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PACKAGE LEAFLET: INFORMATION FOR THE USER

NUROFEN®

Nurofen for Children 200mg/5ml Orange oral suspension

Nurofen for Children 200mg/5ml Strawberry oral suspension

Contains Ibuprofen

This leaflet is valid for Nurofen for Children 200mg/5ml Orange oral suspension and Nurofen for Children 200mg/5ml 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:

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 of 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.

Other warnings

- Serious skin reactions (such as Steven-Johnson syndrome) have been reported very rarely in association with the used of NSAIDs. The use of this medicine 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 this medicine.
- Side effects may be minimized 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.
- 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 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.

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 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 - 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 sulfinpyrazones (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 canreoate, 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.

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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 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. 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.

<u>This medicine contains maltitol liquid and sodium for Nurofen for Children 200mg/5ml Strawberry oral suspension, and maltitol liquid, sodium and wheat starch for Nurofen for Children 200mg/5ml Orange oral suspension</u>

- **Maltitol liquid:** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **Sodium:** This medicine contains less than 1mmol sodium (23 mg) per 7.5 ml dose, that is to say essentially 'sodium-free'.
- **Wheat starch** (only for Nurofen for Children 200mg/5ml Orange oral 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 have coeliac disease. One ml contains no more than 0.06 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

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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	5ml (equivalent to 200 mg ibuprofen) (use the 5ml end of the measuring spoon)	3 times
10-12 years	7.5ml (equivalent to 300 mg ibuprofen) (use the measuring spoon twice: 5ml end + 2.5ml 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.

<u>Method of administration using the spoon</u>

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.

<u>Duration of treatment</u>

This medicine is for short-term use only. 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:

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 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 ofeosinophils (a type of white blood cells).

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 in 10 people)

- Stomach and intestinal complaints such as 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 in 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 in 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 this medicine 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)

<u>Not known</u>: (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 of side effects

If your child gets 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store this medicine

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 and label. The expiry date refers to the last day of that month.
Do not store above 25 °C.
After opening: use within 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 this medicine contains:

Each ml oral suspension contains 40 mg ibuprofen
Each 5 ml measuring spoon of oral suspension contains 200 mg ibuprofen.
Each 2.5ml measuring spoon of oral suspension contains 100 mg ibuprofen.
The other ingredients are: polysorbate 80, glycerol, maltitol liquid, saccharin sodium, citric acid monohydrate, sodium citrate, xanthan gum, sodium chloride, orange
flavour (containing wheat starch) or strawberry flavour, domiphen bromide and purified water.

What this medicine looks like and contents of the pack

This medicine is an off-white, viscous oral suspension with an orange or strawberry flavour.
Each bottle contains either 30 ml, 50 ml, 100 ml.
The pack contains a double-ended measuring spoon (with a 2.5 ml bowl with 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

<u>Marketing Authorisation Holder:</u>
Reckitt Benckiser Healthcare (UK) Ltd, Dansom Lane, Hull HU8 7DS UK

<u>Manufacturer:</u>
Reckitt Benckiser Healthcare (UK) Ltd, Dansom Lane, Hull HU8 7DS UK

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