

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**. 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.

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 (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 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. Further 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, muscular minor aches and sprains, sore throats and symptoms of cold and flu as well as the symptomatic relief of headaches. Nurofen for Children also brings down a high temperature (fever) including post-immunisation 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 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.

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 renal impairment
- 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
- You or your child are taking other medicines especially:**
 - o other **medicines containing ibuprofen or other NSAIDs**, including those you can buy over the counter
 - o **low dose aspirin** (up to 75 mg a day)
 - o **diuretics** (to help you pass water)
 - o **anticoagulants** (blood thinning medicines e.g. warfarin)
 - o **medicines for high blood pressure** (e.g. captopril, atenolol, losartan)
 - o **lithium** (for mood disorders)
 - o **methotrexate** (for psoriasis, arthritis and types of cancer)
 - o **zidovudine** (for HIV)
 - o **corticosteroids** (an anti-inflammatory drug)
 - o **cardiac glycosides** (for heart problems)
 - o **ciclosporin or tacrolimus** (to prevent organ rejection after transplant)
 - o **mifepristone** (for termination of pregnancy)
 - o **quinolone antibiotics** (for infections)
 - o **SSRI antidepressant drugs**
 - o **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.

- 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
- 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
- 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 breast-fed infant adversely
- if you are elderly talk to your doctor before using this medicine.

Some of the ingredients can cause problems

- This product 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.

3. How to use Nurofen for Children

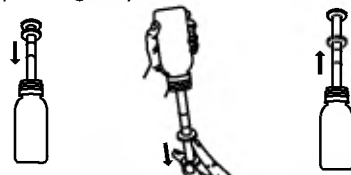
Always shake the bottle thoroughly before use.

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

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.



- 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.

Print Free Area

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.

• For **Short-term use only**

- ▶ 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

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), 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
- severe sore throat with high fever
- unexplained 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 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.

5. How to store Nurofen for Children

Do not use the medicine after the expiry date shown on the bottle label and carton. Store below 25°C.

Keep all medicines out of the sight and reach of children

6. Further information

What is in this medicine?

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 the medicine looks like

Nurofen for Children is an off-white liquid available in 100ml bottles. Each pack contains a dosing syringe (CE 0543).

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

Manufacturer of medicine: Reckitt Benckiser Healthcare UK Ltd, Hull, HU8 7DS and BCM Ltd, Nottingham NG2 3AA

Syringe manufacturer: Reckitt Benckiser Healthcare (UK) Ltd, 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

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.