PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

XEFO® RAPID 8 mg film-coated tablets

Lornoxicam

Sugar free

Read all of this leaflet carefully before you start taking XEFO® RAPID because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- XEFO® RAPID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What XEFO® RAPID is and what it is used for

XEFO® RAPID is a non-steroidal anti-inflammatory drug (NSAID). It is intended for short term treatment of acute mild to moderate pain, where intra-muscular use is inappropriate (not exceeding 72 hours).

2. What you need to know before you take XEFO® RAPID

Do not take XEFO® RAPID

- If you are hypersensitive (allergic) to lornoxicam or any of the other ingredients of XEFO® RAPID (listed in section 6).
- If you are hypersensitive to other NSAIDs including aspirin.
- If you suffer from gastro-intestinal bleeding or perforation, related to previous NSAIDs therapy
- If you are dehydrated
- If you suffer from any bleeding disorders.
- If you suffer from an active, or have a history of, recurrent peptic ulcer.
- If you have serious liver or kidney problems
- If you have a decrease in platelet count.
- If you suffer from severe heart failure.
- If you are older than 65 years, weigh less than 50 kg or are undergoing acute surgery
- If you are pregnant or breastfeeding
- If you are less than 18 years of age

Warnings and precautions

Special care should be taken with XEFO® RAPID:

- If you have a history or experience any unusual abdominal symptoms such as abdominal bleeding
- If you have heart problems, have had a previous stroke or think that you might be at risk of these conditions (e.g., if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- If you have skin reactions such as skin rash, or mucosal lesions or other signs of hypersensitivity

- If you suffer from blood coagulation disorders, impaired renal or liver function, are elderly. Your doctor may monitor you by performing laboratory tests frequently, and dosage adjustment is required in the presence of kidney and liver disease.
- If you are pregnant, due to the risk of development of dysfunction of the kidneys of the foetus, which can lead to too little amniotic fluid surrounding your baby during pregnancy, and in some cases, kidney impairment in newborn babies.

If you develop symptoms such as a fever, rash, swelling of your lymph nodes and/or swelling of your face, you may be suffering from a reaction called Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS). This reaction has been reported in people taking medicines to treat pain and inflammation called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Inflammation of the liver and kidneys may occur, as well as abnormalities of the blood, inflammation of the heart muscle or other muscles in the body. The symptoms of this reaction are sometimes similar to having a virus infection. There is often an increase in disease-fighting white blood cells (eosinophils) in the blood. You may initially develop fever and swelling of your lymph nodes without a rash being present. If you notice any of these signs or symptoms, contact your doctor immediately as you need to stop taking XEFO and be examined by your doctor.

Children and adolescents

XEFO® RAPID is not recommended for use in children under 18 years of age

Other medicines and XEFO® RAPID

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines.) as these medicines may cause undesirable interactions.

Tell your doctor, pharmacist or other healthcare professional if you are taking any of the following medicines:

- Anticoagulants, such as warfarin and heparin used in the treatment of preventing blood clots, or if you are going to be treated with heparin at the same time as you are taking XEFO® RAPID.
- Anti-diabetic medication called sulphonylureas.
- Pain killers that belong to a class called NSAIDs, such as ibuprofen and aspirin
- High blood pressure medication called diuretics
- Medicines for your heart, such as digoxin, angiotensin converting enzyme-inhibitors (ACE-inhibitors), angiotensin receptor blockers (ARB)
- Lithium used in the treatment of depression
- Methotrexate used in the treatment of cancer and some skin diseases
- Cimetidine, used in the treatment of stomach ulcers
- Immunosuppressive medicines, such as ciclosporin
- Corticosteroids which are medicine used to reduces swelling in several conditions including: allergic reactions, skin diseases (psoriasis, hives), breathing problems; certain cancers, blood disorders and eye problems; arthritis, digestive problems.
- Quinolone antibiotics used in the treatment of infections. Medication used in the treatment of prevention of blood clots called anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) used in the treatment of depression
- Inhibitors of CYP2C9-isoenzymes, such as phenytoin (used for treatment of epilepsy), amiodarone (medicine used to treat irregular heartbeats), tranylcypromine (for treatment of depression) and rifampicin (for TB treatment)

XEFO® RAPID with food and drink

XEFO® RAPID must be taken before meals, with sufficient fluid.

Pregnancy and breastfeeding

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.

XEFO® RAPID is not for use in pregnancy and during breastfeeding.

If you use certain medicines called NSAIDs (Non-steroidal anti-inflammatory drugs) from 20 weeks or later during pregnancy, it may cause a rare but serious kidney disfunction in your baby, which can lead to too little amniotic fluid surrounding your baby, and in some cases, it can cause kidney impairment in your newborn baby. Complications of prolonged periods where too little amniotic fluid surrounds your baby, are reduced range of motion of limbs (limb contractures) and delayed maturing of the lungs.

Driving and using machines

If you experience side effects such as dizziness and/or sleepiness while taking XEFO RAPID, you should not drive or operate any machinery.

3. How to take XEFO® RAPID

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

Always take XEFO® RAPID exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

XEFO® RAPID tablets are supplied for oral administration and should be taken before meals with sufficient quantity of liquid. Your doctor will decide on the correct dose you should take. The lowest effective dose for the shortest possible duration of treatment will be used. Your doctor may adjust the dose if necessary.

Treatment of pain

XEFO® RAPID should be taken in doses of 8 mg (one tablet), and the daily dose should in general not exceed 16 mg (two tablets). In some patients, an additional 8 mg (one tablet) may be taken within the first 24 hours, if necessary.

Dose reduction in special groups

For patients with kidney or liver impairment, your doctor may alter your daily dosage.

Elderly

No special dosage modification is required for elderly patients (> 65 years), unless kidney or liver function is impaired, in which case the daily dosage should be restricted

Your doctor will tell you how long your treatment with XEFO® RAPID will last. If you have the impression that the effect of XEFO® RAPID is too strong or too weak, tell your doctor or pharmacist.

If you take more XEFO® RAPID than you should

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

If you forget to take XEFO® RAPID

If you miss a dose of XEFO® RAPID, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten doses.

4. Possible side effects

XEFO® RAPID can have side effects.

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

XEFO® RAPID may be associated with a small increased risk of heart attack or stroke.

If you develop symptoms such as fever, rash, swelling of lymph nodes (DRESS), you should **stop taking XEFO® RAPID and contact your doctor immediately**.

Tell your doctor if you notice any of the following:

Common

Mild and transient headache, dizziness, nausea, abdominal pain, indigestion, diarrhoea, vomiting.

Uncommon

Loss of appetite, difficulty with sleeping, depression, eye infection, dizziness, ringing in the ears, palpitations, increased rate of the heart, flushing, constipation, excess amount of gas in the stomach, burping, dry mouth, inflammation of the stomach, gastric ulcer, duodenal ulcer, mouth ulceration, increase in liver function test results, rash, itching, allergic skin reaction, hair loss, muscle pain, swollen face, weight change, allergy of the nose

Rare

Prolonged bleeding time, allergic reactions, low blood platelet count, confusion, nervousness, irritability, migraine, tremor, difficulty to sleep, taste disorder, tingling or pricking feeling, visual disturbances, high blood pressure, hot flush, bruising, shortness of breath, cough, dark sticky faeces, vomiting blood, inflammation of the mucous membrane of the mouth or oesophagus, difficulty swallowing, swollen tongue, perforated peptic ulcer, liver problems, itchy, dry skin, rash, swollen,

reddened skin, bone pain, muscle pain, muscle spasms, urination at night, urination disorders, physical weakness or lack of energy.

Very rare

Liver damage, swelling, Stevens-Johnson syndrome, which is characterised as extremely serious allergic skin reaction, discolouration of the skin, liver toxicity resulting in jaundice and liver failure, kidney failure

Some side effects may disappear during treatment as your body adjusts to the medicine. These do not need medical attention.

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 Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

By reporting side effects, you can help provide more information on the safety of XEFO® RAPID.

5. How to store XEFO® RAPID

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not store in a bathroom
- Do not use after the expiry date stated on the container

Return all unused medicine to your pharmacist for correct disposal

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

6. Contents of the pack and other information

What XEFO® RAPID contains

- Each film-coated tablet contains 8 mg lornoxicam as the active substance and is sugar-free.
- The other ingredients are calcium hydrogen phosphate anhydrous, calcium stearate, hydroxypropylcellulose, low substituted hydroxypropylcellulose, microcrystalline cellulose, sodium hydrogen carbonate, hypromellose, propylene glycol, talc, titanium dioxide.

What XEFO® RAPID looks like and contents of the pack

White to slightly yellowish, round, biconvex film-coated tablet.

Alu/Alu blister pack. Each blister strip contains 10 film-coated tablets. The blister strips are packed in an outer cardboard box with 10, 20 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

LITHA PHARMA (Pty) Ltd

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This leaflet was last revised in

01 December 2021

Registration number

44/3.1/0331

Registration No.:
Botswana (S2): BOT1302465A/B
Namibia (NS2): 13/3.1/0195

LP3103 10/2021