Proposed Patient Information Leaflet

SCHEDULING STATUS: S2

NUROFEN® for Children Orange

Each 5ml suspension contains 100 mg of Ibuprofen

Contains sugar: maltitol 2226,0 mg per 5 ml

Contains sweetener: 10,0 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 Orange** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **NUROFEN® for Children Orange** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **NUROFEN® for Children Orange** with any other person.
- Ask your 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 Orange** is and what it is used for

2. What you need to know before you use **NUROFEN® for Children Orange**

3. How to use **NUROFEN® for Children Orange**

4. Possible side effects

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

6. Contents of the pack and other information

1 WHAT NUROFEN® FOR CHILDREN ORANGE IS AND WHAT IT IS USED FOR

Relief of pain and fever.

NUROFEN® for Children Orange is used for relieving symptoms of fever, mild to moderate pain and inflammation, associated with cold and flu symptoms, a sore throat, earache, headache, toothache and minor muscular aches and sprains.

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

Do not give NUROFEN® FOR CHILDREN ORANGE to your child:

- If your child is hypersensitive (allergic) to ibuprofen, aspirin, any other anti-inflammatory medicines or any of the other ingredients of **NUROFEN for Children Orange**.
- If your child has a history of stomach ulcers, ulcers of the small intestines or heart disease. In case of pregnancy, in the third trimester.
- If your child has heart disease or ailment.
- If your child has severe kidney or liver impairment
- If your child has porphyria.
- if your child is also taking lithium (lithium is medicine commonly used to manage mood disorders).
- If your child is also taking digoxin (digoxin is medicine use to manage heart diseases).
- If your child is less than 12 months old.

Take special care with NUROFEN® for Children Orange:

- If your child has asthma or suffers from breathing difficulties.
- If your child suffers from abnormal bleeding, heart, liver or kidney disease
- If your child is taking any of the following medicines: Aspirin or other anti-inflammatory medicines
- Medicines for thinning the blood (e.g. warfarin and coumarin anticoagulants)
- Medicines for high blood pressure (e.g. medicines to eliminate excess water- diuretics)
- Methotrexate (anti-cancer medication)
- If your child complains of blurred vision or other visual changes, you should stop giving your child **NUROFEN® for Children Orange**.
- If your child suffers from a skin condition called systemic lupus erythematosus or mixed connective tissue disease
- If your child has high blood pressure

Whilst using NUROFEN® for Children Orange

- At the first sign of any skin reaction (rash, peeling, blistering) or other sign of an allergic reaction, stop using **NUROFEN® for Children Orange** 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 Orange** 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 Orange and consult your doctor at the first appearance of signs of kidney damage.

Other medicines and NUROFEN® for Children Orange:

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 Orange** 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 Orange 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 Orange.**

NUROFEN® for Children Orange is not recommended during pregnancy.

Do not take **NUROFEN® for Children Orange** (or give it to your child) in the last trimester of pregnancy or during breastfeeding.

NUROFEN® for Children Orange may impair fertility in women, but this is reversible when treatment is discontinued. **NUROFEN® for Children Orange** 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 Orange,** 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 Orange** 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 Orange** affects them.

NUROFEN® for Children Orange contains maltitol:

Do not take if **NUROFEN® for Children Orange** if your child is intolerant to some sugars including fructose.

3 HOW TO TAKE NUROFEN® for Children Orange

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

Always use **NUROFEN® for Children Orange** 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.

Children:

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

Do not give **NUROFEN® for Children Orange** to children under one year unless at the advice of 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 aged ≥ 12	Above 40 kg	10 to 20 ml (two to four teaspoons) 3 to 4 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.



- Place the end of the syringe in the child's mouth. Press the syringe plunger slowly to release the medicine.
- After use replace the cap. Wash the syringe in warm water and leave to dry, store out of reach of children.

If your child receives more NUROFEN® for Children Orange than they should.

- The most likely symptoms of overdosage are stomach pain, nausea (feeling sick), vomiting and dizziness.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to give your child NUROFEN® for Children Orange.

- If your child misses a dose of this medicine, give it to your child as soon as you remember. Give any remaining doses for that day at evenly spaced intervals. Do not give a double dose to make up for forgotten individual doses.

4 POSSIBLE SIDE-EFFECTS

NUROFEN® for Children Orange can have side effects.

Not all side-effects reported for **NUROFEN® for Children Orange** are included in this leaflet. Should your child's general health worsen while taking **NUROFEN® for Children Orange**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking NUROFEN® for Children Orange 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 Orange****. 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 Orange**.

5. HOW TO STORE NUROFEN® for Children Orange

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 Orange 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, Orange flavour 2M16014 and xantham gum.

Contains sweeteners: maltitol 44,5 % w/w and sodium saccharin 0,2 % w/w.

Contains preservative: domiphen bromide 0,01 % m/v.

What NUROFEN® for Children Orange looks like and contents of the pack:

NUROFEN® for Children Orange is an off-white Orange-flavoured syrupy suspension.

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

Holder of certificate of registration

Reckitt Benckiser Pharmaceuticals (Pty) Ltd.

8 Jet Park Road, Elandsfontein, 1601

South Africa

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/