

PACKAGE LEAFLET: INFORMATION FOR THE USER

NUROFEN® FOR CHILDREN ORANGE 100MG/5ML ORAL SUSPENSION (ibuprofen)

Your medicine is available using the above name but will be referred to as Nurofen for Children throughout this leaflet.

**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 different 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**
- 5. How to store Nurofen for Children**
- 6. Contents of the pack and other information**

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.

Talk to your doctor or pharmacist if:

- 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

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, ticlopedine), 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.

See 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 breast-feeding

- ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant
- you should only take this product on a doctor's advice during the first 6 months of pregnancy
- DO NOT** take Nurofen for Children if you are in the last 3 months of your pregnancy or while breast-feeding

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**
- Risk of a 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.

Nurofen for Children contains maltitol

- If you have been told by a doctor that you have an intolerance to fructose, contact your doctor before taking this medicine.
- Maltitol may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.
- This medicinal product contains 1.2mmol (or 27.75mg) sodium per dose (15ml). To be taken into consideration by patients on a controlled sodium diet.

3. How to use Nurofen for Children

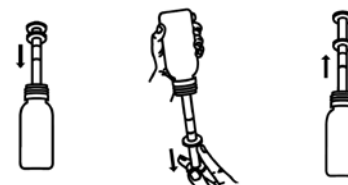
Always shake the bottle thoroughly before use.

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

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

Using the 5ml 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 Weighing over 5kg	One 2.5ml dose 3 times in 24 hours
6 months – 12 months	One 2.5ml dose 3 times in 24 hours
1 year – 3 years	One 5ml dose 3 times in 24 hours
4 years – 6 years	One 7.5ml (5ml + 2.5ml) dose 3 times in 24 hours
7 years – 9 years	One 10ml (5ml + 5ml) dose 3 times in 24 hours
10 years – 12 years	One 15ml (5ml + 5ml + 5ml) dose 3 times in 24 hours
<ul style="list-style-type: none">Doses should be given every 6 – 8 hours. Leave at least 4 hours between doses.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 from 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 anyone has taken too much medicine

If you accidentally give or take more than the recommended dose, contact your doctor straight away.

If you forget to give the medicine

If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 4 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, e.g. Stevens-Johnson syndrome, itching or bruising, racing heart, fluid retention (swollen ankles or decreased levels of passing urine)
- stiff neck, headache, nausea, vomiting, fever and disorientation.

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 stool, 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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nurofen for Children

Keep out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

If your medicine appears to be discoloured or shows any other signs of deterioration, please return to your pharmacist who will advise you further.

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

6. Contents of the pack and other information

What is in this medicine?

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

Also contains: maltitol syrup, citric acid, sodium citrate, sodium chloride, sodium saccharin, domiphen bromide, polysorbate 80, xanthan gum, orange flavour, glycerol (E422) and purified water.

What the medicine looks like

Nurofen for Children is an off-white liquid available in an amber-coloured 150ml bottle with a 5ml dosing syringe.

Manufacturer

Manufactured by: Reckitt Benckiser Healthcare Limited, Dansom Lane, Hull, HU8 7DS, UK.

Procured from within the EU by the PPA holder:

Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

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This leaflet gives you the most important information. If you have any questions after you have read it, ask your doctor or pharmacist who will be able to help.

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