PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

NUROFEN® for Children STRAWBERRY

Each 5ml suspension contains 100 mg of Ibuprofen

Contains sugar: maltitol 2226,0 mg per 5 ml

Contains sweetener: saccharin 10,0 mg per 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 STRAWBERRY** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **NUROFEN® for Children STRAWBERRY**carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **NUROFEN® for Children STRAWBERRY** 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 three (3) days.

What is in this leaflet:

1. What **NUROFEN® for Children STRAWBERRY** is and what it is used for
2. What you need to know before you use **NUROFEN® for Children STRAWBERRY**
3. How to use **NUROFEN® for Children STRAWBERRY**
4. Possible side effects

5. How to store **NUROFEN® for Children STRAWBERRY**

6. Contents of the pack and other information

1. WHAT NUROFEN® FOR CHILDREN STRAWBERRY IS AND WHAT IT IS USED FOR:

The active ingredient is ibuprofen. Ibuprofen belongs to a group of medicines non-steroidal anti-inflammatory drugs (NSAIDs). These medicines provide relief by changing the body's response to pain, inflammation and fever.

NUROFEN® FOR CHILDREN STRAWBERRY is used for relieving pain (including headaches, migraines, back pain, muscular aches, dental pain and menstrual pain) and fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NUROFEN® FOR CHILDREN STRAWBERRY:

Do not use NUROFEN® FOR CHILDREN STRAWBERRY if you or your child suffer from the following:

- Allergic reaction to ibuprofen, aspirin (or other similar painkillers known as NSAIDs) or other ingredients of NUROFEN® FOR CHILDREN STRAWBERRY;
- Stomach ulcers, shortness of breath, asthma, runny nose or hives after using aspirin or other similar painkillers (NSAIDs);
- Heart failure;
- Severe liver impairment;
- Severe kidney impairment
- Stomach ulcers or bleeding in the gut (or you previously suffered from these);
- Taking lithium or digoxin treatment.

Do not take **NUROFEN® FOR CHILDREN STRAWBERRY** if you are in the last trimester of pregnancy.

Do not give **NUROFEN® FOR CHILDREN STRAWBERRY** to children under 12 months old.

Warning and precautions:

Take special care with NUROFEN® FOR CHILDREN STRAWBERRY if you or your child:

- are already taking any other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or aspirin.
- have tonsillitis (inflamed tonsils) or think you may have a bacterial throat infection (as you may need antibiotics).
- have or have ever had asthma or suffer from allergies.
- suffer from a skin condition called systemic lupus erythematosus or mixed connective tissue disease.
- have a history of hypertension (high blood pressure) or heart failure.
- have a history of bowel disease (ulcerative colitis, Crohn's disease).
- if you generally bruise easily or experience abnormal bleeding.
- have heart or liver problems.
- have had a stroke.
- If you are elderly (as you may be more likely to have side effects).
- Pregnant or struggling to conceive.

Whilst using NUROFEN® FOR CHILDREN STRAWBERRY:

- At the first sign of any skin reaction (rash, peeling, blistering) or other sign of an allergic reaction, stop using **NUROFEN® FOR CHILDREN STRAWBERRY** and consult a doctor at once.
- Report any unusual abdominal symptoms (especially bleeding) to your doctor.

- If you do not get better, you get worse, or develop new symptoms, talk to a doctor.
- Medicines such as **NUROFEN® FOR CHILDREN STRAWBERRY** may be associated with an increased risk of heart attack or stroke. Any risk is more likely with higher doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment (see **section 3**).
- 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 STRAWBERRY** and consult your doctor at the first appearance of signs of kidney damage.

Other medicines and NUROFEN® FOR CHILDREN STRAWBERRY:

Always tell your health care provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Do not use **NUROFEN® FOR CHILDREN STRAWBERRY** together with aspirin or similar painkillers due to an increased risk of side effects.

Tell your doctor or pharmacist if you or your child need to use NUROFEN® FOR CHILDREN STRAWBERRY with any of the following:

- Warfarin and other blood anti-clotting medicines
- ACE inhibitors, angiotensin-II-antagonists (medicines which lower blood pressure)
- Diuretics (water tablets) including potassium sparing diuretics
- SSRIs (selective serotonin re-uptake inhibitors) for depression
- Cardiac glycosides (for heart problems) such as digoxin
- Ciclosporine (to prevent organ rejection after transplant)
- Corticosteroids (to reduce inflammation)

- Lithium (for mood disorders)
- Methotrexate (for psoriasis, arthritis and cancer)
- Mifepristone (used to terminate pregnancy) NSAIDs should not be used for 8 – 12 days after taking mifepristone, as they can reduce the effect of mifepristone
- Oral antidiabetic medicines
- Phenytoin (for epilepsy)
- Probenecid, sulfinpyrazone (for gout and arthritis)
- Quinolone antibiotics (for bacterial infections) such as ciprofloxacin, levofloxacin
- Tacrolimus (immunosuppressant used after organ transplant)
- Zidovudine (for HIV).

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **NUROFEN® FOR CHILDREN STRAWBERRY.**

NUROFEN® FOR CHILDREN STRAWBERRY is not recommended during pregnancy. Do not take **NUROFEN® FOR CHILDREN STRAWBERRY** (or give it to your child) in the last trimester of pregnancy or during breastfeeding.

NUROFEN® FOR CHILDREN STRAWBERRY may impair fertility in women, but this is reversible when treatment is discontinued. **NUROFEN® FOR CHILDREN STRAWBERRY** is not recommended if you have difficulty falling pregnant.

Driving and using machines:

Dizziness and blurred vision have been reported with the use of **NUROFEN® FOR CHILDREN STRAWBERRY,** therefore may negatively influence your child's ability to perform any tasks that require concentration.

It is not always possible to predict to what extent **NUROFEN® FOR CHILDREN STRAWBERRY** may interfere with the daily activities of the patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **NUROFEN® FOR CHILDREN STRAWBERRY** affects them.

NUROFEN® FOR CHILDREN STRAWBERRY contains maltitol:

Do not take **NUROFEN® FOR CHILDREN STRAWBERRY** if you are intolerant to some sugars including fructose.

3. HOW TO TAKE NUROFEN® FOR CHILDREN STRAWBERRY:

Do not share medicines prescribed for you or your child with any other person.

Always use **NUROFEN® FOR CHILDREN STRAWBERRY** exactly as described in the leaflet or your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Do not give **NUROFEN® FOR CHILDREN STRAWBERRY** to children under 12 months, unless at the advice of a doctor.

The usual dose is:

Age	**Body weight**	**Daily dosage in 5 ml spoonful**
1 – 2 years	7 to 12 kg	2,5 ml (half a teaspoon) 3 to 4 times daily
3 – 7 years	14 to 23 kg	2,5 to 5 ml (half a teaspoon to 1 teaspoon) 4 to 4 times daily
8 – 12 years	25 to 40 kg	10 ml (two teaspoons) 3 to 4 times daily
Adults and children	Above 40 kg	10 to 20 ml (two to four teaspoons) 3 to 4

aged ≥ 12 years		times daily

Using the 5 ml easy dosing syringe:

- Push the syringe firmly into the plug (hole) in the neck of the bottle.
- Shake the bottle well.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the liquid to the correct mark on the syringe.
- Turn the bottle the right way up and remove the syringe from the plug and bottle by gently twisting the syringe.



*If you take more **NUROFEN® FOR CHILDREN STRAWBERRY** than you should:*

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdosage may include nausea, vomiting, drowsiness and being disorientated.

*If you forget to take use **NUROFEN® FOR CHILDREN STRAWBERRY**:*

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

4. POSSIBLE SIDE EFFECTS:

NUROFEN® FOR CHILDREN STRAWBERRY can have side effects.

Not all side effects reported for **NUROFEN® FOR CHILDREN STRAWBERRY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **NUROFEN® FOR CHILDREN STRAWBERRY**, please consult your health care provider for advice.

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

- Anaphylaxis, indicated by swelling of mouth, throat and face or limbs, and inability to breathe.
- Asthma or worsening of your asthma.
- Allergic reactions such as rash, hives, itchy skin.
- DRESS syndrome: life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat.
- Severe skin reactions like Stevens-Johnson syndrome and toxic epidermal necrolysis: these are indicated by fever and body aches, painful/reddish rash on the skin, mouth, throat and/or genitals followed by blistering.
- Severe low blood pressure (can be indicated by fainting or loss of consciousness).

These are all very serious side effects. If you have them, you may have had a serious reaction to NUROFEN® FOR CHILDREN STRAWBERRY. You 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:

Less frequent side effects:

- Blood disorders, this can make you prone to opportunistic illnesses, bruising easily and being prone to bleeding. First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.
- Aseptic meningitis (inflammation of the brain): signs include stiff neck, headache, nausea, vomiting, fever or disorientation.
- High blood pressure
- Vomiting blood
- Painful ulcers in the stomach and mouth
- Bleeding in the gut
- Liver disease (may be indicated by tummy pain and yellowing of the eyes and skin)

Side effects with unknown frequencies:

- Heart disease: may be indicated by chest pain, fatigue, leg swelling and/or shortness of breath.
- Kidney disease: signs may include reduced urine output, nausea and swelling of feet/legs and ankles
- Potassium deficiency (indicated by muscle weakness and cramps)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Skin rash
- Abdominal pain, nausea, diarrhoea (runny tummy), flatulence, indigestion, constipation, vomiting, black or tarry stools.

Side effects with unknown frequencies:

- Photosensitivity reactions.

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 STRAWBERRY**.

5. HOW TO STORE NUROFEN® FOR CHILDREN STRAWBERRY:

Store at or below 25 °C.

Store all medicines out of reach of children.

Do not refrigerate / freeze.

Keep well closed and protect from light.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What NUROFEN® FOR CHILDREN STRAWBERRY contains:

Each 5 ml contains ibuprofen 100 mg as the active ingredient.

The inactive ingredients are citric acid monohydrate, glycerol, maltitol, polysorbate 80, purified water, sodium chloride, sodium citrate, sodium saccharin, strawberry falvour 500244E and xantham gum.

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

An off-white coloured, strawberry-flavoured syrup suspension.

A 100 ml or 150 ml, amber coloured, plastic bottle with a child-resistant, tamper-evident polyethylene cap.

Reckitt

Holder of certificate of registration:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

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1406

Consumer Care Line: 0861 11 1100

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Access to the corresponding Professional Information:

Available online at https://cpdcentre.co.za/rb-product-inserts/