

PACKAGE LEAFLET: INFORMATION FOR THE USER

NUROFEN® for Children Orange

100 mg/5 ml oral suspension

ibuprofen

Read all of this leaflet carefully before you use this medicine.

It contains important information.

Keep this leaflet: you might need it again.

If you have any further questions after you have read it ask your doctor or pharmacist.

- This medicine is designed to help bring down a high temperature and relieves pain from headaches, earache, sore throats, minor aches and sprains, cold and flu symptoms, teething and toothache.
- This medicine is suitable for most babies over 3 months of age, children and adults.
- Follow the dosage instructions carefully. Section 3 shows the difference amounts that children need.
- **Speak to your doctor if your child:**
 - ▶ Suffers from any of the conditions listed in Section 2 of the leaflet
 - ▶ Is taking other medicines. See section 2.
 - ▶ Is not getting better, or you feel at all concerned. See section 3
 - ▶ Develops a rash, breathing problems or diarrhoea and gets very tired. See Section 3.

Do not use this medicine and speak to your doctor if you are pregnant, think you may be pregnant or trying to get pregnant or are breast-feeding. See Section 2.

In this leaflet:

1. **What Nurofen for Children is and what it is used for**
2. **Before giving Nurofen for Children to your child**
3. **How to use Nurofen for Children**
4. **Possible side effects**
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1. What Nurofen for Children is and what it is used for

The active ingredient (which makes this medicine work) is ibuprofen which is a non-steroidal anti-inflammatory (NSAID) painkiller. Ibuprofen is used as an analgesic (painkiller) for the relief of teething and toothache pain, earache, headache, muscular minor aches and sprains, sore throats and cold and flu symptoms. Nurofen for Children also reduces a high temperature (fever).

2. Before giving Nurofen for Children to your child

This medicine is suitable for the majority of people, but certain people should not use it. Talk to your pharmacist or doctor if you are at all unsure.

Do not give this medicine to your child if:

- They suffer from hypersensitivity to any of the ingredients in this medicine (see section 6)
- They have ever had a reaction (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat or stomach bleeding) after taking ibuprofen, aspirin or other non steroidal anti-inflammatory (NSAID) medicines
- They weigh less than 5kg or are under 3 months of age
- They are taking any other anti-inflammatory (NSAID) painkillers, or aspirin
- They have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- They have severe kidney, heart or liver failure
- They have inherited problems coping with fructose/fruit sugar (hereditary fructose intolerance). This is because the body can make some fructose from the ingredient maltitol.

Warnings and precautions

Talk to your doctor or pharmacist if:

- Your child has an infection - please see heading 'Infections' below
- Your child has or has had high blood pressure, heart problems or a stroke because there is a small increased risk of heart problems with ibuprofen
- Your child has a condition which may put them at risk of heart problems, such as diabetes or high cholesterol
- Your child has a condition which increases tendency to bleeding or they have bleeding in the skull
- Your child has asthma or any allergic disease of the lungs
- Your child has, or has had liver, kidney, heart or bowel problems
- Your child has SLE (Systemic Lupus Erythematosus, a condition of the immune system), exfoliative dermatitis, Stevens-Johnson syndrome, or any similar disease
- Your child suffers from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- You previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- When stomach ulcer or bleeding occurs in patients receiving Nurofen for Children the treatment should be withdrawn.
- There is a risk of renal impairment in dehydrated children and adolescents.
- Your child has chicken pox as it is advisable to avoid the use of Nurofen for Children.

There is some evidence that drugs which inhibit cyclooxygenase / prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment (see "Pregnancy and Breast Feeding").

Signs of an allergic reaction to this medicine including breathing problems, swelling of the face and neck region (angioedema) and chest pain have been reported with ibuprofen. Stop Nurofen for Children immediately and contact your doctor or medical emergencies if you notice any of these signs.

Take special care with Nurofen for Children:

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Nurofen for Children and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections: Nurofen for Children may hide signs of infections such as fever and pain. It is therefore possible that Nurofen for Children may delay appropriate treatment of infection which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take/give your child this medicine while you/they have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

You or your child are taking other medicines, especially:

- Other medicines containing ibuprofen, aspirin or other NSAIDs, including those you can buy over the counter
- Diuretics (to help you pass water)
- Anticoagulants (blood thinning medicines e.g. warfarin)
- Medicines for high blood pressure (e.g. captopril, atenolol, losartan)
- Lithium (for mood disorders)
- Methotrexate (for psoriasis, arthritis and types of cancer)
- Zidovudine (for HIV)
- Corticosteroids (an anti-inflammatory drug)
- Probenecid (to treat gout)
- Aminoglycosides (a type of antibiotic)
- Oral hypoglycemic agents (oral medicines to treat diabetes)
- Cardiac glycosides (for heart problems)
- Ciclosporin or tacrolimus (to prevent organ rejection after transplant)
- Quinolone antibiotics (for infections)
- SSRI antidepressant drugs
- Antiplatelet drugs e.g. dipyridamole, clopidogrel.

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting, e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of a healthcare professional before you use ibuprofen with other medicines.

- If you have taken mifepristone now or in the last 12 days

Seek the advice of your doctor or pharmacist if any of the above apply. If you are not sure what types of medicines your child is taking, show the medicine to the doctor or pharmacist.

If you are an adult taking this medicine

The warnings and information given in this section apply and in addition the following:

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

Pregnancy

Do not take ibuprofen if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn child. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take ibuprofen during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, ibuprofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into breast milk. Nurofen for Children may be used during breast-feeding, if it is used at the recommended dose and for the shortest possible time.

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.

Other warnings

- 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
- If you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- Ibuprofen belongs to a group of medicines which may impair fertility in women, see section "Pregnancy and Breast feeding".
- Risk of heart attack or stroke: 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
- Elderly: elderly patients are more prone to side effects such as stomach bleeding and perforation which may be fatal. Talk to your doctor or pharmacist before taking this medicine.

Driving and using machines

There are no known effects on driving or use of machines.

Important information about some of the ingredients of Nurofen for Children

- Nurofen for children contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Maltitol may have a mild laxative effect.
- Calorific value 2.3 kcal/g maltitol.
- This medicine contains 9.08 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.45% of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains only very low levels of gluten (from wheat starch). It is

regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One 5 ml dosage unit contains no more than 0.225 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

3. How to use Nurofen for Children

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you or your child has an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see Section 2).

Always shake the bottle thoroughly before use.

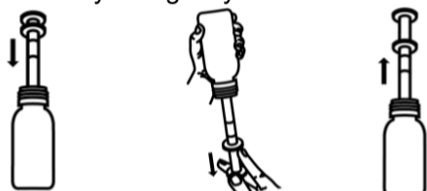
To remove the cap, push it down and turn it anti-clockwise.

For children with sensitive stomachs the product can be taken during a meal.

Use either the two ended measuring spoon (2.5 ml and 5 ml) or the 5 ml dosing syringe provided in the pack to ensure accurate dosing.

Using the 5 ml easy dosing syringe

- Push the syringe firmly into the plug (hole) in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. See section "How much medicine to use".
- Turn the bottle the right way up, remove the syringe from the bottle plug by gently twisting the syringe.
- Place the end of the syringe into the child's mouth and gently press the plunger down to slowly and gently release the medicine.



- After use replace the bottle cap. Disassemble the syringe, wash the parts in warm water and allow to dry. Store out of the reach of children.

How much medicine to use

DO NOT give to babies under 3 months or babies weighing less than 5kg.

AGE	DOSE
3 months - 6 months 5-7.6 kg	One 2.5 ml dose 3 times in 24 hours.
6 months -12 months 7.7-9 kg	One 2.5 ml dose 3 times in 24 hours
1 year-3 years 10-16 kg	One 5 ml dose 3 times in 24 hours
4 years-6 years 17- 20 kg	One 7.5 ml (5 ml + 2.5 ml) dose 3 times in 24 hours
7 years - 9 years 21- 30 kg	One 10 ml (5 ml + 5 ml) dose 3 times in 24 hours
10 years - 12 years 31-40 kg	One 15 ml (5 ml + 5 ml + 5 ml) dose 3 times in 24 hours

- Do not dose more frequently than at 6 hour intervals.
- For Short-term use only

WARNING: Do not exceed the stated dose

For infants aged 3-5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist. If in children aged 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Talk to your doctor

- If your child's symptoms do not go away as soon as possible or worsen.
- If you are not sure of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness, speak to your doctor straight away.

If you take more Nurofen than you should

if you have taken more Nurofen than you should, or if children have taken this medicine by accident, always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, headache, ringing in the ears, confusion, nystagmus (shaky eye movement) or more rarely diarrhoea. In addition, at high doses, vertigo, blurred vision, low blood pressure, excitation, disorientation, coma, hyperkalaemia (raised blood potassium levels), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, exacerbation of asthma in asthmatics, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling and breathing problems have been reported.

If you forget to give the medicines

If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 6 hours ago.

Do not give a double dose.

4. Possible side effects

Like all medicines, Nurofen for Children can cause side effects, although not everybody gets them.

The most common side effect is irritation of the stomach which can cause problems such as indigestion and heartburn.

If your child experiences any of the following, stop giving this medicine and tell your doctor immediately

- Blood in the stools (faeces/motions)
- Black tarry stools
- Vomiting blood or dark particles that look like coffee grounds
- Unexplained wheezing, shortness of breath, skin rash (which may be severe with blistering or peeling of the skin), serious skin reaction, itching or bruising, racing heart, fluid retention (swollen ankles or decreased levels of passing urine)

- Stiff neck, headache, nausea, vomiting, fever and disorientation.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Steven Johnson syndrome, toxic epidermal necrolysis].
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

If your child experiences any of the following side effects, stop giving this medicine and tell your doctor

- Unexplained stomach pain, indigestion, heartburn, nausea or vomiting
- Yellowing of the eyes, pale stools and dark urine, liver problems
- Severe sore throat with high fever
- Unexplained bleeding, or have bleeding in the skull, bruising or tiredness or getting more infections, such as colds, than normal.

Other side effects which may occur are:

Uncommon

- headache

Rare

- diarrhoea, wind or constipation. Tell your doctor if these last for more than a few days or become troublesome

Very rare

- kidney problems, kidney failure may occur with ibuprofen
- stroke or heart problems may occur with ibuprofen. This is unlikely at the dose level given to children
- worsening of colitis and Crohn's disease
- high blood pressure
- severe skin infections and soft tissue complications during chicken pox (varicella) infection

Not known

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophilis (a type of white blood cells)
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis - AGEP). Stop using Nurofen for Children if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Nurofen for Children

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further Information

What is in this medicine?

The active substance is ibuprofen. Each 5 ml of suspension contains 100 mg ibuprofen.

The other ingredients are maltitol syrup, purified water, glycerin, citric acid, sodium citrate, sodium chloride, sodium saccharin, orange flavour (contains wheat starch), xanthan gum, polysorbate 80, domiphen bromide.

What the medicine looks like

Nurofen for Children is an off-white liquid available in a 150 ml bottle. Each pack contains a dosing syringe.

Manufacturer of medicine: Reckitt Benckiser Healthcare International Ltd, UK or RECKITT BENCKISER HEALTHCARE (UK) LIMITED, United Kingdom or RB NL Brands B.V., Schiphol Blvd 207, 1118 BH Schiphol, the Netherlands or ALMIRALL HERMAL GMBH, Reinbek, Germany.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number:

Nurofen for Children 100mg/5ml Oral Suspension – PPA0465/337/001
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