

**Applicant:** Reckitt Benckiser Pharmaceuticals (Pty) Ltd  
**Product:** Nurofen Express  
**Dosage:** Tablet  
**Strength:** 342 mg ibuprofen lysine salt (equivalent to 200 mg ibuprofen)  
PI/PIL approval: 26 Jan 2024

### 1.5.5.2 CLEAN PROPOSED PIL FOR NUROFEN EXPRESS (NEW PIL)

#### SCHEDULING STATUS

S1

#### NUROFEN EXPRESS

342 mg ibuprofen lysine salt equivalent to 200 mg ibuprofen

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share NUROFEN EXPRESS 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 7 days.

#### What is in this leaflet

1. What NUROFEN EXPRESS is and what is it used for
2. What you need to know before you use NUROFEN EXPRESS
3. How to take NUROFEN EXPRESS
4. Possible side effects
5. How to store NUROFEN EXPRESS
6. Contents of the pack and other information

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## **1. What NUROFEN EXPRESS is and what it is used for**

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

NUROFEN EXPRESS is indicated for the short-term relief of headache and back pain of musculo-skeletal origin, feverishness, muscular aches and pain, menstrual pain, dental pain and for the relief of pain associated with migraine.

## **2. What you need to know before you take NUROFEN EXPRESS**

**Do not take NUROFEN EXPRESS if:**

- You are hypersensitive (allergic) to ibuprofen or any of the other ingredients of NUROFEN EXPRESS (listed in section 6).
- You have or have had stomach ulcer, perforation or bleeding related to previous NSAIDs.
- You have had a worsening of asthma, skin rash, itchy runny nose or hives after taking ibuprofen, aspirin or similar medicines.
- You are pregnant or breastfeeding.
- You are suffering from heart failure.
- You have severe kidney or liver problems.
- You are under 12 years old.

### **Warnings and precautions**

Take special care with NUROFEN EXPRESS:

- If you have or have had high blood pressure.

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- If you are elderly, as you are more likely to experience the side effects listed in this leaflet.
- If you have a history of gastrointestinal bleeding or perforation (PUBs).
- If you have kidney or bowel problems.
- If you have asthma or other allergies
- If you are taking medicines for treating blood clotting conditions (coumarin anticoagulants).
- If you have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)

**Treatment with NUROFEN EXPRESS 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 EXPRESS may cause impairment of female fertility but this is reversible upon withdrawal of treatment.

### **Other medicines and NUROFEN EXPRESS**

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

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

- Corticosteroids: (medicines for treating severe allergies and skin problems): increased risk of stomach problems.
- Medicines for treating blood clots (e.g. warfarin) due to an risk of increased of bleeding.
- Antidepressants known as selective serotonin reuptake inhibitors (SSRIs) due to an risk of increased of stomach bleeding.
- Medicines for treating heart failure due to worsening of heart condition.
- Medicines for high blood pressure and water tablets as NUROFEN EXPRESS may reduce their effects.
- 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 EXPRESS 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 (bleeding disorder).
- NSAIDs: Use of two or more NSAIDs concomitantly could result in an increase in side effects.

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### **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 this medicine.

NUROFEN EXPRESS is not recommended in pregnancy and it should not be used by mothers breastfeeding their infants.

### **Driving and using machines**

Caution is advised as NUROFEN EXPRESS may impair your vision.

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

## **3. How to take NUROFEN EXPRESS**

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

Always take NUROFEN EXPRESS 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.

### **The usual dose is:**

#### **Adults and children over 12 years:**

Initial dose 2 tablets taken with water, then if necessary, 1 or 2 tablets every four hours.

**Do not exceed 6 tablets in any 24 hours.**

**Do not give to children under 12 years.**

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

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

#### **If you take more NUROFEN EXPRESS than you should**

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

#### **If you forget to take NUROFEN EXPRESS**

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

#### **4. Possible side effects**

NUROFEN EXPRESS can have side effects.

Not all side effects reported for NUROFEN EXPRESS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUROFEN EXPRESS, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Signs of intestinal bleeding such as bright red faeces, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- Signs of serious allergic reaction such as difficulty breathing or unexplained wheezing, dizziness or faster heartbeat, swelling of mouth, throat and face or limbs.
- Asthma or worsening of your asthma.

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- 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 EXPRESS

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)

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**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.
- various skin rashes
- pain

**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 EXPRESS.

**5. How to store NUROFEN EXPRESS**

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Store all medicines out of the reach of children.

Store at or below 30 °C in a dry place, protected from light.

Store in the original package

Do not use after the expiry date stated on the carton

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 EXPRESS contains**

The active substance is 342 mg ibuprofen lysine salt equivalent to 200 mg ibuprofen.

The Other ingredients are: Povidone, sodium starch glycolate, magnesium stearate, hydroxypropylmethyl-cellulose, talc, Opaspray White M-1-71118 (solids), Opacode S-4-277001 Black

### **What NUROFEN EXPRESS looks like and contents of the pack**

Film-coated tablets

NUROFEN EXPRESS is a white to off white, film-coated capsule-shaped tablet with an identifying logo printed in black on one face.

NUROFEN EXPRESS is presented in cartons containing 12 and 24 PVC/PVDC laminate to aluminium foil blister- packed tablets.

### **Holder of Certificate of Registration:**

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

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34/2.7/0290

**Access to the corresponding Professional Information**

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