

## 1.3.2 PROPOSED PATIENT INFORMATION LEAFLET FOR NUROFEN TABLETS

### SCHEDULING STATUS:

S1

### NUROFEN TABLETS

Ibuprofen 200 mg per tablet

Contains sugar: sucrose 116,1 mg per tablet

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

- NUROFEN TABLETS are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use NUROFEN TABLETS carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share NUROFEN TABLETS 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 seven (7) days.

### What is in this leaflet:

1. What NUROFEN TABLETS is and what it is used for
2. What you need to know before you take NUROFEN TABLETS
3. How to take NUROFEN TABLETS
4. Possible side effects
5. How to store NUROFEN TABLETS

## 6. Contents of the pack and other information

### 1. What NUROFEN TABLETS 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 body's response to pain.

NUROFEN TABLETS are 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 take NUROFEN TABLETS:

#### Do not take NUROFEN TABLETS if:

- You are allergic to ibuprofen, aspirin (or other similar painkillers known as NSAIDs) or other ingredients of NUROFEN TABLETS;
- You have suffered from ulcers, shortness of breath, asthma, runny nose or hives after using aspirin or other similar painkillers (NSAIDs);
- You are suffering from heart failure;
- You have severe liver impairment;
- You have severe kidney impairment;
- You have stomach ulcers or bleeding in the gut (or you previously suffered from these);
- Children aged < 12 years old;
- You are in the last trimester of pregnancy.

#### Take special care with NUROFEN TABLETS:

***The following conditions may be aggravated whilst on treatment with NUROFEN TABLETS, you must consult your doctor if any of the following apply to you before continuing with treatment:***

Problems with bleeding;

Taking medicines for treating blood clotting conditions (coumarin anticoagulants);

Heart disease and/ or stroke;

High blood pressure;

Stomach problems such as bleeding or ulcers in the gut (especially if you are an elderly);

Asthma or other allergies;

Using similar painkillers like aspirin (NSAIDs);

Joint pain skin disorders (systemic lupus erythematosus and mixed connective tissue disease);

Impaired kidneys;

Liver impairment.

***Treatment with NUROFEN TABLETS may lead to the following problems. If any of the following happens, discontinue treatment and consult your doctor:***

Drug reaction with eosinophilia and systemic symptoms (DRESS): 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.

Fertility problems in women: NUROFEN TABLETS may cause impairment of female fertility but this is reversible upon withdrawal of treatment.

If you have been taking NUROFEN TABLETS for a couple of days and your symptoms persist or become worse as you might be suffering from an underlying infection that cannot

be treated by NUROFEN TABLETS. Your doctor will need to assess you in order to administer proper treatment for your condition.

**Other medicines and NUROFEN TABLETS:**

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

Do not take NUROFEN TABLETS together with aspirin or similar painkillers due to an increased risk of side effects.

***Caution is advised if you are taking NUROFEN TABLETS concomitantly with any of the following medicines:***

- Corticosteroids (medicines for treating severe allergies and skin problems): increased risk of stomach problems.
- Medicines for high blood pressure and water tablets as NUROFEN TABLETS may reduce their effect.
- Medicines for treating blood clots (e.g. warfarin) due to an increased risk of bleeding.
- Antidepressants known as selective serotonin reuptake inhibitors (SSRIs) due to an increased risk of stomach bleeding.
- Medicines for treating heart failure due to worsening of heart condition.
- Lithium (for depression) as lithium related side effects may be increased.
- Methotrexate (for treating rheumatoid arthritis and some cancers) as co-administration may increase undesirable effects related to methotrexate.
- Ciclosporin and tacrolimus (used for prevention of organ transplant) as this may lead to kidney impairment.

- Mifepristone (for terminating pregnancy) because NUROFEN TABLETS can make mifepristone ineffective.
- Quinolone antibiotics (e.g. levofloxacin used in the treatment of bacterial infections like pneumonia and other respiratory and urinary infections) as this may lead to seizures.
- Zidovudine (for treatment of HIV infection) due to an increased risk of joint bleeds and/or swelling in people with haemophilia.

**NUROFEN TABLETS with food:**

NUROFEN TABLETS must be taken with food.

**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 TABLETS.**

Do not take NUROFEN TABLETS in the last trimester of pregnancy or during breastfeeding.

NUROFEN TABLETS are not recommended in pregnancy.

If you are planning to have a baby, NUROFEN TABLETS may impair your ability to fall pregnant. However, this is reversible upon withdrawal of treatment.

**Driving and using machines:**

NUROFEN TABLETS have negligible influence on driving or operating machinery.

**NUROFEN TABLETS contain the sugar sucrose:**

NUROFEN TABLETS may not be suitable for if you have intolerance to some sugars, contact your doctor before taking NUROFEN TABLETS.

### 3. How to take NUROFEN TABLETS:

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

Always take NUROFEN TABLETS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

- The usual dose is 1 to 2 tablets every four hours.
- For migraines, take 2 tablets three times a day.
- Do not exceed 6 tablets in any 24 hours.

Tablets must be taken with water.

Do not give NUROFEN TABLETS to children under 12 years.

If symptoms persist for more than 7 days or worsen or new symptoms occur, consult your doctor.

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

#### ***If you take more NUROFEN TABLETS than you should:***

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

The following signs may occur: nausea, vomiting, stomach pain, headache, dizziness, drowsiness, involuntary eye movement, blurred vision, ringing in the ear. Rare symptoms include low blood pressure (you may experience light-headedness) and loss of consciousness.

#### ***If you forget to take NUROFEN TABLETS:***

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

**4. Possible side effects:**

NUROFEN TABLETS can have side effects.

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

***If any of the following happens, stop taking NUROFEN TABLETS 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 TABLETS. 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

*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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NUROFEN TABLETS.

### **5. How to store NUROFEN TABLETS:**

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

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

#### **What NUROFEN TABLETS contains:**

The active ingredient is ibuprofen 200 mg per tablet.

#### **The other ingredients are:**

Tablet core: colloidal anhydrous silica, croscarmellose sodium, sodium citrate, sodium lauryl sulphate and stearic acid.

Sugar coat ingredients: acacia spray dried, carmellose sodium, macrogol 6000, sucrose, tal and titanium dioxide.

Black printing ink: iron oxide black (E172), propylene glycol and Shellac.

#### **What NUROFEN TABLETS look like and contents of the pack:**

Coated tablets.

A white, sugar-coated tablet, overprinted NUROFEN TABLETS in black on one side.

NUROFEN TABLETS are presented in cartons containing 12 or 24 blister-packed tablets.

**Holder of Certificate of Registration:**

Reckitt Benckiser Pharmaceuticals (Pty) Ltd.

8 Jet Park Road

Elandsfontein

1601

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**Registration numbers:**

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- Namibia: 90/2.7/00467 NS1
- Botswana: B9301905 (S3)
- Zambia: 133/014 (P)
- Zimbabwe: 90/3.1/2414 (P.I.M)

**Manufacturer:** Reckitt Benckiser Healthcare International Ltd.

**Access to the corresponding Professional Information:**

To be included as package leaflet with the marketed carton packs.