

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Nurofen for Children  
100mg Chewable Capsules, Soft  
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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

### What is in the leaflet

1. What Nurofen for Children 100mg chewable capsules are and what they are used for
2. What you need to know before you give Nurofen for Children 100mg chewable capsules
3. How to take Nurofen for Children 100mg chewable capsules
4. Possible side effects
5. How to store Nurofen for Children 100mg chewable capsules
6. Contents of the pack and other information

### 1. What Nurofen for Children 100mg chewable capsules are and what they are used for?

The active ingredient (which makes this medicine work) is ibuprofen which is a non-steroidal anti-inflammatory (NSAID) painkiller.

Nurofen for Children 100mg chewable are used in **children from 7 to 12 years** for the relief of mild to moderate pain such as a sore throat, dental pain, earache, headache, minor aches and sprains, and symptoms of cold and flu.

Ibuprofen also brings down a high temperature (fever).

**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 give Nurofen for Children 100mg chewable capsules

**Do not give this medicine to your child if they:**

- Are **allergic** to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- Have ever had a **reaction** (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat) after taking **ibuprofen, low dose aspirin (acetylsalicylic acid)** (up to 75 mg a day) **or other non-steroidal anti-inflammatory (NSAID) medicines**, or any of the other ingredients in this medicine (see Section 6 and Section 2: Important information about some of the ingredients)
- They are allergic to peanuts or soya as this medicinal product contains soya lecithin
- Are **under 7 years of age**
- Have (or have had two or more episodes) of a **stomach ulcer, perforation or bleeding**
- 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
- Has or has had **high blood pressure, heart problems or a stroke** because there is a small increased risk of heart problems with ibuprofen
- Has a condition which may put them at risk of heart problems, such as **diabetes or high cholesterol**
- Has **asthma** or any **allergic disease of the lungs**
- Has, or has had **liver, kidney or bowel problems**
- Is **dehydrated**, as there is a risk of kidney problems in dehydrated children and adolescents
- Has **SLE** (Systemic Lupus Erythematosus, a condition of the immune system affection connective tissue resulting in joint pain, skin changes and disorders of other organs) or a mixed connective tissue disease
- Has **hereditary blood formation disorder** (acute intermittent porphyria)
- Suffers from **chronic inflammatory bowel disease** such as Crohn’s disease or ulcerative colitis
- Has just had **major surgery**
- During chicken pox (varicella) it is advisable to avoid use of Nurofen for Children 100mg chewable capsules.

### Infections

Nurofen for Children may hide signs of infection 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 take/give this medicine while you/your child has an infection and symptoms of the infection persist or worsen, consult a doctor without delay.

### Skin Reactions

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 associated with ibuprofen treatment. Stop using Nurofen for Children 100mg chewable capsules and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

### **If you are an ADULT taking this medicine**

The warnings and information given in this section apply and also the following:

- 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. 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.
- **DO NOT** take Nurofen for Children 100mg chewable capsules if you are in the last 3 months of your 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.
- Medicines such as Nurofen for Children 100mg chewable capsules 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
- 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.
- If you have a blood clotting disorder or if you have another bleeding disorder, 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.

### **Elderly patients**

If you are elderly, talk to your doctor before using this medicine, as you may be more likely to suffer from side effects.

### **Other medicines and Nurofen for Children 100mg chewable capsules**

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- Other medicines containing **ibuprofen or other NSAIDs**
- **low dose aspirin (acetylsalicylic acid)** (up to 75 mg a day)
- **diuretics** (to help you pass water)
- **anticoagulants** (blood thinning medicines e.g. warfarin)
- Medicines for high blood pressure (e.g. **captopril, atenolol, losartan**)
- **lithium** (for mood disorders)
- **phenytoin** (antiepileptic)
- **methotrexate** (for psoriasis, arthritis and types of cancer)
- **zidovudine** (for HIV)
- **corticosteroids** (anti-inflammatory medicines such as prednisone)
- **cardiac glycosides** (for heart problems)
- **ciclosporin or tacrolimus** (to prevent organ rejection after transplant)
- **mifepristone** (for termination of pregnancy)
- **quinolone antibiotics** (for infections)
- **probenecid and sulfinpyrazone** (used to treat gout)
- **SSRI antidepressant** medicines
- antiplatelet medicines (blood thinning medicines) e.g. **dipyridamole, clopidogrel**
- **sulfonylurea** medicines (to lower the blood glucose level)

**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.**

### **Nurofen for Children 100mg chewable capsules with food and drink**

Ibuprofen may be taken on an empty stomach without water. However, a small number of people might experience mild indigestion with this medicinal product. If your child experiences mild indigestion, it is recommended to take this medicine with food or milk, to avoid gastrointestinal problems.

**Nurofen for Children 100mg chewable capsules contain soya lecithin.** If you are allergic to peanuts or soya do not use this medicinal product

**Nurofen for Children 100mg chewable capsules contain glucose and sucrose.** 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 be harmful to the teeth.

Nurofen for Children 100mg chewable capsules contain less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium free”

### **3. How to give Nurofen for Children 100mg chewable capsules**

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

This medicine is for oral use.

The capsules should be chewed and then swallowed. Capsules can be taken with or without liquid.

This medicine is for short term use only.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

**Do not give Nurofen for Children 100mg chewable capsules to children under 7 years of age.**

The recommended dose is:

<b>Age</b>	<b>Dose</b>
7 years – 9 years	Two capsules 3 times in 24 hours
10 years – 12 years	Three capsules 3 times in 24 hours

Doses should be given approximately every 6 to 8 hours (or with a minimum of 6 hours between each dose if required).  
WARNING: Do not exceed the stated dose.  
If in children this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

#### **If you give more Nurofen for Children 100mg chewable capsules than you should:**

If you give more medicine than you should, or if someone has taken more medicine than they 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 of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

#### **If you forget to give Nurofen for Children 100mg chewable capsules**

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** to make up for a forgotten dose.

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 100mg chewable capsules can cause side effects, although not everybody gets them.

**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, light-headedness, racing heart, fluid retention (swollen ankles or decreased levels of passing urine)
- Stiff neck, headache, nausea, vomiting, fever and disorientation
- Swelling of the face
- 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] [very rare – may affect up to 1 in 10,000 people]
- Widespread rash, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cells) (DRESS syndrome) [not known – frequency cannot be estimated from the available data]
- 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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis) [not known – frequency cannot be estimated from the available data].

**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 and/or skin, 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 (affects 1 to 10 users in 1,000)**

- Headache

**Rare (affects 1 to 10 users in 10,000)**

- Diarrhoea, wind, vomiting or constipation. Tell your doctor if these last for more than a few days or become troublesome

**Very rare (affects less than 1 user in 10,000)**

- Kidney and liver problems
- Stroke or heart problems. This is unlikely at the dose level given to children

- Worsening of inflammation of the large intestine (colitis) and chronic inflammatory bowel disease (Crohn's disease)
- High blood pressure

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

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Skin becomes sensitive to light.

### **Reporting of 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 report side effects directly in Ireland via HPRA Pharmacovigilance. Website: [www.hpra.ie](http://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 100mg chewable capsules**

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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

## **6. Contents of the pack and other information**

### **What Nurofen for Children 100mg chewable capsules contain**

- The active substance is ibuprofen. Each chewable capsule contains 100mg of ibuprofen
- The other ingredients are: Gelatin, Purified water, Glucose liquid, Sucrose, Fumaric acid (E297), Sucralose, Citric acid (E330), Acesulfame K (E950), disodium edetate, Glycerin, Natural Orange Flavour\*, Red iron oxide (E172), Yellow iron oxide (E172) and Opacode White NS078-18011\*\*  
Processing aids: Medium chain triglycerides, Soya lecitin, Stearic Acid and Isopropyl alcohol.  
\*the flavour contains: (R)-p-mentha-1,8-diene (d-limonene), Ethyl acetate and Alpha-Pinene  
\*\*the ink contains: purified water, titanium dioxide (E171), propylene glycol, isopropyl alcohol, HPMC 2910/Hypromellose 3cP (E464)

### **What Nurofen for Children 100mg chewable capsules look like and contents of the pack**

Nurofen for Children 100mg chewable capsules are orange, square shaped chewable soft gelatin capsules with "N100" in white ink.

Nurofen for Children 100mg chewable capsules are available in PVC/PE/PVdC/Al blisters.

Packs of 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30 and 32 capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holders**

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

### **Manufacturer:**

Reckitt Benckiser Healthcare International Ltd, Thane Road, Nottingham, NG90 2DB, UK

RB NL Brands, B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL

**Licence Number:** PA 979/69/1

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

NL Nurofen voor Kinderen Sinaasappel 100 mg, kauwcapsules, zacht

IE Nurofen for Children 100 mg, Chewable Capsules, soft

RO Nurofen Junior 7 ani+ cu aroma de portocale 100 mg capsule moi masticabile

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