PATIENT INFORMATION LEAFLET NUROFEN FOR

CHILDREN 200 mg/ 5 mL SUSPENSION

SCHEDULING STATUS

S2

NUROFEN FOR CHILDREN STRAWBERRY 4 % *m/v*

NUROFEN FOR CHILDREN ORANGE 4 % *m/v*

Ibuprofen 200 mg per 5 ml oral suspension

Contains sweeteners: sodium saccharin 11 mg and maltitol liquid 2226 mg per 5 mL

Contains preservative: domiphen bromide 0,5 mg per 5 ml

Read all of this leaflet carefully because it contains important information for you:

NUROFEN® FOR CHILDREN 4 % is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use NUROFEN® FOR CHILDREN 4 % carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NUROFEN® FOR CHILDREN 4 % with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet:

1. What NUROFEN® FOR CHILDREN 4 % is and what it is used for

2. What you need to know before you use NUROFEN® FOR CHILDREN 4 %

3. How to use NUROFEN® FOR CHILDREN 4 %

4. Possible side effects

5. How to store NUROFEN® FOR CHILDREN 4 %

6. Contents of the pack and other information

1. What NUROFEN® FOR CHILDREN 4 % is and what it is used for:

The active ingredient (which makes this medicine to 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.

NUROFEN® FOR CHILDREN 4 % 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.

2. What you need to know before you use NUROFEN® FOR CHILDREN 4 %:

Do NOT give NUROFEN® FOR CHILDREN 4 % to children who:

- are allergic to ibuprofen or other similar painkillers (NSAIDs) or any of the other ingredients of NUROFEN® FOR CHILDREN 4 % (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 failure.
- has kidney impairment, or severe acute (sudden) or chronic (long term) kidney disease
- 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 NUROFEN® FOR CHILDREN 4 % if you are in the last 3 months of pregnancy.

Warnings and precautions:

Take special care and check with a doctor or pharmacist before using NUROFEN® FOR CHILDREN 4 % 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 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 NUROFEN® FOR CHILDREN 4 %"**).
- has or has had asthma or allergic diseases as 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.

- 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 use of NSAIDs. The use of NUROFEN® FOR CHILDREN 4 % 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 using NUROFEN® FOR CHILDREN 4 %.

Side effects may be minimised by using the minimum effective due 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, use of NUROFEN® FOR CHILDREN 4 % should be avoided.

Kidney damage, leading to problems with waste removal of acids from your blood and abnormally low levels of potassium in your body may occur. As a result, you may experience difficulty urinating, muscle weakness and light-headedness. Discontinue use of NUROFEN FOR CHILDREN 4 % and consult your doctor at the first appearance of signs of kidney damage.

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.

NSAIDS may mask symptoms of infection or fever.

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Gastro-intestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs such as NUROFEN® FOR CHILDREN 4 % at any time during treatment, with or without warning symptoms or a previous history of serious gastro-intestinal events. When gastro-intestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastro-intestinal bleeding, ulceration or perforation is higher with increasing NSAIDs 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.

Anti-inflammatory/pain-killer medicines like NUROFEN® FOR CHILDREN 4 % may be associated with an 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 4 % 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 family history of heart disease or stroke, or if you are a smoker.

Consult your doctor before using NUROFEN® FOR CHILDREN 4 % if any of the above-mentioned conditions concern your child.

Elderly:

Caution is advised because of an increased risk of side effects, when taking NSAIDS, particularly those relating to the stomach and bowel. See **section 4 "Possible side effects**" for more information.

You must report any unusual abdominal symptoms such as intestinal bleeding (which may be indicated by tarry stools), vomiting, nausea and pain in the belly, particularly in the early stages of treatment.

Other medicines and NUROFEN® FOR CHILDREN 4 %:

Always tell your health care provider if your child is taking any other medicines.

(This includes all complementary or traditional medicines).

NUROFEN® FOR CHILDREN 4 % may affect or be affected by some other medicines.

Do not use NUROFEN® FOR CHILDREN 4 % together with these medicines:

- Other NSAIDs including COX-2 inhibitors – this may increase the risk of side effects.
- Aspirin (low-dose) – the blood-thinning effect may be impaired.

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines, especially:

- Digoxin (for heart insufficiency – the effect of digoxin may be enhanced, which may lead to heart problems.
- Glucocorticoids medicine containing cortisone or cortisone-like substances – this increases the risk of gastro-intestinal ulcers or bleeding.
- Medicines for thinning the blood (such as warfarin) – ibuprofen may enhance the effects of these medicines, making you or your child more prone to bleeding.
- Phenytoin (for epilepsy) - the effect of phenytoin may be enhanced.
- Selective serotonin reuptake inhibitors (medicines used for depression)- these may increase the risk of gastro-intestinal bleeding.

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- Lithium (a medicine for manic depressive illness and depression) – the effect of lithium may be enhanced.
- Probenecid and sulfinpyrazone (medicines for gout) –this may increase NUROFEN® FOR CHILDREN 4 % side effects.
- Medicines for high blood pressure and water tablets due to an increased risk of kidney problems.
- Potassium sparing diuretics e.g. amiloride, potassium canrenoate, spironolactone, triamterene – this may lead to hyperkalaemia (too much potassium in your body), leading to heart problems.
- 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.
- Mifepristone (for terminating pregnancy)- **NUROFEN FOR CHILDREN 4 %** must not be used 8-12 days after taking mifepristone.
- Sulfonylureas (antidiabetic medicines) – the blood sugar levels can be affected.
- Quinoline antibiotics – the risk for convulsions (fits) may be increased.
- Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections – the effect of ibuprofen may be increased, therefore your doctor may need to adjust your NUROFEN® FOR CHILDREN 4 % dose.
- Baclofen (for treating muscle spasms)– undesirable effects such as kidney impairment may occur.
- Ritonavir (for treatment of HIV infection)– it may increase side effects related to NUROFEN® FOR CHILDREN 4 %.

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- Aminoglycosides (some antibiotics for treating bacterial infections)– due to increased of side effects related to these antibiotics.

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 NUROFEN® FOR CHILDREN 4 %.

Pregnancy

Do not use NUROFEN® FOR CHILDREN 4 % if you are in the last 3 months of pregnancy due to serious kidney problems in the unborn baby and maternal complication pre-birth resulting in delayed or prolonged labour. Avoid the use of NUROFEN® FOR CHILDREN 4 % in the first 6 months of pregnancy due to a risk of foetal malformations, unless your doctor advises you otherwise.

Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into breast milk. NUROFEN® FOR CHILDREN 4 % may be used during breast-feeding, if it is used at the recommended dose and for the shortest possible time.

Fertility

NUROFEN® FOR CHILDREN 4 % belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping NUROFEN® FOR CHILDREN 4 %.

Driving and using machinery:

Dizziness and blurred vision have been reported with the use of **NUROFEN for Children 4 %,** therefore exercise caution as your child's ability to drive and use machines may be impaired.

NUROFEN® FOR CHILDREN 4 % contains:

Maltitol liquid: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NUROFEN® FOR CHILDREN 4 %.

Sodium: NUROFEN® FOR CHILDREN 4 % contains less than 1 mmol sodium (23 mg) per 7,5 ml dose, that is to say essentially "sodium-free".

Wheat starch: NUROFEN® FOR CHILDREN 4 % 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 NUROFEN® FOR CHILDREN 4 %.

3. HOW TO TAKE NUROFEN® FOR CHILDREN 4 %

Do not share medicines prescribed for you with any other person.
Always take NUROFEN® FOR CHILDREN 4 % exactly as described in this leaflet or as your doctor, or pharmacist, or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

NUROFEN® FOR CHILDREN 4 % is twice the strength of normal ibuprofen suspension and you should be careful that you take the correct dose:

The usual dose for pain and fever:

Child's age	How much	How often in 24 hour?

7 to 9 years	5 ml (equivalent to 200 mg ibuprofen) (use the 5 ml end of the measuring spoon)	3 times
10 to 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.

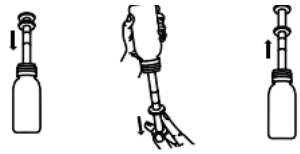
Not intended for children under 7 years old and weighing less than 20 kg.

WARNING: Do not exceed the stated dose.

Method of administration using the spoon.

For oral use:

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: NUROFEN® FOR CHILDREN 4 % is for short-term use only. If NUROFEN® FOR CHILDREN 4 % is required for more than 3 days or if symptoms worsen or persist, consult your doctor.

If you take more NUROFEN® FOR CHILDREN 4 % than you should:

If you have taken more NUROFEN® FOR CHILDREN 4 % than you should, or if children have taken this medicine by accident, always contact a doctor or pharmacist or go to your nearest hospital or poison centre.

- 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 NUROFEN® FOR CHILDREN 4 %:

Do not take a double dose to make up for forgotten individual doses

If your child misses a dose of NUROFEN® FOR CHILDREN 4 %, give it to your child as soon as you remember and then follow the next dose according to the dose interval detailed above. If you have further questions on the use NUROFEN® FOR CHILDREN 4 % ask your doctor or pharmacist.

4. Possible side effects

NUROFEN® FOR CHILDREN 4 % can have side effects.

Not all side-effects reported for NUROFEN® FOR CHILDREN 4 % are included in this leaflet. Should your child's general health worsen or if the child experiences any untoward effects while taking NUROFEN® FOR CHILDREN 4 %, please consult your health care provider for advice.

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

If any of the following happens, stop using NUROFEN® FOR CHILDREN 4 % and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity (allergic) reactions with hives and itch
- 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 reactions 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 NUROFEN® FOR CHILDREN 4 %.
- 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).
- Severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnsons syndrome, erythema multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia)

These are all very serious side effects. If you have them, you may have had a serious reaction to NUROFEN® FOR CHILDREN 4 %. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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.
- Respiratory tract reactivity comprising asthma, bronchospasm or breathing difficulty
- Heart attack, heart problems and/or stroke
- 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.
- 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)
- Palpitations
- 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 therapy immediately and consult a doctor. Any self-treatment with pain killers or medicines that reduce fever (antipyretic medicines) must be avoided.
- 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.
- High blood pressure, vasculitis
- Passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function), swelling (oedema) and cloudy urine (nephrotic

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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® FOR CHILDREN 4 % and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure

- Potassium deficiency (indicated by muscle weakness and cramps)
- Oesophagitis, pancreatitis, and formation of intestinal diaphragm-like strictures (may be indicated by abdominal pain).

Tell your doctor if you notice any of the following

Frequent:

- 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.

Less frequent:

- Headache, dizziness, sleeplessness, agitation, irritability or tiredness.
- Visual disturbances
- Various skin rashes
- Hypersensitivity reactions with hives and itch
- Tinnitus (ringing in the ears)
- Increased uric acid concentrations in the blood
- Decreased haemoglobin levels, which may cause anaemia (indicated by light-headedness, pallor and fatigue)
- Psychotic reactions, depression

Frequency not known:

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- Painful urination
- Urine changes such as bloody or cloudy urine, foul smelling urine
- Decreased appetite
- Being sensitive to light

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of **NUROFEN® for Children Sugar-Free**.

5. How to store NUROFEN® FOR CHILDREN 4 %:

Store all medicines out of reach of children.

Store at or below 25 °C. Keep bottle well closed and away from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the carton and label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What NUROFEN® FOR CHILDREN 4 % contains:

The active substance is ibuprofen.

The other ingredients are citric acid monohydrate, domiphen bromide, glycerol, maltitol liquid, polysorbate 80, purified water, sodium chloride, sodium citrate, sodium saccharin, permitted flavour and xanthan gum.

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Permitted flavour:

NUROFEN® FOR CHILDREN 4 % STRAWBERRY: strawberry flavour 500244E:

- Strawberry flavour contains natural & artificial flavourings, maltodextrin (wheat), modified starch E1450 (maize), Arabic gum E414.

NUROFEN® FOR CHILDREN 4 % ORANGE: orange flavour 500244E:

- Orange flavour (contains natural & artificial flavourings, maltodextrin (wheat), modified starch E1450 (maize), Arabic gum E414).

What NUROFEN® FOR CHILDREN 4 % looks like and contents of the pack:

NUROFEN® FOR CHILDREN 4 % STRAWBERRY: off-white strawberry-flavoured syrupy

NUROFEN® FOR CHILDREN 4 % ORANGE: an off-white orange-flavoured syrupy suspension.

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

The pack contains a double ended measuring spoon (with a 2,5 ml bowl with 1,25 ml inner mark at one end and a 5 ml bowl at the other end) to measure the dose correctly. Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Reckitt Benckiser Pharmaceutical (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

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22 February 2022

Registration Number:

NUROFEN FOR CHILDREN STRAWBERRY 4% *m/v:* *49/2.7/0178*

NUROFEN FOR CHILDREN ORANGE 4 % *m/v:* *49/2.7/0179*

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