

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Nurofen for Children Six Plus  
Orange 200mg/5ml Oral Suspension  
ibuprofen

For use in children from 20kg body weight (6 years) to 40kg body weight (12 years).

**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:**

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. This product has been specifically formulated for children as it is given by mouth to:

- Reduce fever
- Relieve symptoms of mild to moderate pain

You must talk to a doctor if your child does not feel better or if your child feels worse after 3 days.

### **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 pain killers (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 or severe kidney failure
- Have severe heart failure
- Have inherited problems coping with fructose/fruit sugar (see important information about the ingredients)

- 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 (through 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 an infection – please see heading ‘Infections’ below
- 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 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 you take other 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 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. 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 s shortness of breath may occur
- Suffers from hay-fever, 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.
- 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 a risk of renal impairment in dehydrated children

#### **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/take this medicine while your child/you have an infection and symptoms of the infection persist or worsen, consult a doctor without delay.

#### **Skin reactions**

Serious skin reactions have been reported in association with Nurofen for Children treatment. You should stop taking Nurofen for Children and seek medical attention immediately, if you develop any skin rash, lesions 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.

Gastrointestinal 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 or 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. 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.

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 (medical 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 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, 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) interactions may be possible
- Quinolone antibiotics since the risk of 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. 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. Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor advises you otherwise. 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.

#### Driving and using machines

For short-term use this medicine has no or negligible influence on the ability to drive and use machines.

- Nurofen for Children contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- May have a mild laxative effect
- Calorific value 2.3 kcal/g maltitol
- This medicine contains less than 1 mmol sodium (23 mg) in each dose, that is to say, essentially “sodium-free”
- 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 have coeliac disease
- One 5 ml dosage unit contains no more than 0.315 micrograms of gluten
- If you have a wheat allergy (different from coeliac disease) you should not take this medicine.

### 3. How to use Nurofen for Children

**Always take 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 worse (see section 2).

The usual dose for pain and fever:

| <b>Childs weight (age)</b> | <b>How much?</b>   | <b>How often in 24 hours? *</b> |
|----------------------------|--|---------------------------------|
| 20-29kg (6-9 years)        | 5ml (equivalent to 200mg ibuprofen)                                    | 3 times                         |
| 30-40kg (10-12 years)      | 7.5ml (equivalent to 300mg ibuprofen).<br>Use spoon twice: 5ml + 2.5ml | 3 times                         |

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

**Not intended for use in children under 6 years of age or under 20kg**

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

**WARNING: do not exceed the stated dose.**

### **Method of administration using the spoon**

For oral use.

1. Shake the bottle well
2. Use the end of the spoon that corresponds to the required dose
3. Pour the medicine onto the spoon
4. Place the spoon in the child's mouth and administer the dose
5. 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. If the child's symptoms persist for more than 3 days seek medical advice. If symptoms worsen consult your doctor.

### **If you use more Nurofen for Children than you should:**

If you have taken more Nurofen for Children than you should, or if children have taken this medicine by accident, always contact a doctor or nearest hospital to get an opinion on the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, headache, ringing in the ear, confusion, shaky eye movement (nystagmus) 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 and exacerbation of asthma in asthmatics, 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 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, as your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Nurofen for Children 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 our 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 had any of the following side effects, they become worse or you notice any affects 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
- 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 1,000 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 kidney damage or kidney failure
- Psychotic reactions, depression
- High blood pressure, vasculitis
- Palpitations
- Liver dysfunction, damage to the liver (first signs could be discolouration 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 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.
- 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 eosinophils (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 generalized 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

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

Reporting side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can report side effects directly via HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie).

## **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.

Each 5ml spoonful of oral suspension contains 200mg ibuprofen.

Each 2.5ml spoonful of oral suspension contain 100mg ibuprofen.



The ibuprofen content is equivalent to 4.0% w/v.

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.

### **What Nurofen for Children looks like and contents of the pack**

Nurofen for Children is an off-white, viscous suspension with an orange flavour.

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

The pack contains a double-ended measuring spoon (with a 2.5ml bowl with a 1.25ml inner mark at one end, and a 5ml bowl at the other end) to measure the dose correctly.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

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

Manufacturer: RB NL Brands, B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL  
PA 979/56/1

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

|                 |  |
|-----------------|--|
| Belgium         | Nurofen voor Kinderen Suikervrij 4%  |
| Bulgaria        | Нурофен за Юноши Портокал 200 mg/5 ml перорално суспензия                        |
| Cyprus          | Nurofen για Παιδιά 4%<br>Πορτοκάλι   |
| Czech Republic  | Nurofen proděti 4% pomeranč  |
| Germany         | Nurodon Junior Fieber- und Schmerzsaft Orange 40 mg/ml Suspension zum Einnehmen. |
| Hungary         | Nurofen narancsízű 4% szuszpenzió gyermekeknek                                   |
| Ireland         | Nurofen for Children Six plus Orange 200mg/5ml Oral Suspension                   |
| Luxembourg      | Nurofen pour Enfants 4% suspension buvable                                       |
| Netherlands     | Nurofen voor Kinderen Sinaasappel suspensie, suspensie 200 mg/5ml                |
| Poland          | Nurofen dla dzieci Juiniór pomarańczowy  |
| Portugal        | Nurofen Laranja 40 mg/ml Suspensao Oral  |
| Romania         | Nurofen Junior, cu aromă de portocale 200 mg/5 ml suspensie orală                |
| Slovak Republic | Nurofen pre deti 4% pomeranč   |

This leaflet was last approved in upon approval