Essential Information for: Nurofen for Children 200 mg/5 ml Orange Oral Suspension (PL 00063/0742) & Nurofen for Children 200 mg/5 ml Strawberry Oral Suspension (PL 00063/0743)

Active Ingredients: Each ml of oral suspension contains 40 mg ibuprofen.

Indications: Children aged 7 to 12 years: Rheumatic or muscular pain, headache, dental pain, feverishness, symptoms of cold and influenza.

Dosage and Administration: For oral administration and short-term use only.
Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.
For children weighing more than 20kg, the daily dosage is 20mg/kg bodyweight in divided doses. Using the dosing device provided this can be achieved as follows;
Children 7-9 years: Single dose of 200mg (5ml)(Using the 5ml end of the measuring spoon). Frequency of dosing 3 times in 24 hours.
Children 10-12 years: Single does 300mg (7.5ml)(using the measuring spoon twice (5ml end & 2.5ml end). Frequency of dosing 3 times in 24 hours.
If the child's symptoms persist for more than three days, consult a doctor. This product should only be given to children between 7-12 years of age and weighing more than 20kg. Leave at least four hours between doses and do not give more than the recommended amount in any 24 hours period. For patients with sensitive stomachs it is recommended that Nurofen for Children 200 mg/5 ml orange or strawberry is taken during a meal.
If in children aged 7 to 12 years this medicinal product is required for more than three days, or if symptoms worsen, a doctor should be consulted. This product should only be given to children who weigh more than 20kg.

Special patient groups Renal insufficiency.
No dose reduction is required in patients with mild to moderate impairment to renal function. Hepatic insufficiency No dose reduction is required in patients with mild to moderate impairment to hepatic function.

Contraindications: In patients with hypersensitivity to the active substance or to any of the excipients. In patients who have previously shown hypersensitivity reactions (e.g bronchospasm, asthma, rhinitis, angioedema or urticaria) associated with acetylsalicylic acid, ibuprofen or other non-steroidal anti-inflammatory medicinal products. In patients with a history of gastrointestinal bleeding or perforation, related to previous NSAID therapy. In patients with active, or a history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). In patients with cerebrovascular or other active bleeding. In patients with severe hepatic failure or severe renal failure. In patients with severe heart failure (NYHA IV). In patients with unclarified blood-formation disturbances. During the last trimester of pregnancy. In patients with severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).

Precautions and Warnings: Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.
Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. The elderly are at increased risk of the consequences of adverse reactions. Caution is required in patients with: Systemic lupus erythematosus as well as those with mixed connective tissue disease, due to increased risk of aseptic meningitis. Congenital disorder of porphyrin metabolism (e.g. acute intermittent porphyria). Gastrointestinal disorders and chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease). A history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Renal impairment as renal function may further deteriorate. Hepatic dysfunction. Directly after major surgery. Hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk for them of

allergic reactions occurring. These may be present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria. In patients who have already reacted allergically to other substances as an increased risk of hypersensitivity reactions occurring also exists for them on use of this product. Respiratory Bronchospasm may be precipitated in patients suffering from, or with a history of, bronchial asthma or allergic disease. Other NSAIDs Use with concomitant NSAIDs including cyclo-oxygenase-2 selective inhibitors should be avoided. Gastrointestinal safety: Gastrointestinal bleeding, ulceration or perforation, which can be fatal, have been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.
The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective medicinal products (eg Misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose acetylsalicylic acid, or other medicinal products likely to increase gastrointestinal risk. Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stage of treatment. Caution should be advised in patients receiving concomitant medicinal products which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet medicinal products such as acetylsalicylic acid. When gastrointestinal bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn. NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. Dermatological effects: Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Nurofen for Children 200 mg/5 ml Orange and Strawberry should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Exceptionally, varicella can be at the origin of serious cutaneous and soft tissues infectious complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of ibuprofen in case of varicella. Cardiovascular and cerebrovascular effects Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 mg/day) is associated with an increased risk of arterial thrombotic events. Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided. Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required. Other notes: Severe acute hypersensitivity reactions (for example anaphylactic shock) are observed very rarely. At the first signs of a hypersensitivity reaction after taking/administering Nurofen for Children 200 mg/5 ml Orange or Strawberry therapy must be stopped. Medically required measures, in line with the symptoms, must be initiated by specialist personnel. Ibuprofen may temporarily inhibit the blood-platelet function (thrombocyte aggregation). Patients with coagulation disturbances should therefore be

monitored carefully. In prolonged administration of Nurofen for Children 200 mg/5 ml Orange and strawberry, regular checking of the liver values, the kidney function, as well as of the blood count is required. Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications. Through concomitant consumption of alcohol, active substance-related undesirable effects, particularly those that concern the gastrointestinal tract or the central nervous system, may be increased on use of NSAIDs. NSAIDs may mask symptoms of infection and fever. Renal: In general the habitual use of analgesics, especially the combination of different analgesics, can lead to lasting renal lesions with the risk of renal failure (analgesic nephropathy). There is a risk of renal impairment in dehydrated children. Excipient warnings: This medicinal product contains maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicinal product. This medicinal product contains 1.87 mg sodium per 1 ml suspension. To be taken into consideration by patients on a controlled sodium diet. Wheat starch in Nurofen for Children 200 mg/5 ml Orange Oral Suspension contains only very low levels of gluten, regarded as gluten-free, and is very unlikely to cause problems if you have coeliac disease. One ml contains no more than 0.06 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

Side effects: The adverse events observed most often are gastrointestinal in nature. Adverse events are mostly dose-dependent in particular the risk of occurrence of gastrointestinal bleeding which is dependent on the dose range and duration of treatment. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Clinical studies suggest that use of ibuprofen, particularly at high dose (2400 mg daily), may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Exacerbation of infection-related inflammations (e.g. development of necrotizing fasciitis) coinciding with the use of nonsteroidal anti-inflammatory drugs has been described. This is possibly associated with the mechanism of action of the nonsteroidal anti-inflammatory drugs. If signs of an infection occur or get worse during use of Nurofen for Children 200 mg/5 ml Orange or strawberry, the patient is recommended to go to a doctor without delay. It is to be investigated whether there is an indication for an antimicrobial/antibiotic therapy. The blood count should be checked regularly in long-term therapy. The patient is to be instructed to inform a doctor at once and no longer to take Nurofen for Children 200 mg/5 ml Orange or strawberry if one of the symptoms of hypersensitivity reactions occurs, which can happen even on first use, the immediate assistance of a doctor is required. The patient is to be instructed to withdraw the medicinal product and to go to a doctor immediately if severe pain in the upper abdomen or melaena or haematemesis occurs.

System Organ Class	Frequency	Adverse Event

Infections and infestations	Very rare	Exacerbation of infections related inflammation (e.g development of necrotizing fasciitis), in exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection
Blood and Lymphatic system disorders	Very Rare	Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding and bruising. In such cases, the patient should be advised to discontinue this medicinal product, to avoid any self-medication with analgesics or antipyretics and to consult a physician.
Immune System Disorders	Uncommon	Hypersensitivity reactions consisting of [1]:
		Urticaria and pruritus
	Very rare	Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock). Exacerbation of asthma.
	Not known	Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea.
Psychiatric disorders:	Very rare	Psychotic reactions, depression
Nervous System Disorders	Uncommon	Central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness

	Very Rare	Aseptic meningitis[2]
Eye disorders	Uncommon	Visual disturbances
Ear and labyrinth disorders	Rare	Tinnitus
Cardiac Disorders	Very Rare	Cardiac failure, palpitations and oedema, myocardical infarction
Vascular Disorders	Very rare	Hypertension, vasculitis
Gastrointestinal Disorders	Common	Gastrointestinal complaints such as abdominal pain, nausea and dyspepsia, diarrhoea, flatulence, constipation, heartburn, vomiting and slight gastro-intestinal blood losses that may cause anaemia in exceptional cases.
	Uncommon	Gastrointestinal ulcers, perforation or GI bleeding, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.
	Very Rare	Oesophagitis and formation of intestinal diaphragm-like strictures, pancreatitis.
Hepatobiliary Disorders	Very Rare	Hepatic dysfunction, hepatic damage, particularly in long-term theapy, hepatic failure, acute hepatitis.
Skin and Subcutaneous Tissue Disorders	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, alopecia

	Not Known	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)
Renal and Urinary Disorders	Rare	Kidney-tissue damage (papillary necrosis) and elevated urea concentration in the blood may also occur rarely; elevated uric acid concentrations in the blood.
	Very rare	Formation of oedemas, particularly in patients with arterial hypertension or renal insufficiency, nephrotic syndrome, interstitial nerphritis that may be accompanied by acute renal insufficiency.
Investigations	Rare	Decreased haemoglobin levels

Description of Selected Adverse Reactions

[1]Hypersensitivity reactions have been reported following treatment with Ibuprofen. These may consist of (a) non-specific allergic reaction and anaphlaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely, exfoliative and bullous dermatoses (including toxic epidermal necrolysis, Stevens Johnson Syndrome and erythema multiforme).

[2]The pathogenic mechanism of drug-induced aseptic meningitis is not fully understood. However, the available data on NSAID-related aseptic meningitis points to an immune reaction (due to a temporal relationship with drug intake, and disappearance of symptoms after drug discontinuation). Single cases of symptoms of aseptic meningitis (such as stiff neck, headache, nausea, vomiting, fever or clouding of consciousness) have been observed during treatment with Ibuprofen in patients with existing autoimmune disorders (such as systemic lupus erythematosus, mixed connective tissue disease).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App.

Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) Ltd on: 0333 2005345.

Product licence Number: PL 00063/0742 (Nurofen for Children 200 mg/5 ml Orange Oral Suspension) & Pl 00063/0743 (Nurofen for Children 200 mg/5 ml Strawberry Oral Suspension

Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, HU8 7DS. **Legal category**: P **MRRP**: £6.49**. Date of preparation**: October 2020– For full information refer to SmPC:
https://www.medicines.org.uk/emc/product/10458 - Orange
https://www.medicines.org.uk/emc/product/10459 - Strawberry

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