

NUROFEN®Nurofen for Children 200 mg / 5 ml **Orange**

oral suspension

Nurofen for Children 200 mg / 5 ml **Strawberry**

oral suspension

Contains Ibuprofen

This leaflet is valid for Nurofen for Children 200 mg / 5 ml Orange oral suspension and Nurofen for Children 200 mg / 5 ml Strawberry oral suspension (referred to as 'this medicine' in 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 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 3 days.

In this leaflet:

- What this medicine is and what it is used for**
- What you need to know before you use this medicine**
- How to use this medicine**
- Possible side effects**
- How to store this medicine**
- Contents of the 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 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. This medicine is used in children from 7 to 12 years old for relief from rheumatic or muscular pain, headache, dental pain, feverishness, symptoms of cold and influenza.

This medicine is twice the strength of normal ibuprofen suspension and you should be careful that you use the correct dose.

2. What you need to know before you use this medicine**Do NOT give this medicine 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 Aspirin or other similar painkillers (NSAIDs).
- have ever had a 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 and bleeding).
- have severe liver or severe kidney failure.
- have severe heart failure.
- have bleeding of the brain (cerebrovascular bleeding) or other active bleeding.
- 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 medicine 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 kidney function.
- has liver disorders. In prolonged administration of this medicine regular checking of the liver values, the kidney function, as well as of the blood count, is required.
- is taking medicines 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 medicines (such as aspirin).
- is taking another NSAID medicine (including COX-2 inhibitors such as celecoxib or etoricoxib) as taking these together should be avoided (see section 'Other medicines and this medicine').
- 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.
- has just undergone major surgery as medical surveillance is required.
- is dehydrated as there is a risk of kidney problems in dehydrated children.
- 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 warnings

- Side effects may be minimised by using the minimum effective dose for the shortest duration.
- In general terms, the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems. The 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 medicines.
- 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 this medicine' and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective medicines (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also those requiring concomitant low-dose aspirin, or other medicines 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.
- If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

You should discuss your treatment with your doctor or pharmacist before taking this medicine 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 this medicine if any of the above mentioned conditions concern 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 this medicine

Tell your doctor or pharmacist if your child is using or has recently used or might use any other medicines. This medicine 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 this medicine. You should therefore always seek the advice of your doctor or pharmacist before you use this medicine with other medicines.

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

- Other NSAIDs including COX-2 inhibitors - this may increase the risk of side effects.
- Digoxin (for heart insufficiency) - the effect of digoxin may be enhanced.
- Glucocorticoids medicines containing cortisone or cortisone-like substances - this may increase the risk of gastrointestinal ulcers or bleeding.
- Anti-platelet medicines - this may increase the risk of bleeding.
- Aspirin (low dose) - the blood-thinning effect may be impaired.
- Medicines for thinning the blood (such as warfarin) - ibuprofen may enhance the effects of these medicines.
- Phenytoin (for epilepsy) - the effect of phenytoin may be enhanced.
- Selective serotonin reuptake inhibitors (medicines used for depression) - these may increase the risk of gastrointestinal bleeding.
- Lithium (a medicine for manic depressive illness and depression) - the effect of lithium may be enhanced.
- Probenecid and sulfapyrazone (medicines for gout) - the excretion of ibuprofen may be delayed.
- Medicines for high blood pressure and water tablets - ibuprofen 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 - this may lead to hyperkalaemia.
- Methotrexate (a medicine for cancer or rheumatism) - the effect of methotrexate may be enhanced.
- Tacrolimus and cyclosporine (immunosuppressive medicines) - kidney damage may occur.
- Zidovudine: (a medicine for treating HIV/AIDS) - the use of this medicine may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV+ haemophiliacs.
- Sulfonylureas (antidiabetic medicines) - the blood sugar levels can be affected.
- Quinolone antibiotics - the risk for convulsions (fits) may be increased.
- Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections - 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 - it may increase the plasma concentrations of NSAIDs.
- Aminoglycosides - NSAIDs may decrease the excretion of aminoglycosides.

This medicine with alcohol

You should not drink alcohol while using this medicine. 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 this medicine.

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 take this medicine 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 baby. It may affect you and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take this medicine 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, this medicine 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. This medicine may be used during

breast-feeding, if it used at the recommended dose and for the shortest possible time.

Fertility

This medicine 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.

This medicine contains maltitol liquid and propylene glycol for Nurofen for Children 200 mg/5 mg**Strawberry oral suspension and maltitol liquid and wheat starch for Nurofen for Children 200 mg/5 mg****Orange oral suspension**

- Maltitol liquid:** If you or your child have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking this medicine or giving it to your child.

- Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per 7.5 ml dose, that is to say essentially 'sodium-free'.
- Wheat starch** (only for Orange flavour suspension): Wheat starch in this medicine contains only very low levels of gluten, regarded as gluten-free, and is very unlikely to cause problems if you or your child have coeliac disease. One ml contains no more than 0.06 micrograms of gluten. If you or your child have wheat allergy (different from coeliac disease) you should not take this medicine or give it to your child.

- Propylene Glycol** (only for Strawberry flavour) This medicine contains 16.45 mg propylene glycol in each 5 ml.

3. How to use this medicine

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

This product is twice the strength of normal ibuprofen suspension and you should be careful that you use the correct dose.

The usual dose for pain and fever:

Child's age	How much?	How often in 24h*
7-9 years	5 ml (equivalent to 200 mg ibuprofen) (use the 5 ml end of the measuring spoon)	3 times
10-12 years	7.5 ml (equivalent to 300 mg ibuprofen) (use the measuring spoon twice: 5 ml end + 2.5 ml end)	3 times

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

Not intended for children under 7 years old and weighing less than 20 kg.**WARNING: Do not exceed the stated dose.****Method of administration using the spoon****For oral use**

- Shake the bottle well
- Use the end of the spoon that corresponds to the required dose
- Pour the medicine onto the spoon
- Place the spoon in the child's mouth and administer the dose
- After use replace the cap. Wash the spoon in warm water and allow to dry.

Duration of treatment

This medicine is 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). If this medicine is required for more than 3 days or if symptoms worsen, a doctor should be consulted.

If you use more of this medicine than you should:

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), or more rarely diarrhoea. In addition, headache, gastrointestinal bleeding, blurred vision, ringing in the ear, confusion and shaky eye movement, and exacerbation of asthma in asthmatics. At high doses, drowsiness, excitation, disorientation, chest pain, palpitations, loss of consciousness, coma convulsions (mainly in children), vertigo, weakness and dizziness, blood in urine, low blood pressure, hyperkalaemia, metabolic acidosis, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, cold body feeling, and breathing problems have been reported.

If you or your child forget to take this medicine:

Do not take a double dose to make up for the forgotten dose. If you do forget to take a dose, take it as soon as you remember and then take the next dose according to the dose 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, this medicine can cause side effects, although not everybody gets them.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms.

Although side effects are uncommon, 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 medicine 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.

- 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.

Like all medicines, this medicine can cause side-effects, although not everybody gets them.