**SCHEDULING STATUS:** **S1**

**LENAFEN, 200 mg, tablets**

**Ibuprofen**

**Contains sugar: Lactose monohydrate 274,625 mg**

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

LENAFEN is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use LENAFEN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LENAFEN 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 10 days.

**What is in this leaflet**

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

## 1. What LENAFEN is and what it is used for

LENAFEN is used for:

- The treatment of mild to moderate pain and fever of inflammatory origin for a treatment period not exceeding 10 days.

## 2. What you need to know before you take LENAFEN.

**Do not take LENAFEN:**

- If you are allergic (hypersensitive) to or have had an allergic reaction (e.g., asthma, rhinitis, angioedema, urticaria) to ibuprofen or any other ingredient in LENAFEN (listed in section 6), aspirin or other related pain relievers.
- If you have or have ever had a stomach ulcer, perforation or bleeding due to NSAIDs.
- If you suffer from severe liver, kidney or from heart failure.
- If you are pregnant, do not use NSAIDs at 30 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.
- If you are taking other NSAIDs or aspirin.
- If you have history of recurrent bleeding/perforations or you suffer from conditions involving an increased tendency to bleed e.g., haemophiliacs (disorder in which the blood does not clot normally).

## Warnings and precautions

If you are taking LENAFEN for longer than the recommended time or at higher than recommended doses you are at risk of serious harms.

These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine

Special care should be taken with LENAFEN:

- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.
- If you are suffering from bleeding disorders or have a history of allergic reaction to aspirin or NSAIDs.
- If you are asthmatic or suffer from kidney, liver or bowel problems, gastrointestinal bleeding, ulceration or perforation, or any allergic reactions e.g., hayfever.
- If you have heart problems.
- If you are receiving blood thinning medication e.g. Warfarin
- If you are elderly or you are giving to an elderly person because of increase reaction to NSAIDs such as LENAFEN and should take the lowest dose available.
- If you are suffering from Systemic Lupus Erythematosus (SLE) a condition of the immune system.

- If you are trying to become pregnant (ibuprofen belongs to a group of medicines (NSAIDs) which may impair fertility in women). This effect is usually reversible upon stopping the medicine. Tell your doctor before taking this medicine if you have problems becoming pregnant.
- If you are breastfeeding.
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- If you are suffering from heart problems, have had a previous stroke or think that you may be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker). Medicines such as LENAFEN may be associated with an increased risk of heart attack (myocardial infarction) or stroke. Do not exceed the recommended dose or duration of treatment.
- There is an increased risk of the elderly having side effects.
- Serious skin reactions, some of them fatal, including shedding of scaly dead skin and blistering of the skin, mouth, eyes and genitals have been reported.
- Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Children**

No information available.

**Other medicines and LENAFEN**

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

The use of LENAFEN together with the following medicines may cause undesirable effects.

In particular, LENAFEN can affect the following medicines:

- Some medicines that are anticoagulants (i.e., thin blood/ prevent clotting e.g., aspirin/acetylsalicylic acid, warfarin, clopidogrel, ticlodipine).
- Some medicines that reduce high blood pressure (ACE-inhibitors, beta-blockers such as atenolol and other medicines may affect or be affected by treatment with ibuprofen.
- Diuretics (for water retention).
- Digoxin, used to treat heart conditions.
- Lithium.
- Zidovudine (an anti-viral medicine).
- Steroids (used in the treatment of anti-inflammatory conditions).
- Methotrexate (used to treat certain cancers).
- Medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response) medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression.
- Antibiotics called quinolones.
- Aminoglycosides (a type of antibiotic).
- Mifepristone.
- Cholestyramine.
- Herbal medicines, e.g., Gingko biloba.
- Phenytoin (Anti-epileptic drug, used to control seizures).
- Any other anti-inflammatory pain killer, including aspirin.
- Sulfonylureas (used to treat diabetes).

- Voriconazole or fluconazole (used to treat fungal infections).

**LENAFEN with food and drink**

Take your LENAFEN tablets with or after food.

**Pregnancy, breastfeeding and fertility**

You should not take LENAFEN if you are planning to fall pregnant, as LENAFEN may impair female 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 LENAFEN (see Section 2 “What you need to know before you take LENAFEN”).

**Driving and using machinery**

It is not always possible to predict to what extent LENAFEN 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 LENAFEN affects them.

LENAFEN may make you feel dizzy or drowsy. If the tablets affect you in this way, do not drive, operate machinery or do anything that requires you to be alert.

**LENAFEN contains lactose**

LENAFEN contains lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take LENAFEN.

**3. How to take LENAFEN**

Do not share medicines prescribed for you with others.

Always take LENAFEN exactly as described in this leaflet. You should check with your doctor

or pharmacist if you are unsure.

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

The usual dose is:

**Adults and children over 12 years:**

**Initial dose**

Take 1 or 2 tablets orally every four to six hours after food or milk.

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

Not to be given to children under 12 years.

Do not take this medicine continuously for fever for more than 3 days or for more than 10 days for pain without consulting a doctor.

If you have the impression that the effect of LENAFEN is too strong or too weak, tell your doctor or pharmacist.

**If you take more LENAFEN 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.

The most likely symptoms of overdosage are stomach pain, nausea and vomiting, abdominal pain, lethargy and drowsiness.

**If you forget to take LENAFEN**

Take your missed dose as soon as you remember if within a few hours after missing a dose.

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

**4. Possible side effects**

LENAFEN can cause side effects.

Not all side effects reported for LENAFEN are included in this leaflet.

Should your general health worsen or if you experience any unwanted effects while taking LENAFEN, please consult your health care provider for advice.

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

- If you have an allergic reaction such as flushing, itching, nausea and vomiting, swelling of the mouth and tongue, bruising, painful red areas peeling or blistering, wheezing or shortness of breath, a sudden drop in blood pressure;
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LENAFEN. 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:**

- If you have any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces;
- if you have a severe headache, high temperature, stiffness of the neck or intolerance to bright light;
- unexplained stomach pain or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting;
- unexplained wheezing, shortness of breath, skin rash, itching or bruising;
- yellowing of the eyes and/or skin;
- severe sore throat with high fever;
- LENAFEN has been associated with an increased risk of heart attack (myocardial infarction) or stroke;
- blood disorders, kidney problems, liver problems;

- LENAFEN may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).
- Skin becomes sensitive to light

LENAFEN, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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

**Tell your doctor and stop taking LENAFEN if you experience:**

- Headache, hallucinations, dizziness, tingling of hands and feet, ringing in the ears, diarrhoea, constipation, flatulence (wind), unexpected sensitivity of the skin to the sun, tiredness, malaise, mood swings, depression and confusion;
- LENAFEN may worsen the symptoms of Crohn's disease or colitis;
- Blurred or disturbed vision or seeing/hearing strange things;
- Fluid retention (e.g. swollen ankles).

Tell your doctor if you notice any if the following:

Frequent side effects:

- Dizziness
- Nausea
- Abdominal pain
- Skin rash

Less frequent side effects:

- Rhinitis (runny nose)
- Aseptic meningitis (inflammation of the brain and spinal cord) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation
- Leukopenia (Reduced white blood cells)
- Thrombocytopenia (Reduced cells in the blood that helps with blood clotting) with or without purpura (Purple, red or brown patches on the skin)
- Agranulocytosis (Severe and dangerous lowered white blood cell count)
- Aplastic anaemia (Bone marrow damage)
- Haemolytic anaemia (Blood condition)
- Toxicity to the liver
- Confusional state
- Nervousness
- Insomnia
- Drowsiness
- Tinnitus (Ringing sound in the ears)
- Hypertension (high blood pressure)
- Peptic ulcers (ulcer in the stomach)
- Perforation or gastrointestinal bleeding
- Vomiting
- Diarrhoea
- Constipation
- Melaena (Black tarry stool)
- Haematemesis (Vomiting blood)
- Hepatitis (inflammation of the liver)
- Jaundice (yellowing of the skin and eyeballs)
- Bullous reactions (reaction from medicines resulting in blistering)

- Stevens-Johnson syndrome and Toxic epidermal necrolysis (Life threatening skin disorders)
- Itching
- Eosinophilia (increased number of white blood cells)
- Impaired renal function (kidneys do not work properly)

Side effects with unknown frequency:

- Neutropenia (low white blood cells)
- Allergic reactions, e.g., asthma or difficulty with breathing
- Anxiety
- Depression
- Hallucination
- Optic neuritis and toxic optic neuropathy (Condition affecting the eye and vision)
- Headache
- Paraesthesia (Tingling and pricking sensation in the limbs)
- Somnolence (Sleepiness)
- Visual disturbances such as decreased ability to see or reduced field of vision
- Vertigo (Motion sickness)
- Oedema (Swollen tissues due to fluid build-up)
- Heart failure
- Pancreatitis (Inflammation of the pancreas)
- Flatulence (Wind)
- Dyspepsia (Indigestion)
- Ulcerative stomatitis (disease that presents as painful ulcers in the mouth)
- Exacerbation of colitis and Crohn's disease (increased inflammation in your colon and digestive tract)
- Abnormal liver function and liver failure

- Photosensitivity reaction (sensitivity to light)
- Kidney disorders and acute renal (kidney) failure
- Chronic abuse of analgesics has been associated with nephropathy (Deterioration of kidney function)

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LENAFEN.

You may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

**5. How to store LENAFEN**

Store at or below 25 °C

Protect from light.

Protect from moisture.

Keep the blisters in the carton until required for use.

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

Return all unused medicine to your pharmacist.

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

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

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

**What LENAFEN contains**

- The active substance is 200 mg Ibuprofen.
- The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, povidone, polyethylene glycol, polyvinyl alcohol, purified talc, sodium starch glycollate, starch (maize), titanium dioxide (C.I. 77891) (E171).

**Contains sugar:** Lactose monohydrate 274,625 mg

**What LENAFEN looks like and contents of the pack**

A white, film-coated biconvex tablet.

12 or 24 tablets are packed in a clear polyvinylchloride blister strips sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

**Holder of Certificate of Registration**

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**This leaflet was revised on**

14 January 2026

Access to the corresponding Professional Information

For the Professional Information for LENAFEN scan the QR code.

The same information is available at:

www.adcock.com/products/productinformation

**Registration Number**

L/2.7/354

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