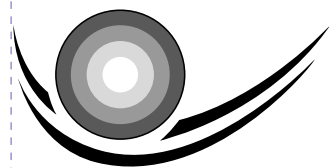


# NUROFEN<sup>®</sup>

for Children

Six Plus **Orange**

200mg / 5ml Oral Suspension



Ibuprofen

6 years to 12 years

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Nurofen for Children carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your child's symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nurofen for Children is and what it is used for
2. Before you use Nurofen for Children
3. How to use Nurofen for Children
4. Possible side effects
5. How to store Nurofen for Children
6. Further information

## 1. WHAT NUROFEN FOR CHILDREN IS AND WHAT IT IS USED FOR

Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, inflammation and high body temperature. Nurofen for children is for the short-term symptomatic treatment of:

- fever
- mild to moderate pain

## 2. BEFORE YOU USE NUROFEN FOR CHILDREN

Do not give Nurofen for Children to children who:

- are allergic (hypersensitive) to ibuprofen or other similar painkillers (NSAIDs) or to any of the other ingredients of the product (see section 6 for further information)
  - have ever suffered from shortness of breath, asthma, a runny nose or hives after using acetylsalicylic acid (aspirin) or other similar painkillers (NSAIDs)
  - have ever had gastrointestinal bleeding or perforation, related to previous use of NSAIDs
  - currently have or have had recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (two or more episodes of proven ulceration or bleeding)
  - have severe liver, kidney or heart failure
  - have bleeding of the brain (cerebrovascular bleeding) or other active bleeding
  - suffer from blood clotting disorders as ibuprofen may increase bleeding time
  - Unclassified blood-formation disturbances
- If an adult is taking this product, do not take if you are in the last 3 months of pregnancy.

Take special care with Nurofen for Children if your child:

- is taking any other NSAID painkillers or acetylsalicylic acid (aspirin) with a daily dose above 75mg
- has certain diseases of the skin (systemic lupus erythematosus (SLE) or mixed connective tissue disease)
- has or has ever had bowel disease (ulcerative colitis or Crohn's disease) as these conditions may be exacerbated (see section 4 'possible side effects')
- has ever had high blood pressure and/or heart failure
- has reduced renal function
- has liver disorders
- caution should be advised if other medicines are taken which could increase the risk of ulceration or bleeding, such as oral corticosteroids (such as prednisolone), medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (a medicine for depression) or anti-platelet agents (such as acetylsalicylic acid).
- is taking another NSAID medicine (including COX-2 inhibitors such as celecoxib or etoricoxib) as taking these together should be avoided.
- Undesirable effects may be minimised by using the minimum effective dose for the shortest duration.
- In general, the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems.
- Shortness of breath may occur if you have or have had asthma, a chronic runny nose, nasal polyps or allergic diseases.
- Serious skin reactions (such as Steven-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. The use of Nurofen for Children should be stopped immediately at the first appearance of skin rash, mucosal lesions, or any other signs of allergic reactions.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- During chicken pox (varicella) it is advisable to avoid use of Nurofen for Children
- have just undergone major surgery

- is dehydrated as there is an increased risk of kidney problems
- Medicines such as Nurofen for Children may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [3 days].

Gastro-intestinal 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 serious gastro-intestinal events. When gastro-intestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastro-intestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2 Do not take Nurofen for Children) and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also those requiring concomitant low-dose aspirin, or other drugs likely to increase gastrointestinal risk.

NSAIDs such as ibuprofen may mask the symptoms of infection and fever

Consult a doctor before using Nurofen for Children if any of the above mentioned conditions affect your child.

If an adult is taking this medicine: Elderly The elderly have an increased risk of adverse events when taking NSAIDs, particularly those relating to the stomach and bowel. See section 4 'possible side effects' for more information.

Patients with a history of gastro-intestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment

### Taking other medicines

Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription, in particular:

- corticosteroids (such as prednisolone) since this may increase the risk of gastrointestinal ulceration or bleeding
- another NSAID medicine (including COX-2 inhibitors such as celecoxib or etoricoxib)
- Some medicines that are anti-coagulants (against clotting) (e.g. acetylsalicylic acid/aspirin, warfarin, ticlopidin), some medicines against high blood pressure (ACE-inhibitors, e.g. captopril, beta-receptor blocking medicines, angiotensin II antagonists), and even some other medicines may affect or be affected by the treatment of ibuprofen. Therefore always seek the advice of a doctor

- before you use ibuprofen with other medicines.
- anti-platelet agents (such as acetylsalicylic acid) and selective serotonin-reuptake inhibitors (a medicine for depression) since

this may increase the risk of gastrointestinal side effects

- medicines for high blood pressure and water tablets (diuretics) since NSAIDs may diminish the effects of these medicines and there could be a possible increased risk for the kidney. In this case make sure your child drinks enough water during the day.
- lithium (a medicine for depression) since the effect of lithium may be enhanced
- methotrexate (a medicine for cancer or rheumatism) since the effect of methotrexate may be enhanced
- tacrolimus (a medicine to suppress the immune reaction) since the risk of kidney toxicity is increased
- cyclosporin (a medicine to suppress the immune reaction) since there is limited evidence of an increased risk for kidney toxicity.
- Zidovudin (a medicine for treating Aids) since the use of Nurofen for Children may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
- Sulphonylureas: Clinical investigations have shown interactions between NSAIDs and antidiabetics (sulphonylureas). Although interactions between ibuprofen and sulphonylureas have not been described to date, a check of blood-glucose values is recommended as a precaution on concomitant intake.
- Probenecid and sulfapyrazone: Medicinal products that contain probenecid or sulfapyrazone may delay the excretion of ibuprofen.
- Digoxin, phenytoin and lithium: ibuprofen may increase plasma concentrations of these medicines.
- Quinolone antibiotics, since taking these and NSAIDs can increase the risk of having convulsions.
- Cholestyramine since taking NSAIDs with cholestyramine can delay and decrease the uptake of NSAIDs
- Voriconazole and fluconazole since taking these medicines can increase exposure to NSAIDs

If an adult is taking this medicine:

### Pregnancy and breast-feeding

**Pregnancy** Tell your doctor if you become pregnant during intake of Nurofen for Children. Do not use this medicine if you are in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor advises you otherwise.

### Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into breast milk. As no harmful effects to infants are known to date, it is not usually necessary to interrupt breast-feeding during short-term use of ibuprofen at the recommended doses.

### Female fertility

Nurofen for Children belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

For short-term use this medicine has no or negligible influence on the ability to drive and use machines.

### Important information about some of the ingredients of Nurofen for Children

- Nurofen for Children contains maltitol liquid. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Nurofen for Children contains wheat starch. Suitable for people with coeliac disease.
- Patients with wheat allergy (different from coeliac disease) should not take this medicine.

## 3. HOW TO USE NUROFEN FOR CHILDREN

Always use Nurofen for Children exactly as indicated. You should check with your doctor or pharmacist if you are unsure.

### For oral use

The usual dose for pain and fever:

Child's Age (Weight)	How much?	Frequency (in a 24 hour period)*
6 - 9 years (20-30kg)	5ml (one 5ml spoonful (large end))	3 times
9- 12 years (30-40kg)	7.5ml (One 5ml spoonful (large end) and one 2.5ml spoonful (small end))	3 times

\*Doses should be given approximately every 6 to 8 hours.

Not intended for use in children under 6 years of age or under 20kg

For patients with sensitive stomachs it is recommended that Nurofen for children is taken during a meal

**WARNING:** do not exceed the stated dose.

### Method of administration using the spoon

1. Shake the bottle well
2. Use the end of the spoon that corresponds to the required dose
3. Pour the medicine onto the spoon
4. Place the spoon in the child's mouth and administer the dose
5. After use replace the cap. Wash the spoon in warm water and allow to dry.

### Duration of treatment

This medicine is for short-term use only. If the child's symptoms persist for more than 3 days seek medical advice. If symptoms worsen consult your doctor.

If your child takes more Nurofen for Children than they should:

If you accidentally give or take more than the recommended dose Nurofen for Children, contact your doctor straight away. Symptoms of an overdose include feeling sick, being sick, pain in the abdomen, headache, dizziness, feeling sleepy, twitchy eyes, blurred vision, ringing in the ears, and rarely low blood pressure, blood composition changes, kidney problems and loss of consciousness.

If you or your child forget to take Nurofen for Children:

Do not take or give a double dose to make up for a forgotten dose. If you do forget to take or give a dose, take or give it as soon as you remember and then take or give the next dose according to the dosing interval detailed above.

If you have any further questions on the use of this product ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Nurofen for Children can cause side effects, although not everyone gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Your child may get one of the known side effects of NSAIDs. If they do, or if you have concerns, stop giving this medicine to your child and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects. The following frequencies are taken as a basis when evaluating side effects:

very common:	affects more than 1 user in 10
common:	affects 1 to 10 users in 100
uncommon:	affects 1 to 10 users in 1,000
rare:	affects 1 to 10 users in 10,000
very rare:	affects less than 1 user in 10,000
not known:	frequency cannot be estimated from the available data

**STOP TAKING this medicine and seek immediate medical help if your child develops:**

- signs of intestinal bleeding such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- signs of rare but serious allergic reaction such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine. If any of these symptoms occur, call a doctor at once.
- severe skin reactions such as rashes covering the whole body, peeling, blistering or flaking skin.

Tell your doctor you have any of the following side effects, they become worse or you notice any effects not listed.

**Common** (affects 1 to 10 users in 100)

- heart burn, abdominal pain, feeling sick, being sick, flatulence (wind), diarrhoea, constipation.
- Uncommon** (affects 1 to 10 users in 1,000)
- inflammation of the stomach, worsening of colitis and Crohn's disease
  - headache, dizziness, sleeplessness, agitation, irritability or tiredness
  - visual disturbances
  - gastrointestinal ulcers which may bleed or burst
  - mouth ulcers and/or swelling and irritation of the mouth
  - hypersensitivity reactions with skin rashes and itching, and asthma attacks (possibly with drop in blood pressure)

**Rare** (affects 1 to 10 users in 10,000)

- tinnitus (ringing in the ears)
- Very rare** (affects less than 1 user in 10,000)
- inflammation of the oesophagus or pancreas, blockages in the gut
  - severe forms of skin reactions including rash with redness and blistering which may peel, accompanied by fever, chills aching muscles and feeling unwell, Stevens-Johnson syndrome. In exceptional cases, serious infections of the skin have occurred during chicken pox (varicella).
  - passing less urine than normal and swelling (acute kidney failure or inflammation may be possible). Damage to the kidney or increased urea concentrations in the blood (first signs are passing less urine than normal, cloudy urine, blood in the urine, back pain, swelling possibly of the legs and generally feeling miserable)
  - problems in blood cell production (first signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding, unexplained or unusual bruising).
  - psychotic reactions and depression
  - worsening of inflammation due to infection. If signs of an infection occur or get worse during use of Nurofen for Children, speak to your doctor.
  - swelling, high blood pressure, palpitations, heart failure, heart attack.
  - liver problems or inflammation of the liver. Liver failure or damage, particularly in long-term term use, shown by yellowing of the skin and eyes or pale stools and dark urine.
  - very rarely, the symptoms of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness clouding have been observed when using ibuprofen. Patients with autoimmune disorders (SLE, mixed connective-tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur.

Medicines such as this may be associated with a small increased risk of heart attack (myocardial infarction) or stroke

If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

You can report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: + 353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, email: imbpharmacovigilance@imb.ie.

## 5. HOW TO STORE NUROFEN FOR CHILDREN

Keep out of reach and sight of children. Do not use Nurofen for Children after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month. Do not store above 25 °C.

Shelf life after opening the bottle: 6 months.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

What Nurofen for Children contains:

The active substance is ibuprofen. Each 5ml oral suspension contains 200mg ibuprofen.

The other ingredients are: citric acid monohydrate, sodium citrate, sodium chloride, sodium saccharin, polysorbate 80, domiphen bromide, maltitol liquid, glycerol, xanthan gum, orange flavour (containing wheat starch) and purified water.

What Nurofen for Children looks like and contents of the pack

Nurofen for Children is an off-white, oral suspension. Each bottle contains 100ml or 200ml. The pack contains a spoon (with a 2.5ml bowl with a 1.25ml inner mark at one end and a 5ml bowl at the other end). Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus Dublin 24.

Manufacturer: Reckitt Benckiser Healthcare UK Ltd., Dansom Lane, Hull, HU8 7DS, UK PA 979/56/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Nurofen voor Suikervrij 4%
Bulgaria	Nurofen for Children 4% orange
Cyprus	Nurofen για Παιδιά 4% Πορτοκάλι
Czech Republic	Nurofen pro děti 4% pomeranč
France	Nurofen 40mg /ml enfants orange
Finland	Nurofen Junior 4%
Germany	Nurodon Junior Fieber- und Schmerzmittel 40 mg/ml Suspension zum Einnehmen.
Hungary	Nurofen narancsízű 4% szuszpenzió gyermekeknek
Iceland	Nurofen Junior 4%
Ireland	Nurofen for Children Orange 200mg/5ml Oral Suspension
Luxembourg	Nurofen pour Enfants 4% suspension orale
Netherlands	Nurofen voor Kinderen Sinaasappel suikervrije suspensie, suspensie 200 mg/5ml
Norway	Nurofen Junior 4%
Poland	Nurofen dla dzieci Junior pomarańczowy
Romania	Nurofen Junior, cu aromă de portocală, 200 mg/5 ml, suspensie orală
Slovak Republic	Nurofen pre deti 4% pomeranč
Slovenia	Nurofen za otroke z okusom pomaranče 40 mg/ml peroralna suspenzija
Sweden	Nurofen Junior 4%
UK	Nurofen for Children 200mg/5ml Orange Oral Suspension

This leaflet was last approved in February 2014