

Essential Information Nurofen for Children Strawberry Baby / Nurofen for Children 3 months to 9 years Strawberry / Nurofen for Children Cold, Pain and Fever Strawberry Flavour 100mg/5mL Oral Suspension. PL00063/0667

Name and active: Nurofen for Children Strawberry Baby, Nurofen for Children 3 months to 9 years Strawberry, Nurofen for Children Cold, Pain and Fever Strawberry Flavour. Ibuprofen 100mg/5ml (2.0%w/v) Oral suspension. **Therapeutic indications:** 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, headache, minor aches and sprains. **Posology and Administration:** For oral administration. For short term use only. Use the lowest effective dose for the shortest duration necessary to control symptoms. For patients with sensitive stomachs the product can be taken with or after food. For children between 3 months and 9 years of age. The recommended daily dose is 20–30 mg per kg of body weight, divided into equal doses, with dosing intervals of 6–8 hours (see the pack for detail). Leave at least 4 hours between doses. Do not take more than the recommended dose in 24 hours. Do not exceed the recommended dose. Not suitable for children under 3 months. Do not use this product in children weighing less than 5 kg. For infants aged 3–6 months ask for medical advice if symptoms worsen or not later than 24 hours if symptoms persist. If in children from 6 months this medicinal product is required for more than 3 days, or if symptoms worsen, consult a doctor. For children under 6 months ask for medical advice after 24 hours use (3 doses) if the symptoms persist. Special patient groups: children with Juvenile Rheumatoid Arthritis: The usual daily dose of up to 30 to 40 mg per kg of body weight, in three to four divided doses may be taken. Post-immunisation pyrexia: One 2.5 ml dose followed by one further 2.5 ml dose 6 hours later if necessary. Do not exceed two 2.5ml doses in 24 hours. If the fever is not reduced, consult a doctor. **Contraindication:** Hypersensitivity to ibuprofen or to any of the excipients. History of hypersensitivity reactions in response to ibuprofen, acetylsalicylic acid or other NSAIDs. Active or a 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 hepatic failure, renal failure or heart failure. Last trimester of pregnancy. **Precautions and warnings:** Do not give this product if the child is under 3 months old or weighs less than 5 kg; has (or has had two or more episodes of) a stomach ulcer, perforation or bleeding; is allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers, or fructose; is taking other NSAID painkillers, or aspirin with a daily dose above 75mg. Consult a doctor or pharmacist before use for someone who has or had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems; is dehydrated; has chicken pox; smokers; pregnant, breastfeeding or women trying to get pregnant; elderly. You must consult a doctor if symptoms persist or worsen, or if the medicine is needed for more than 24h for a child of 3 to 6 months, or for more than 3 days for a child over 6 months. Contains Maltitol Liquid. **Side effects:** Blood and Lymphatic System Disorders including Haematopoietic disorders, anaemia, leucopenia, thrombocytopenia, pancytopenia and agranulocytosis; Immune System Disorders including hypersensitivity with urticaria and pruritus, severe hypersensitivity reactions, including facial, tongue and throat swelling, dyspnoea, tachycardia, and hypotension (anaphylaxis, angioedema or severe shock); Nervous System Disorders including headache, aseptic meningitis, cardiac disorders including hypertension, Respiratory, Thoracic and Mediastinal Disorders including Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea; Gastrointestinal Disorders including abdominal pain, nausea and dyspepsia, diarrhoea, flatulence, constipation and vomiting, peptic ulcer, gastrointestinal perforation or gastrointestinal haemorrhage, melaena, and haematemesis, mouth ulceration and gastritis, exacerbation of colitis and Crohn's disease; Hepatobiliary Disorders including liver disorders; Skin and Subcutaneous Tissue Disorders including skin rash, Bullous reactions, including Stevens-Johnson Syndrome, erythema multiforme and toxic epidermal necrolysis, Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome); Renal and Urinary Disorders including Acute renal failure, papillary necrosis, especially in

long-term use, associated with increased serum urea and oedema Investigations including haemoglobin decreased; Infections and infestations including exacerbation of infections related inflammation has been described, in exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection. **Legal category:** GSL. **Product licence Numbers:** PL 00063/0667. **Licence Holder:** Reckitt Benckiser Healthcare (UK) Limited HU8 7DS. **Last revision of SmPC:** May 2018. **RRP:** £3.99 100 ml

For full information refer to:

Nurofen for children Strawberry Baby	https://www.medicines.org.uk/emc/product/5616/smpc
Nurofen for children 3 months to 9 years Strawberry	https://www.medicines.org.uk/emc/product/8137/smpc
Nurofen for children Cold Pain and Fever Strawberry Flavour	https://www.medicines.org.uk/emc/product/3249/smpc

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: 0333 200 5345**