reckitt Benckiser Healthcare (UK) Ltd, Wellcroft Road Slough, SL1 4AQ United Kingdom **Legal category:** GSL **MRRP:** £1.40 50g, £2.55 125g, £4.89 500g (excl VAT) **Date of preparation:** September 2013

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

E45 Moisturising Lotion

Size 200ml and 500ml

MLS ACBS and ACBS

Description: E45 Lotion is light, unperfumed and can be used all over your body, face and hands to care for dry sensitive skin. Use it every day to help keep your skin soft, supple and moisturised and to prevent it from becoming dry. The gentle, hypo-allergenic formulation is easily absorbed and can be used on sensitive skin. E45 Lotion is suitable for the whole family including babies.

E45 Itch Relief Cream Active Ingredients: Lauromacrogols 3.0% w/w and Urea 5.0%w/w. **Indications:** For the treatment of pruritus, eczema, dermatitis and scaling skin conditions where an antipruritic and/or hydrating effect is required. It may also be used for the continued treatment and follow-up treatment of these skin diseases. **Dosage and administration:** Adults, children, infants over 1 month of age and elderly: Apply to each affected area twice a day. The duration of treatment depends on the clinical response. **Contra-indications**: Paients with known hypersensitivity to any of the ingredients. It should not be used to treat acute erythroderma, acute inflammatory, oozing or infected skin lesions. **Precautions and Warnings:** May cause irritation if applied to broken or inflamed skin. **Side effects:** E45 Itch Relief Cream has been reported to cause a burning sensation, erythema, pruritus or the formation of pustules. Consult the SPC for further information.**Product licence number:** PL 00327/0122 **Product licence holder:** Crookes Healthcare Ltd, Nottingham, NG2 3AA **Legal category:** GSL **MRRP:** £2.55 50g, £3.47 100g, £14.99 500g (excl VAT) **Date of preparation:** September 2013.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Gaviscon Double Action Mint: Active ingredients: Each 10ml dose contains sodium alginate 500mg, sodium bicarbonate 213mg and calcium carbonate 325mg. Also contains methyl and propyl hydroxybenzoates and sodium saccharin. **Indications:** Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example, following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity). **Dosage instructions:** For oral administration. Adults and children 12 years and over: 10-20ml after meals and at bedtime, up to four times per day. Children under 12 years: Should be given only on medical advice. Elderly: No dose modifications necessary for this age group.
Contraindications: Hypersensitivity to any of the ingredients, including the esters of hydroxybenzoates (parabens). **Precautions and warnings:** Each 20 ml dose has a sodium content of 254.5 mg (11.06 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment. Each 20 ml contains 260 mg (6.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. Treatment of children younger than 12 years of age is not generally recommended, except on medical advice. If symptoms do not improve after seven days, the clinical situation should be reviewed.
Due to the presence of calcium carbonate which act as an antacid, a time-interval of 2 hours should be considered between Gaviscon intake an the administration of other medicinal products, especially H2-antihistaminics tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, and diphosphonates. **Pregnancy and lactation:** Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience the medicinal product may be used during pregnancy and lactation. **Side-effects:** Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. Ingestion of large quantities of calcium carbonate may cause alkalosis, hypercalcaemia, acid rebound, milk alkali syndrome or constipation. These usually occur following larger than recommended dosages. **Retail price: (Ex. VAT).** 300 ml £5.85, 150mL £3.60. **Marketing authorisation:** 00063/0552. **Supply classification:** GSL**. Holder of marketing authorization:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull HU8 7DS. **Date of preparation:** February, 2011.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Gaviscon Double Action Tablets: Active ingredients: Each tablet contains sodium alginate 250 mg, sodium bicarbonate 106.5mg and calcium carbonate 187.5mg. Also contains mannitol, aspartame and xylitol. **Indications:** Treatment of acid related symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy. **Dosage Instructions:** For oral administration, after being thoroughly chewed. Adults and children 12 years and over: Two to four tablets after meals and at bedtime, up to four times per day. Children under 12 years: Should be given only on medical advice. Elderly: No dose modifications necessary for this age group. **Contraindications:** This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients. **Precautions and warnings:** The sodium content of a two-tablet dose is 110.75 mg (4.82 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment. Each two-tablet dose contains 150 mg (3.75 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. Due to its aspartame content this product should not be given to patients with phenylketonuria. If symptoms do not improve after seven days, the clinical situation should be reviewed. Prolonged use should be avoided. As with other antacid products, taking Gaviscon Double Action Tablets can mask the symptoms of other more serious, underlying medical conditions. Gaviscon Double Action Tablets should not be used in the following cases: Patients with server/impaired renal function/-insufficiency Patients with hypophosphatemia. There is a possibility of reduced efficacy in patients with very low levels of gastric acid. There is increased risk for hypernatremia in children with gastroenteritis or suspected renal insufficiency. Treatment of children younger than 12 years of age is not generally recommended, except on medical advice. Due to the presence of calcium carbonate which acts as an antacid, a time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially H2-antihistaminics, tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine and diphosphonates. **Pregnancy and lactation :** Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience, the medicinal product may be used during pregnancy and lactation. Nevertheless, taking into account the presence of calcium carbonate it is recommended to limit the treatment duration as much as possible. **Side-effects:** Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. Ingestion of large quantities of calcium carbonate may cause alkalosis, hypercalcaemia, acid rebound, milk alkali syndrome or constipation. These usually occur following larger than recommended dosages. **Retail price:** (Ex. VAT).Gaviscon Double Action Tablets, 8 tablets - £1.80, 16 tablets - £2.69, 32 tablets - £4.49. **Marketing authorisation:** PL 00063/0157 **Supply classification:** GSL **Holder of marketing authorisation:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull HU8 7DS. **Date of preparation:** March, 2012.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Gaviscon Advance Peppermint Flavour Oral Suspension and Gaviscon Advance Aniseed Suspension: Active substances Each 5 ml dose contains sodium alginate 500.0mg and potassium hydrogen carbonate 100.0mg. **Indications:** Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn, indigestion (occurring due to the reflux of stomach contents), for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy, accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough. Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy. **Dosage Instructions:** Adults and children 12 years and over: 5-10 ml after meals and at bedtime (one to two 5 ml measuring spoons). Children under 12 years: Should be given only on medical advice. Elderly: No dose modification is required for this age group **Contraindications:** Hypersensitivity to any of the ingredients, including the esters of hydroxybenzoates (parabens). **Precautions and Warnings:** Each 10 ml dose has a sodium content of 106 mg (4.6 mmol) and a potassium content of 78 mg (2.0 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment or when taking drugs which can increase plasma potassium levels.Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. There is a possibility of reduced efficacy in patients with very low levels of gastric acid. If symptoms do not improve after seven days, the clinical situation should be reviewed. This medicinal product contains Methyl hydroxybenzoate and Propyl hydroxybenzoate, which may cause allergic reactions (possibly delayed). **Side-Effects:** Very rarely (<1/10,000) patients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. **Retail Price:** Gaviscon Advance Peppermint Flavour Oral Suspension and Gaviscon Advance Aniseed Suspension- - 150ml £4.99, 300ml £8.79. **Marketing Authorisation:** Gaviscon Advance Peppermint Flavour Oral Suspension- PL 00063/0612. Gaviscon Advance Aniseed Suspension - PL 00063/0108. **Supply Classification : P Marketing authorisation Holder:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS. **Date of Preparation:** January 2013.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Strepsils Extra Strength Blackcurrant

Strepsils Extra Strength Blackcurrant (PL 00063/0392), **Active Ingredients:** Hexylresorcinol 2.4mg. **Indication:** As an antiseptic and local anaesthetic for the relief of sore throat and its associated pain. **Dosage Instructions**: For oral administration. Adults and children (over 6 years old): One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours. Not suitable for children under 6 years. Elderly: There is no need for dosage reduction in the elderly. **Contraindications**: Hypersensitivity to any of the ingredients. **Warnings & Precautions:** Keep all medicines out of the reach of children.If symptoms persist consult your doctor. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. **Side Effects:** Occasional hypersensitivity reactions. Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic. **MRRP:** Strepsils Honey and Lemon 24s £3.69 Strepsils Extra 24s £4.09. **Legal classification**: GSL. **License Holder:** Reckitt Benckiser Healthcare UK Ltd., Slough, SL1 3UH. **Prepared:** 18/06/2013

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Strepsils Honey and Lemon

Strepsils Honey and Lemon (PL 00063/0397), **Active Ingredients:** Amylmetacresol 0.6mg, 2,4-Dichlorobenzyl alcohol 1.2mg. **Indication:** For the symptomatic relief of mouth and throat infections. **Dosage Instructions**: For oral administration. Adults and children (over 6 years old): One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours. Not suitable for children under 6 years. Elderly: There is no need for dosage reduction in the elderly. **Contraindications**: Hypersensitivity to any of the ingredients. **Warnings & Precautions:** Keep all medicines out of the reach of children.If symptoms persist consult your doctor. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. **Side Effects:** Occasional hypersensitivity reactions. Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic. **MRRP:**
Strepsils Honey and Lemon 24s £3.69 Strepsils Extra 24s £4.09. **Legal classification**: GSL. **License Holder:** Reckitt Benckiser Healthcare UK Ltd., Slough, SL1 3UH. **Prepared:** 18/06/2013

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

STREFEN HONEY & LEMON

Name and actives: Strefen Honey & Lemon contains Flurbiprofen BP 8.75mg per lozenge **Indication:** Symptomatic relief of sore throat **Dosage and administration:** Adults and children over the age of 12 years: One lozenge sucked/dissolved slowly in the mouth every 3 - 6 hours as required. Maximum 5 lozenges in a 24 hour period. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 3 days. It is recommended that this product should be used for a maximum of three days. **Children:** Not indicated for children under 12 years. **Elderly**: No dose modification is required. As with all lozenges, to avoid local irritation, Strefen Honey and Lemon should be moved around the mouth whilst sucking. **Contraindications:** Hypersensitivity to flurbiprofen or any of the excipients in the product. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs. Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). History of gastrointestinal bleeding or perforation, related to previous NSAIDS therapy. Severe heart failure, renal failure or hepatic failure. Last trimester of pregnancy. **Special warnings and precautions for use:** Pregnancy and lactation: Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Strefen Honey and Lemon should, if possible, be avoided during the first 6 months of pregnancy. During the 3rd trimester, flurbiprofen is contraindicated as there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. Flurbiprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely. **Undesirable effects:** Strefen Honey and Lemon have the potential for inducing transient local irritation of the buccal mucosa. The most frequently reported adverse event in clinical trials was taste perversion. Hypersensitivity reactions have been reported and these may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea (c) various skin reactions e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme) The list of the following adverse effects relates to those experienced with NSAIDS at doses available over the counter for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur. Hypersensitivity reactions:Uncommon: Hypersensitivity reactions with urticaria and pruritis Very rare: severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock).Exacerbation of asthma and bronchospasm. Gastrointestinal:The most commonly observed adverse events are gastrointestinal in nature.Uncommon: abdominal pain, nausea, dyspepsia Rare: Diarrhoea, flatulence, constipation and vomiting
Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis. Exacerbation of colitis and Crohn's disease Nervous System:Uncommon: Headache Very rare: Aseptic meningitis – single cases have been reported very rarely.Renal: Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum and oedema.

Hepatic:Very rare: liver disorders.Haematological:Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.Dermatological:Uncommon: Various skin rashes Very rare: Severe forms of skin reactions such as bullous reactions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur. Immune System: In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed Cardiovascular and Cerebrovascular Oedema, hypertension and cardiac failure, have been reported in association with NSAID treatment.
Clinical trial and epidemiological data suggest that the use of NSAIDS (particularly at high doses 2400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) **MRRP:** £3.99 16 lozenges **Product licence number:** PL 00327/0135 **Product Licence Holder:** Crookes Healthcare Ltd., Nottingham NG2 3AA **Legal category: P** Date of preparation: 08/06/2012

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Lemsip Max Apple & Cinnamon Flavour Powder for Oral Solution.

Active ingredients: Each sachet contains Paracetamol 1000mg, Phenylephrine hydrochloride 12.2 mg. **Indications:** For relief of the symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion and lowering of temperature. **Dosage Instructions:** Oral administration after dissolution in water. Adults and children over 12: One sachet dissolved by stirring in hot water and sweetened to taste. The dose may be repeated in 4-6 hours. No more than four doses should be taken in 24 hours. Not to be given to children under 12 without medical advice. There is no indication that dosage need be modified in the elderly. **Contraindications:** Hypersensitivity to any of the active substances or any other ingredient. Severe coronary heart disease and cardiovascular disorders. Hypertension. Hyperthyroidism. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors. **Precautions and Warnings:** Use with caution in patients with Raynaud's phenomenon or diabetes mellitus. Each sachet contains approximately 2.2 g of carbohydrate. This product contains 2.2 g sucrose per dose (total sugars 2.2 g). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicinal product contains 5.61 mmol (or 129.0 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet. Due to its aspartame content this product should not be given to patients with phenylketonuria. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Patients should be advised not to take other paracetamol-containing products concurrently. Phenylephrine should be used with care in patients with diabetes mellitus, closed angle glaucoma and prostatic enlargement. **Pregnancy and lactation:** Due to the vasoconstrictive properties of phenylephrine the product should not be used in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion There is no information on use in lactation.. The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. Epidemiological studies in human pregnancy have shown no ill-effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breastmilk, but not in a clinically significant amount. Available published data do not contraindicate breast feeding. **Side-Effects:** Paracetamol: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been a few reports of blood dyscrasias including thrombocytopenia leucopenia, pancytopenia, neutropenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Acute pancreatitis after ingestion of above normal amounts. Phenylephrine hydrochloride, high blood pressure with headache and vomiting, probably only in overdosage. Rarely palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males. **Legal status:** General Sales List. **Price (ex VAT):** £5,49. 5, 7, 9 and 10 sachets. **Marketing Authorisation Number:** PL 00063/0163 **Marketing Authorisation Holder :** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS. **Date of revision of the text:** 16/04/2013

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Lemsip Cold and Flu Lemon (PL 00063/0034)
Active Ingredients: Each sachet contains paracetamol 650mg and phenylephrine hydrochloride 10 mg. **Indications:** For the relief of the symptoms of colds and influenza, including the relief of aches and pains and nasal congestion, sore throat and lowering of temperature.
Dosage & Administration: Oral administration after dissolution in water. Adults and children 12 years and over: Contents of one sachet dissolved by stirring in hot water and sweetened to taste. The dose may be repeated every 4 to 6 hours as required. No more than four doses should be taken in 24 hours. There is no indication that dosage need be modified for the elderly. Not to be given to children under 12. **Contraindications:** Hypersensitivity to paracetamol, phenylephrine or any other ingredient, severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors. **Warnings & Precautions**: Use with caution in patients with Raynaud's Phenomenon or diabetes. Each sachet contains approximately 2.6g of carbohydrate. Due to its aspartame content this product should not be given to patients with phenylketonuria. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Patients should be advised not to take other paracetamol-containing products concurrently. Phenylephrine should be used with care in patients with cardiovascular disease, diabetes mellitus, closed angle glaucoma, prostatic enlargement and hypertension. Speed of absorption of paracetamol increased by metoclopramide or domperidone and reduced by cholestyramine. The anticoagulant effect of warfarmn and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Hepatotoxicity of paracetamol increased by alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, particularly after overdose. Hypertensive interactions occur between phenylephrine and monoamine oxidase inhibitors including moclobemide. Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects. Phenylephrine may reduce the efficacy of beta-blockers and antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa). The risk of hypertension and other cardiovascular side effects may be increased. Tricyclic antidepressants (e.g. amitriptyline): may increase the risk of cardiovascular side effects with phenylephrine. Concomitant use of phenylephrine with digoxin and cardiac glycosides may increase the risk of irregular heartbeat or heart attack. **Pregnancy and lactation** : The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding.
Side effects: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been a few reports of blood dyscrasias including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Acute pancreatitis after ingestion of above normal amounts. Adverse effects of Phenylephrine hydrochloride are high blood pressure with headache and vomiting, probably only in overdose. Rarely palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males. **Legal status**: GSL. **Price** (incl VAT): £2.19 5 sachets and £3.39 10 sachets. **Marketing Authorisation number**: PL 00063/0034. **Marketing Authorisation Holder / Manufacturer** : Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull HU8 7DS. Date of revision of text : 19/08/11.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Lemsip Max All in One Cold and Flu Capsules (PL 00063/0551)

Active Ingredients: Each capsule contains Paracetamol 500 mg, Phenylephrine hydrochloride 6.1 mg And Guaifenesin 100mg. **Indications**: For the relief of symptoms of cold and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion, lowering of temperature and chesty coughs. **Dosage Instructions**: Adults (Aged 16 years and over): Two capsules every 4-6 hours to a maximum of four doses in any 24 hours. Do not exceed eight capsules in any 24 hours. Children (12-15 years): One capsule every 4-6 hours to a maximum of four doses in any 24 hours. Do not exceed 4 capsules in any 24 hours. Swallow whole with water. Do not chew. Not recommended for children under 12 years of age. **Contraindications**: Hypersensitivity to any of the ingredients. Severe coronary heart disease and cardiovascular disorders. Hypertension. Hyperthyroidism. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors. **Precautions and Warnings**: Use with caution in patients with Raynaud's phenomenon or diabetes mellitus. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Phenylephrine should be used with care in patients with closed angle glaucoma and prostatic enlargement The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta-blockers. Drugs, which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors because of a risk of hypertensive crisis. Guaifenesin may increase the rate of absorption of paracetamol. Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxy-indoleactic acid or vanillylmandelic acid. **Pregnancy and lactation**: Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk, but not in a clinically significant amount. Available published data do not contraindicate breast-feeding. Phenylephrine hydrochloride: Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation. Guaifenesin: Has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy. The product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation. **Side-Effects**: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Phenylephrine hydrochloride: High blood pressure with headache, vomiting and rarely, palpitations. Also, rare reports of allergic reactions. Guaifenesin has occasionally been reported to cause gastro-intestinal discomfort, nausea and vomiting, particularly in very high doses. **Legal status**: General Sales List. Price (ex VAT): £3.29 8 and £4.29 16 capsules. **Marketing Authorisation Number**: PL 00063/0551 **Marketing Authorisation Holder :** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS. Date of revision of the text: 22/05/11.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Lemsip Cough Max for Mucus Cough & Cold 1000mg/200mg/12.2mg Powder for Oral Solution (PL 00063/0168)

Active Ingredients: Each sachet contains Paracetamol 1000mg, Guaifenesin 200 mg and Phenylephrine hydrochloride 12.2 mg. **Indications:** For the relief of symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion, lowering of temperature and chesty coughs. **Dosage Instructions**: Oral administration after dissolution in water.Adults and adolescents 12 years and over: One sachet dissolved by stirring in hot water and sweetened to taste. Dose may be repeated in 4-6 hours. No more than four doses should be taken in 24 hours. Not to be given to children under 12 without medical advice. **Contraindications**: Hypersensitivity to any of the ingredients. Severe coronary heart disease. Hypertension. **Precautions and Warnings**: Use with caution in patients with Raynaud's phenomenon or diabetes mellitus. This product also contains 1973.3mg sucrose per sachet dose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Contains a source of phenylalanine. May be harmful for people with phenylketonuria. Phenylephrine should be used with care in patients with hyperthyroidism, cardiovascular disease, diabetes mellitus, closed angle glaucoma, prostatic enlargement and hypertension. Speed of absorption of paracetamol increased by metoclopramide or domperidone and reduced by cholestyramine. The anticoagulant effect of warfarmn and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta-blockers. Drugs, which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors. Guaifenesin may increase the rate of absorption of paracetamol. Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxyindoleactic acid or vanillylmandelic acid**. Pregnancy and lactation**: Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk, but not in a clinically significant amount. Available published data do not contraindicate breast-feeding. Phenylephrine hydrochloride: Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation. Guaifenesin: Has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy. The product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation**. Side-Effects**: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Phenylephrine hydrochloride: High blood pressure with headache, vomiting and rarely, palpitations.Also, rare reports of allergic reactions. Guaifenesin has occasionally been reported to cause gastro-intestinal discomfort, nausea and vomiting, particularly in very high doses. **Legal status**: General Sales List**. Price** (ex VAT): £5.49 10 sachets. **Marketing Authorisation Number**: PL 00063/0168. **Marketing Authorisation Holder** : Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS. Date of revision of the text: 22/05/11. – For full information refer to SPC (http://www.medicines.org.uk/emc/)".

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456

Lemsip Cough for Mucus Cough 100mg/2.5mg/5ml Oral Solution (PL 00338/5026R)
Active Ingredients: Each 5ml contains Guaifenesin 100 mg, Cetylpyridinium chloride 2.5mg, Sucrose 1.75g and Purified honey 0.5g. Also contains glucose and ethanol.
Indications: For the symptomatic relief of acute chesty coughs and catarrh associated with influenza, colds and mild throat infections. **Dosage Instructions:** For oral administration. Adults and children over 12: One or two 5ml spoonfuls to be taken and swallowed slowly every three or four hours. Not recommended for children under 12 years.
Contraindications: Hypersensitivity to active substances or to any of the excipients.
Precautions and Warnings: Ask your doctor before use if you suffer from a chronic cough, if you have asthma or are suffering from an acute asthma attack. Stop use and ask a healthcare professional if your cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash, or persistent headache. Do not take with a cough suppressant. Not suitable for children under 12 years. Patients with rare glucose-galactose malabsorption should not take this medicine. Can cause transient abnormality in platelet aggregation patterns determined one hour after ingestion. If urine is collected within 24 hours of a dose of the medicinal product, a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA). **Pregnancy and lactation**: No known contraindications. There is limited amount of data from the use of Guaifenesin in pregnant women. There is no information on use in lactation. Therefore, it should not be used during pregnancy or breastfeeding unless advised by a doctor or a pharmacist. **Side-Effects**: The following side effects may be associated with the use of Guaifenesin. Gastro-intestinal disorders: Nausea and vomiting. Immune system disorders: Hypersensitivity reactions. **Legal status**: General Sales List. **Price**: £3.99 100ml and £5.99 200ml. **Marketing Authorisation Number**: PL 00338/5026R. **Marketing Authorisation Holder** : 103-105 Bath Road, Slough, Berkshire, SL1 3UH UK. Date of revision of the text: 23/03/2013.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Lemsip Cough Max for Mucus Cough & Cold 500mg/100mg/6.1mg Capsules (PL 00063/0551)

Active Ingredients: Each capsule contains Paracetamol 500 mg, Phenylephrine hydrochloride 6.1 mg And Guaifenesin 100mg. **Indications**: For the relief of symptoms of cold and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion, lowering of temperature and chesty coughs. **Dosage Instructions**: Adults (Aged 16 years and over): Two capsules every 4-6 hours to a maximum of four doses in any 24 hours. Do not exceed eight capsules in any 24 hours. Children (12-15 years): One capsule every 4-6 hours to a maximum of four doses in any 24 hours. Do not exceed 4 capsules in any 24 hours. Swallow whole with water. Do not chew. Not recommended for children under 12 years of age. **Contraindications**: Hypersensitivity to any of the ingredients. Severe coronary heart disease and cardiovascular disorders. Hypertension. Hyperthyroidism. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors. **Precautions and Warnings**: Use with caution in patients with Raynaud's phenomenon or diabetes mellitus. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Phenylephrine should be used with care in patients with closed angle glaucoma and prostatic enlargement. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta-blockers. Drugs, which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors because of a risk of hypertensive crisis. Guaifenesin may increase the rate of absorption of paracetamol. Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxy-indoleactic acid or vanillylmandelic acid. **Pregnancy and lactation**: Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk, but not in a clinically significant amount. Available published data do not contraindicate breast-feeding. Phenylephrine hydrochloride: Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation. Guaifenesin: Has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy. The product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation. **Side-Effects**: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Phenylephrine hydrochloride: High blood pressure with headache, vomiting and rarely, palpitations. Also, rare reports of allergic reactions. Guaifenesin has occasionally been reported to cause gastro-intestinal discomfort, nausea and vomiting, particularly in very high doses. **Legal status**: General Sales List. Price: £4.99 16 capsules. **Marketing Authorisation Number**: PL063/0551.**Marketing Authorisation Holder** : Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS. Date of revision of the text: 22/05/11.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456.

Nurofen Cold & Flu: Each tablet contains 200 mg of ibuprofen and 30mg of Pseudoephedrine Hydrochloride. **Indications**: For the relief of symptoms cold and 'flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses. **Dosage and Administration**: Adults and children over 12 years: Take 1 or 2 tablets with water, up to three times a day as required. Leave at least 4 hours between doses. Do not take more than 6 tablets in any 24 hour period. Not for use by children under 12 years of age. Do not use for more than 10 days, or if symptoms worsen, without medical advice. **Contraindications**: Known hypersensitivity to ibuprofen or other ingredients. History of bronchospasm, asthma, rhinitis, or urticaria, associated with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). History of, or existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. Severe hepatic failure, severe renal failure or severe heart failure. Concomitant NSAIDs, including COX-2 inhibitors. Last trimester of pregnancy. Patients with serious cardiovascular disease, tachycardia, hypertension, angina pectoris, hyperthyroidism, diabetes, phaeochromocytoma, closed angle glaucoma, prostatic enlargement. Avoid during lactation. **Special warnings and precautions for use**: SLE and mixed connective tissue disease. Gastrointestinal disorders and chronic inflammatory intestinal disease. Hypertension and/or cardiac impairment. Renal impairment. Hepatic dysfunction. Bronchial asthma or allergic disease. GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of GI events. Caution with concomitant medications which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin. Withdraw treatment if GI bleeding or ulceration occurs. Possible reversible effects on fertility. Avoid use during the first 6 months of pregnancy if possible. **Side effects**: Hypersensitivity reactions including: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea, (c) various skin reactions e.g. pruritus, urticaria, angiodema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme). Gastrointestinal disturbance including: peptic ulcer, perforation or GI haemorrhage, headache, acute renal failure, liver disorders, haematopoietic disorders including anaemia. **Product Licence Number**: PL 00063/0375 (previously PL 00327/0060). **Licence Holder**: Reckitt Benckiser Healthcare (UK) Ltd, SL1 4AQ (previously Crookes Healthcare Limited). **Legal category**: P **MRRP**: £ 5.99 (24 tablets) **Date**: August 2011– For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.. **Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456**

Nurofen Cold & Flu Relief 200mg/5mg Tablets: Each tablet contains: 200.0 mg Ibuprofen and 5.0 mg Phenylephrine hydrochloride. **Indications**: For the relief of symptoms of cold and flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses. **Dosage & Administration:** Adults, the elderly and children over 12 years: Two tablets every 8 hours. Leave at least 4 hours between doses and do not exceed six tablets in any 24 hour period The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.Not to be given to children under 12 years. **Contraindications:** Known hypersensitivity to ibuprofen, phenylephrine hydrochloride or other ingredients. History of bronchospasm, asthma, rhinitis, or urticaria, associated with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). History of, or existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. Severe hepatic failure, severe renal failure or severe heart failure. Concomitant NSAIDs, including COX-2 inhibitors. Last trimester of pregnancy. **Warnings & Precautions**: Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. SLE and mixed connective tissue disease. Gastrointestinal disorders and chronic inflammatory intestinal disease. Hypertension and/or cardiac impairment. Renal or prostate impairment. Hepatic dysfunction. Bronchial asthma or allergic disease. Diabetes mellitus. Glaucoma. GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of GI events. Caution with concomitant medications especially with the ones which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin. Withdraw treatment if GI bleeding or ulceration occurs. Do not use with MAOIs or betablockers. Possible reversible effects on fertility. Avoid use during the first 6 months of pregnancy and breastfeeding. **Side effects:** Hypersensitivity reactions including: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea, (c) various skin reactions e.g. pruritus, urticaria, angiodema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme). Gastrointestinal disturbance including: peptic ulcer, perforation or GI haemorrhage, headache, acute renal failure, liver disorders, haematopoietic disorders including anaemia. Product licence number PL 00063/0541. **Licence Holder**: Reckitt Benckiser Healthcare (UK) Limited, HU8 7DS. **Legal category**: GSL. **MRRP inc**. VAT: £ 5.49 (16 tablets). Date: April 2013. – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456

Nurofen Day & Night Cold & Flu 200mg/5mg Tablets: Each tablet contains: 200.0 mg Ibuprofen and 5.0 mg Phenylephrine hydrochloride. **Indications**: For the relief of symptoms of cold and flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses. **Dosage & Administration:** Adults, the elderly and children over 12 years: Two tablets every 8 hours. Leave at least 4 hours between doses and do not exceed six tablets in any 24 hour period The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.Not to be given to children under 12 years. **Contraindications:** Known hypersensitivity to ibuprofen, phenylephrine hydrochloride or other ingredients. History of bronchospasm, asthma, rhinitis, or urticaria, associated with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). History of, or existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs. Severe hepatic failure, severe renal failure or severe heart failure. Concomitant NSAIDs, including COX-2 inhibitors. Last trimester of pregnancy. **Warnings & Precautions**: Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. SLE and mixed connective tissue disease. Gastrointestinal disorders and chronic inflammatory intestinal disease. Hypertension and/or cardiac impairment. Renal or prostate impairment. Hepatic dysfunction. Bronchial asthma or allergic disease. Diabetes mellitus. Glaucoma. GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of GI events. Caution with concomitant medications especially with the ones which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin. Withdraw treatment if GI bleeding or ulceration occurs. Do not use with MAOIs or betablockers. Possible reversible effects on fertility. Avoid use during the first 6 months of pregnancy and breastfeeding. **Side effects:** Hypersensitivity reactions including: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea, (c) various skin reactions e.g. pruritus, urticaria, angiodema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme). Gastrointestinal disturbance including: peptic ulcer, perforation or GI haemorrhage, headache, acute renal failure, liver disorders, haematopoietic disorders including anaemia. Product licence number PL 00063/0556. **Licence Holder**: Reckitt Benckiser Healthcare (UK) Limited, HU8 7DS. Legal category: GSL. **MRRP**: £ 5.49 (16 tablets). **Date**: April 2013. – For full information refer to SPC (http://www.medicines.org.uk/emc/)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0500 455 456