

PACKAGE LEAFLET INFORMATION FOR THE USER

Nurofen for Children 40 mg/ml oral suspension

For use in children from 5 kg body weight (3 months) to 40 kg body weight (12 years)

Ibuprofen

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child gets any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor if your child does not feel better or if your child feels worse after 24 hours (infants aged 3-5 months, weighing more than 5kg) or after 3 days (children aged from 6 months).

For countries where the product is Rx the following wording should be used
Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist

This medicine has been prescribed for your child only. Do not pass it onto others. It may harm them, even if their symptoms are the same as your child's.

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Nurofen for Children is and what it is used for
2. What you need to know 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. Contents of the pack and other 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 and high body temperature. Nurofen for children is for the short- term symptomatic treatment of :

- fever
- mild to moderate pain

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NUROFEN FOR CHILDREN

Do not give Nurofen for Children to children who:

- are allergic to ibuprofen or other similar painkillers (NSAIDs) or to any of the other ingredients of this medicine (listed in section 6)
- have ever suffered from shortness of breath, asthma, a runny nose, swelling on their face and/or hands or hives after using acetylsalicylic acid 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 failure or severe kidney failure
- have severe heart failure
- have bleeding of the brain (cerebrovascular bleeding) or other active bleeding
- suffer from blood clotting disorders as ibuprofen may increase bleeding time
- have unclarified blood-formation disturbances
- have severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)

Do not take if you are in the last 3 months of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before using this product if your child

- has certain hereditary blood formation disorders (e.g. acute intermittent porphyria)
- suffers from coagulation disturbances
- 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 or currently has high blood pressure and/or heart failure
- has reduced renal function
- has liver disorders. In prolonged administration of Nurofen regular checking of the liver values, the kidney function, as well as of the blood count, is required.
- 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 (see section "taking other medicines")..
- 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. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.
- Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.
- has or has had asthma or allergic diseases as shortness of breath may occur.

- suffers from hayfever, nasal polyps or chronic obstructive respiratory disorders an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria
- 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.
- During chicken pox (varicella) it is advisable to avoid use of Nurofen for Children
- have just undergone major surgery as medical surveillance is required.
- is dehydrated as there is an increased risk of kidney problems in dehydrated children
- NSAIDs may mask symptoms of infection and fever

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 gastrointestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastrointestinal 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.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Nurofen for Children if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

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

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

OTHER MEDICINES AND NUROFEN FOR CHILDREN

Tell your doctor or pharmacist if your child is using or has recently used or might use any other medicines.

Nurofen for Children may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)

- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
Some other medicines may also affect or be affected by the treatment of Nurofen for Children. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen for Children with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell them if you are taking:

Other NSAIDs including COX-2 inhibitors	Since this may increase the risk of side effects
Digoxin (for heart insufficiency)	Since the effect of digoxin may be enhanced
Glucocorticoids (medicinal products containing cortisone or cortisone-like substances)	Since this may increase the risk of gastrointestinal ulcers or bleeding
Anti-platelet agents	Since this may increase the risk of bleeding
Acetylsalicylic acid (low dose)	Since the blood-thinning effect may be impaired
Medicines for thinning the blood (such as warfarin)	Since ibuprofen may enhance the effects of these medicines
Phenytoin (for epilepsy)	Since the effect of phenytoin may be enhanced
Selective serotonin reuptake inhibitors (medicines used for depression)	As these may increase the risk of gastrointestinal bleeding
Lithium (a medicine for manic depressive illness and depression)	Since the effect of lithium may be enhanced
Probenecid and sulfinpyrazones (medicines for gout)	Since the excretion of ibuprofen may be delayed
Medicines for high blood pressure and water tablets	Since ibuprofens may diminish the effects of these medicines and there could be a possible increased risk for the kidney
Potassium sparing diuretics e.g. amiloride, potassium canrenoate, spironolactone, triamterene.	Since this may lead to hyperkalaemia
Methotrexate (a medicine for cancer or rheumatism)	Since the effect of methotrexate may be enhanced
Tacrolimus and cyclosporine (immunosuppressive medicines)	Since kidney damage may occur
Zidovudine: (a medicine for treating HIV/Aids)	Since the use of Nurofen may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
Sulfonylureas (antidiabetic medicines)	Since the blood sugar levels can be affected
Quinolone antibiotics	Since the risk for convulsions (fits) may be increased
Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections	Since the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.
Baclofen	Baclofen toxicity may develop after starting ibuprofen.
Ritonavir	Ritonavir may increase the plasma concentrations of NSAIDs.
Aminoglycosides	NSAIDs may decrease the excretion of aminoglycosides.

Nurofen for Children with alcohol

You should not drink alcohol while using Nurofen for Children. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as Nurofen for Children.

Pregnancy, breast-feeding and fertility

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 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. 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.

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.
- This medicinal product contains 28.09 mg sodium per 15 ml suspension (= 1.87 mg sodium per 1 ml suspension). To be taken into consideration by patients on a controlled sodium diet.

[DE/H/2206/001/DC]:

- 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 this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for pain and fever:

Child's weight (Age)	How much?	How often in 24h?*
From 5kg (3-5 months)	1.25ml (equivalent to 50 mg ibuprofen)	3 times
7-9 kg (6 – 11 months)	1.25ml (equivalent to 50 mg ibuprofen)	3 to 4 times
10-15 kg (1-3 years)	2.5ml (equivalent to 100 mg ibuprofen)	3 times
16-19 kg (4-5 years)	3.75ml (equivalent to 150 mg ibuprofen)	3 times
20-29 kg (6– 9 years)	5ml (equivalent to 200 mg ibuprofen)	3 times
30-40 kg (10 – 12 years)	7.5ml (equivalent to 300 mg ibuprofen) (use syringe twice: 5ml + 2.5ml)	3 times

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

Not recommended for use in children under 3 months of age or under 5kg.

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

WARNING: do not exceed the stated dose.

For packs supplied with a syringe the following wording should be used

Method of administration using the syringe

For oral use

1. Shake the bottle well
2. Remove the cap from the bottle by pushing it down and turning anticlockwise
3. Push the syringe firmly into the plug (hole) in the neck of the bottle.
4. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place gently pull the plunger down drawing the suspension to the correct mark on the syringe.
5. Turn the bottle the right way up and remove the syringe from the plug by gently twisting the syringe.
6. Place the end of the syringe into the child's mouth. Press the plunger slowly down to gently release the suspension. After use replace the cap. Wash the syringe in warm water and allow to dry. Store out of the reach and sight of children.

Duration of treatment

This medicine is for short-term use only. If in children aged from 6 months this medicine is required for more than 3 days or if symptoms worsen, a doctor should be consulted.

For infants aged 3-5 months (weighing from 5kg) medical advice should be sought not later than 24 hours use if symptoms persist.

If symptoms worsen consult your doctor.

If you use more Nurofen for Children than you should:

Consult a doctor immediately. The following signs may occur: nausea, vomiting, stomach pain or more rarely diarrhoea. In addition, headache, gastrointestinal bleeding, vertigo, dizziness, drowsiness, nystagmus, blurred vision, ringing in the ear, low blood pressure, excitation, disorientation, coma, convulsions, loss of consciousness, hyperkalaemia, metabolic acidosis, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis and exacerbation of asthma in asthmatics.

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 medicine 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.

STOP USING 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 if your child has any of the following side effects, they become worse or you notice any effects not listed.

Common (may affect up to 1 to 10 people)

- Stomach and intestinal complaints such as acid burn, stomach pain and nausea, indigestion, diarrhoea, vomiting, flatulence (wind) and constipation and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases..

Uncommon (may affect up to 1 to 100 people)

- gastrointestinal ulcers, perforation or bleeding, inflammation of the mucous membrane of the mouth with ulceration, worsening of existing bowel disease (colitis or Crohn's disease), gastritis
- central nervous system disturbance such as headache, dizziness, sleeplessness, agitation, irritability or tiredness

- visual disturbances
- various skin rashes
- hypersensitivity reactions with hives and itch

Rare (may affect up to 1 to 1000 people)

- tinnitus (ringing in the ears)
- increased urea concentrations in blood, pain in the flanks and/or the abdomen, blood in the urine and a fever may be signs of damage to kidneys (papillary necrosis)
- increased uric acid concentrations in the blood
- decreased haemoglobin levels

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

- oesophagitis, pancreatitis, and formation of intestinal diaphragm-like strictures
- heart failure, heart attack and swelling in the face or hands (oedema)
- passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function), swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure. If one of the above mentioned symptoms occur or if you have a general miserable feeling, stop taking Nurofen and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure.
- Psychotic reactions, depression
- high blood pressure, vasculitis
- palpitations
- liver dysfunction, damage to the liver (first signs could be discoloration of the skin), especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- problems in the blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding and unexplained bruising. In these cases you must stop the therapy immediately and consult a doctor. Any self-treatment with pain killers or medicinal products that reduce fever (antipyretic medicinal products) mustn't be done.
- severe skin infections and soft tissue complications during chicken pox (varicella) infection
- worsening of infection-related inflammations (e.g. necrotizing fasciitis) associated with the use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse, you must go to the doctor without delay. It is to be investigated whether there is an indication for an anti-infective/antibiotic therapy
- symptoms of aseptic meningitis with stiff neck, headache, nausea, vomiting, fever or clouding of consciousness 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.
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia)

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

- Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea.

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

Reporting side effects

If your child gets 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 via the national reporting system listed in appendix V. 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 sight and reach 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.

Do not throw away any medicines via waste water. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nurofen for Children contains:

The active substance is ibuprofen. Each 1ml oral suspension contains 40mg ibuprofen.

[DE/H/2206/001/DC]:

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.

[DE/H/2206/002/DC]:

The other ingredients are; citric acid monohydrate, sodium citrate, sodium chloride, sodium saccharin, polysorbate 80, domiphen bromide, maltitol liquid, glycerol, xanthan gum, strawberry flavour (containing propylene glycol) and purified water.

What Nurofen for Children looks like and contents of the pack

Nurofen for Children is an off-white, viscous suspension with an orange/**strawberry** odour.

Each bottle contains either 30ml, 50ml, 100ml 150ml or 200ml.

The pack contains a syringe (5ml syringe, graduated to 1.25ml, 2.5ml, 3.75ml and 5.0ml)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

To be completed nationally

Manufacturer:

To be completed nationally

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

[DE/H/2206/001/DC]:

Germany	Nuroflex Junior Fieber- und Schmerzsaft Orange 40 mg/ml Suspension zum Einnehmen
Bulgaria	Nurofen for Children Forte Orange 200 mg/5ml oral suspension
Estonia	Nurofen for Children Forte Orange
Latvia	Nurofen for Children Orange 200 mg/5 ml oral suspension
Lithuania	Nurofen for Children Forte Orange
Poland	Nurofen dla dzieci Forte truskakowy
Romania	NUROFLEX cu aromă de portocale 40 mg/ml suspensie orală
Spain	Junifen 40 mg/ml suspension oral sabor naranja

[DE/H/2206/002/DC]:

Country	Proposed Name
Germany	Nuroflex Junior Fieber- und Schmerzsaft Erdbeer 40 mg/ml Suspension zum Einnehmen
Bulgaria	Nurofen for Children Forte Strawberry 200 mg/5 ml oral suspension
Estonia	Nurofen for Children Forte Strawberry
Latvia	Nurofen for Children Strawberry 200 mg/5 ml oral suspension
Lithuania	Nurofen for Children Forte Strawberry
Poland	Nurofen dla dzieci Forte pomaranczowy
Romania	NUROFLEX cu aromă de căpșuni 40 mg/ml suspensie orală
Spain	Junipro 40 mg/ml suspension oral sabor fresa

This leaflet was last approved in {MM/YYYY}

To be completed nationally