

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nurofen for Children
60mg Suppositories Age 3 months to 2 years
Ibuprofen

Read all of this leaflet carefully before you use 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 might 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 3 days.

What is in this leaflet:

1. What Nurofen for Children is and what it is used for
2. What you need to know 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 60mg Suppositories Age 3 months to 2 years 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 Suppositories Age 3 months to 2 years also reduces a high temperature (fever).

2. What you need to know before giving Nurofen for Children Suppositories Age 3 months to 2 years to your child

This medicine is suitable for the majority of children but certain children 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 6kg 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 of bleeding
- They have severe kidney, heart or liver failure

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 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
- Your child suffers from a disorder of the rectum (back passage) or anus
- 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 Suppositories Age 3 months to 2 years the treatment should be withdrawn
- Your child has chicken pox as it is advisable to avoid the use of Nurofen for Children 60mg Suppositories Age 3 months to 2 years

There is a risk of renal impairment in dehydrated children and adolescents

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 give this medicine while your child has an infection and symptoms of the infection persist or worsen, consult a doctor without delay.

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

- Other medicines containing ibuprofen, aspirin or other NSAIDs (e.g. COX-2 inhibitors), including those you can buy over the counter
- Diuretics (to help you pass water)
- Anticoagulants (blood thinning medicines e.g. warfarin, heparin)
- 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.

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

3. How to use Nurofen for Children 60mg Suppositories Age 3 months to 2 years

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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).

Do not swallow.

If your child needs to empty their bowels, make sure it is done before you insert a suppository. Nurofen for Children 60mg Suppositories Age 3 months to 2 years should be inserted into the back passage (rectum).

Before use, wash and dry your hands. Remove one suppository carefully from its wrapping and insert it carefully into your child’s back passage. Wash your hands again afterwards.

Only give this product to a baby under 3 months old if your doctor tells you to.

DOSAGE: Wait for at least 6 hours between doses

AGE	Dosage	Frequency
3 months to 9 months	1 suppository	3 doses in 24 hours
9 months to 2 years	1 suppository	4 doses in 24 hours

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 this medicinal product is required for 3 days, or if symptoms worsen a doctor should be consulted.

This product is for short-term use only. If your child’s symptoms persist for more than 3 days, if pain or fever worsen or new symptoms occur, stop the treatment immediately and consult your doctor or pharmacist.

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 use more Nurofen for Children 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 use Nurofen for Children

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 60mg Suppositories Age 3 months to 2 years 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)
- Swelling of the face, tongue and throat
- 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, Stevens-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). 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 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.

Website: www.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 60mg Suppositories Age 3 months to 2 years

Do not use after the expiry date printed on the foil and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C

Medicine 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.

Keep all medicines out of the reach and sight of children

6. Contents of the pack and other information

What Nurofen for Children 60mg suppositories contain?

The active ingredient is ibuprofen 60mg per suppository

The other ingredients are:

Hard fat.

What Nurofen for Children 60mg suppositories look like and contents of the pack

Nurofen for Children 60mg Suppositories are white or yellowy-white cylindrical suppositories.

Each pack contains 10 suppositories.

Each suppository contains 60mg of the active ibuprofen.

Marketing Authorisation Holder and Manufacturer:

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturers of medicine: Famar A.V.E, Avlon Plant, 49th km National Road, Athens – Lamia, 19011 Avlona Attiki, Greece.

This leaflet was revised: upon approval