

Package Leaflet: Information for the user

NUROFEN®

Nurofen for Children
3 months to 9 years **Orange**

Nurofen for Children
3 months to 9 years **Strawberry**

100mg / 5ml Oral Suspension

Contains Ibuprofen

This leaflet is valid for Nurofen for Children 3 months to 9 years Orange or for Nurofen for Children 3 months to 9 years Strawberry which will be referred to as this medicine throughout this leaflet. The only difference between both products is the flavour. To know the flavour of the medicine you are using, please refer to the carton or label.

Read all of this leaflet carefully before you use this medicine, because it contains important information for you.

Keep this leaflet: you might need it again.

Ask your doctor or pharmacist if you need more information or advice.

- This medicine is designed to help bring down a high temperature (fever and post-immunisation fever), relieve the symptoms of cold and flu and relieve pain from headaches, sore throats, minor aches and sprains, teething and toothache.
- This medicine is suitable for most babies over 3 months of age, children and adults.
- Follow the dose instructions carefully. Section 3 shows the different amount 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 aspirin at a dose above 75 mg a day. See Section 2
 - is taking other medicines. See Section 2.
 - is not getting better, or feeling worse, or you feel at all concerned. See Section 3
 - develops a rash, breathing problems or diarrhoea and gets very tired. See Section 3.
 - gets any side effects. See Section 4. This includes any possible side effects not listed in this leaflet.
- 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 this medicine is and what it is used for
2. What you need to know before giving this medicine to your child
3. How to use this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of pack and other information

1. What this medicine 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, muscular minor aches and sprains, sore throats and symptoms of cold and flu as well as the symptomatic relief of headaches.

This medicine also brings down a high temperature (fever) including post-immunisation fever.

2. What you need to know before giving this medicine 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 have ever had a reaction (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat) 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 with a daily dose above 75 mg
- 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.
- they have a history of stomach bleeding or perforation after taking ibuprofen or other NSAIDs.

Warnings and precautions

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 asthma or any allergic disease of the lungs
- your child has, or has had liver, kidney, heart or bowel problems
- your child is dehydrated as there is a risk of kidney problems

- your child has SLE (Systemic Lupus Erythematosus, a condition of the immune system) or any similar disease
- your child suffers from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- Your child has an infection. This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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 give this medicine to your child while they have an infection and their symptoms of the infection persist or worsen, consult a doctor without delay.

- During chicken pox (varicella) it is advisable to avoid use of this medicine.

Skin reactions

- Serious skin reactions have been reported in association with this medicine. You should stop giving this medicine to your child and seek medical attention immediately, if they develop any skin rash, lesion of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Other medicines and this medicine

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines, especially:

- other medicines containing ibuprofen or other NSAIDs, including those you can buy over the counter
- low dose aspirin (up to 75 mg a day)
- 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)
- cardiac glycosides (for heart problems)
- cidospirin or tacrolimus (to prevent organ rejection after transplant)
- mifepristone (for termination of pregnancy)
- quinolone antibiotics (for infections)
- SSRI antidepressant drugs
- antiplatelet drugs e.g. dipyridamole, clopidogrel.

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.

Other warnings

The following warnings are more likely to concern adults. In any case, consider them carefully before giving or taking this medicine.

- medicines such as this medicine 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
- 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
- in limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breastfed infant adversely
- if you are elderly talk to your doctor before using this medicine.

Pregnancy, breast-feeding and fertility

- 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 this medicine if you are in the last 3 months of your pregnancy

Some of the ingredients can cause problems

- This product contains maltitol. If you or your child have been told by a doctor that you or your child have an intolerance to fructose, contact your doctor before taking this medicine or giving it to your child.
- Maltitol may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use this medicine

Always use this medicine exactly as described in this leaflet, or as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure.

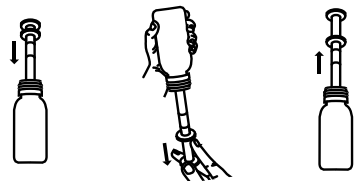
Always shake the bottle thoroughly before use.

To remove the cap, push it down and turn it anti-clockwise. There is a 5ml dosing syringe in the pack which should be used to give the medicine.

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.

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- After use replace the bottle cap. Wash the syringe 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.

Fever caused by Immunisation	
Age	Dose
Babies and children 3 months and over Weighing more than 5kg	One 2.5ml dose up to twice a day

If necessary the second dose should be given 6 hours after the first dose.

- Do not give more than 2 doses in a 24 hour period.
- Do not give to a child under 3 months of age, unless advised to do so by your doctor.

Fever, Pain and Symptoms of Cold and Flu	
Age	Dose
3 - 6 months Weighing over 5kg	One 2.5ml dose 3 times a day. Do not use for more than 24 hours
Do not give to babies aged 3-6 months for more than 24 hours. If symptoms persist after 24 hours or worsen, consult your doctor.	
6 - 12 months	One 2.5ml dose 3 or 4 times in 24 hours
1 - 3 years	One 5ml dose 3 times in 24 hours
4 - 6 years	One 7.5ml (5ml + 2.5ml) dose 3 times in 24 hours
7 - 9 years	One 10ml (5ml + 5ml) dose 3 times in 24 hours

- Doses should be given every 6 - 8 hours. Leave at least 4 hours between doses. Do not take more than the recommended dose in 24 hours.

For Short-term use only

- The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If your child has an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).
- Do not give to children aged 6 months or older for more than 3 days. If symptoms persist after 3 days or worsen, consult your doctor.

WARNING:
Do not take more medicine than the label tells you to

For patients with sensitive stomachs the medicine can be taken with or after food.

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 have given more of this medicine than you should:

If someone has taken more medicine than they 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 can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement.

At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

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.

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

4. Possible side effects

Like all medicines, this medicine 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, asthma, shortness of breath, skin rash (which may be severe with blistering or peeling of the skin), itching or bruising, severe skin reactions including Stevens-Johnson syndrome, racing heart, fluid retention (swollen ankles or decreased levels of passing urine)
- stiff neck, headache, nausea, vomiting, fever and disorientation.
- face, tongue or throat swelling (these can be signs of serious allergic reactions)
- A severe skin reaction known as DRESS (Drug reaction with eosinophilia and systemic symptoms) syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency not known) See also section 2.

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 (these can be signs of kidney or liver problems)
- severe sore throat with high fever
- unexplained bruising or bleeding, tiredness, getting more infections than normal, such as mouth ulcers, colds, sore throat, fever. (These can be signs of anaemia or other blood disorders.)

Other side effects which may occur are:

Uncommon: may affect up to 1 in 100 people

- headache

Rare: may affect up to 1 in 1,000 people

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

Very rare: may affect up to 1 in 10,000 people

- kidney or liver problems 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.
- stomach ulcer, bleeding of the stomach, inflammation of the stomach lining

Not known: frequency cannot be estimated from the available data:

- in exceptional cases, serious infections of the skin and soft tissues have occurred during chicken pox (varicella)
- skin becomes sensitive to light

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store this medicine

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 bottle label and carton.

(The expiry date refers to the last day of that month.) Store below 25°C.

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. Contents of pack and other information

What this medicine contains

The active ingredient is Ibuprofen 100 mg per 5ml of medicine.

The other ingredients are:

Maltitol liquid, water, glycerol, citric acid, sodium citrate, sodium chloride, sodium saccharin, orange or strawberry flavour, xanthan gum, polysorbate 80, domiphen bromide.

What this medicine looks like and contents of the pack

This medicine is an off-white liquid available in 50 ml or 100 ml bottles for strawberry flavour, and 100 ml bottles for orange flavour.

Each pack contains a dosing syringe

Product licence holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ

Manufacturer of medicine: Reckitt Benckiser Healthcare UK, Ltd, Hull, HU8 7DS

Product licence numbers:

PL 00063/0668: Nurofen for Children

3 months to 9 years Orange

PL 00063/0667: Nurofen for Children

3 months to 9 years Strawberry

This leaflet was revised: February 2021

The 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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CUSTOMER INFO:
Minimum Point Size = 9.00pt
(refers to the text within the Orange and Strawberry lozenges in the title section of the leaflet. Everything else is a minimum of 10pt).

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