PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

XEFO® 4, 4 mg film-coated tablets

Contains sugar: Lactose monohydrate 94 mg

XEFO® 8, 8 mg film-coated tablets

Contains sugar: Lactose monohydrate 90 mg

Lornoxicam

Read all of this leaflet carefully before you start taking XEFO

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

1. What XEFO is and what it is used for

XEFO is a non-steroidal anti-inflammatory drug (NSAID) and antirheumatic medicine. It is intended for short term treatment of acute mild to moderate pain and symptomatic relief of pain and inflammation in rheumatoid arthritis and osteoarthritis.

2. What you need to know before you take XEFO

Do not take XEFO:

- if you are hypersensitive (allergic) to lornoxicam or any of the other ingredients of XEFO (listed in section 6);
- if you are hypersensitive to other NSAIDs including acetylsalicylic acid (for instance, aspirin);
- if you suffer from thrombocytopenia (low blood platelet count which increases risk of bleeding or bruising);
- if you suffer from heart failure;
- if you suffer from gastrointestinal bleeding, rupture and bleeding of a blood vessel in the brain, or other bleeding disorders;
- if you have a history of gastrointestinal bleeding or perforation, related to previous therapy with NSAIDs;
- if you suffer from an active peptic ulcer or have a history of recurrent peptic ulcer;
- if you suffer from severe liver impairment;
- if you suffer from severe kidney impairment;
- if you are pregnant or breastfeeding;
- If you are older than 65 years, weigh less than 50 kg or undergoing acute surgery.

Warnings and precautions

Talk to your doctor or pharmacist before taking XEFO. This is particularly important:

- if you have impaired kidney function;
- if you have a history of high blood pressure and/or heart failure;
- if you suffer from ulcerative colitis or Crohn's disease;
- if you have a history of bleeding tendency;
- if you have a history of asthma;
- if you suffer from SLE (*lupus erythematosus*, a rare immunological 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.

Your doctor may have to monitor you by laboratory tests on a frequent basis if:

- you suffer from blood coagulation disorder;
- you suffer from impaired liver function;
- you are elderly;
- or you will be treated with XEFO for more than 3 months.

You should inform your doctor if you are going to be treated with heparin or tacrolimus, while taking XEFO at the same time.

If you experience any unusual abdominal symptoms such as abdominal bleeding, skin reactions such as skin rash, damage to the internal lining of the nostrils, mouth, eyelids, ears, genitals or anus, or other signs of hypersensitivity, you should **stop taking XEFO and contact your doctor immediately**.

Medicines such as XEFO may be associated with a small increase of the risk of **heart attack** (myocardial infarction) or **stroke**. Any risk is more likely with high doses and prolonged treatment. **Do not exceed the recommended dose or the duration of treatment.**

You should discuss your treatment with your doctor or pharmacist if

- you have heart problems;
- you had previously a stroke;
- or you think that you might be at risk of developing these conditions (for example, if you have high blood pressure, diabetes or high cholesterol, or you are a smoker).

Avoid using XEFO during varicella (chickenpox) infections.

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.

Other medicines and XEFO

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

You should avoid using XEFO if you are taking other NSAIDs such as **acetylsalicylic acid** (for instance, aspirin), **ibuprofen** and **COX-2 inhibitors**.

XEFO may interfere with other medicines. Be particularly careful if you are taking any of the following:

- Cimetidine - used in the treatment of heartburn and peptic ulcers;
- Anticoagulants, such as warfarin, heparin or phenprocoumon- used to prevent the formation of blood clots;
- Corticosteroids;
- Methotrexate - used in treatment of cancer and immunological diseases;
- Lithium;
- Immunosuppresive agents, such as ciclosporin or tacrolimus;
- Heart medicines, such as digoxin, ACE inhibitors, beta-adrenergic blockers;
- Diuretics;
- Quinolone antibiotics (e.g. levofloxacin, ofloxacin);
- Anti-platelet agents (e.g. clopidogrel) - medicines used to prevent heart attacks and strokes;
- SSRI (Selective Serotonin Reuptake Inhibitors) – used in the treatment of depression;
- Sulphonylureas, for instance glibenclamide - used in the management of diabetes;
- Inducers and inhibitors of CYP2C9-isoenzymes (such as the antibiotic rifampicin or the antifungal medicine fluconazole), as they might have an effect on the way in which your body breaks down XEFO;
- Angiotensin II receptor blocker - used to treat high blood pressure, kidney damage due to diabetes and congestive heart failure;
- Pemetrexed - used to treat some forms of lung cancer.

XEFO with food and drink

XEFO film-coated tablets are intended for oral use. Take this medicine before meals with a sufficient amount of liquid.

Taking this medicine with food is not recommended because this may reduce its effectiveness.

Fertility, 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.

Fertility

Using XEFO may impair fertility and is not recommended for women attempting to become pregnant. Women who have difficulties becoming pregnant, or who are undergoing investigation of infertility, should consult with a doctor and consider stopping treatment with XEFO.

Pregnancy

XEFO should not be used during pregnancy

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.

Breastfeeding

If you are breastfeeding, treatment with XEFO is not recommended.

Driving and using machines

You should refrain from driving or operating machinery should you feel dizzy or sleepy after taking XEFO.

XEFO contains lactose

Patients with rare hereditary conditions of lactose/fructose or galactose intolerance should not take XEFO.

XEFO contains lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take XEFO

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

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

XEFO tablets are supplied for oral administration and should be taken before meals with sufficient quantity of liquid. **Do not take XEFO with a meal, as food can reduce the effectiveness of XEFO**.

For all patients the appropriate dosing regimen should be based upon individual response to treatment.

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

Treatment of pain

8 mg to 16 mg per day given in 2 to 3 divided doses. The total daily dose should not exceed 16 mg.

Osteoarthritis and rheumatoid arthritis:

Initial recommended total daily dose is 12 mg, divided in two or three doses. Maintenance dose should not exceed 16 mg per day.

Dose reduction in special groups

For patients with kidney or liver impairment, the maximal recommended daily dose is reduced to 12 mg (taken twice or three times a day).

Children

XEFO is not recommended for use in children and adolescents under 18 years of age.

If you take more XEFO than you should

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

In case of an overdose, you may expect the following symptoms: nausea, vomiting, symptoms associated with central nervous system (such as dizziness or disturbances in vision).

Severe symptoms such as ataxia (ascending to coma and cramps), liver and kidney damage and potentially coagulation disorders may also occur.

If you forget to take XEFO

If you miss a dose of XEFO, 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 can have side effects.

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

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

- shortness of breath, chest pains, or ankle swelling appear or get worse;
- severe or continuous stomach pain or your stools become black;
- yellowing of the skin and eyes (jaundice) – these are signs of liver problems;
- an allergic reaction - which can include skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing;
- fever, blistering eruption or inflammation especially on hands and feet or in the mouth area (Stevens-Johnson syndrome);
- exceptionally, serious infections of the skin in case of varicella (chickenpox)

If you experience any unusual abdominal symptoms such as abdominal bleeding, skin reactions such as skin rash, damage to the internal lining of the nostrils, mouth, eyelids, ears, genitals or anus, or other signs of hypersensitivity such as fever, rash, swelling of lymph nodes (DRESS), you should **stop taking XEFO and contact your doctor immediately**.

Undesirable effects associated with using XEFO are given below:

Common side effects (may affect up to 1 in 10 people)

- mild and passing headache and dizziness;

- nausea, stomach pain, indigestion, diarrhoea and vomiting.
- Eye infection (conjunctivitis)

Uncommon side effects (may affect up to 1 in 100 people)

- weight loss (anorexia),
- inability to sleep (insomnia), depression;
- eye discharges (conjunctivitis);
- feeling dizzy, ringing in the ears (tinnitus);
- heart failure, irregular heartbeat, rapid heart rate, feeling flushed;
- constipation, excessive wind (flatulence), belching, dry mouth, gastritis, peptic ulcer, upper abdominal pain, duodenal ulcer, mouth ulcers;
- increase in liver function tests (as seen from blood tests) and feeling unwell (malaise);
- rash, itching, increased sweating, redness of the skin (erythema), angiooedema (rapid swelling of the deeper layers of skin, usually of the face), hives (urticaria), oedema, stuffy nose as a result of an allergy (rhinitis), hair loss (alopecia);
- pain in the joints (arthralgia).

Rare side effects (may affect up to 1 in 1,000 people)

- sore throat;
- anaemia, reduction in the blood cell count (thrombocytopenia and leucopenia), weakness;
- hypersensitivity, including anaphylactoid reaction and anaphylaxis (organism reaction characterized usually by face swelling, flushing, difficulties breathing and lightheadedness);
- confusion, nervousness, agitation, feeling sleepy (somnolence), paraesthesia (tingling sensations), abnormal sense of taste, tremor, migraine, visual disturbances;
- elevated blood pressure, hot flush;
- bleeding, haematoma (bruising), prolonged bleeding time;
- difficulty in breathing (dyspnoea), cough, bronchospasm;
- perforated ulcer, vomiting of blood, gastrointestinal bleeding, black tarry stools;
- inflammation in the mouth, oesophagitis (inflammation of the gullet), gastro-oesophageal reflux, difficulty in swallowing, aphthous stomatitis (ulcers), inflammation of the tongue;

- skin problems, such as eczema, rash;
- bone pain, muscle cramp, muscle pain;
- urinary problems, such as the need to wake up and urinate during the night (nocturia) or an increase in the levels of urea and creatinine in the blood.

Very rare side effects (may affect up to 1 in 10,000 people)

- liver damage, hepatitis (inflammation of the liver), jaundice, cholestasis (interrupted flow of bile from the liver);
- bruising, swelling (oedema), severe skin disorders (Stevens-Johnson syndrome, Toxic epidermal necrolysis);
- inflammation of the linings of the brain (aseptic meningitis) in patients with systemic lupus erythematosus and disorders of connective tissue;
- bruising, NSAID class effects: decreased white blood cells, decreased white blood cells in the blood (neutropenia, agranulocytosis), body stopping production of enough new blood cells (aplastic anaemia), destruction of red blood cells faster than the body can produce them (haemolytic anaemia), kidney toxicity.

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 SAHPRA website or to Acino Pharma via email on drugsafety_ZA@acino.swiss. By reporting side effects, you can help provide more information on the safety of XEFO**.**

5. How to store XEFO

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

6. Contents of the pack and other information

What XEFO contains

- The active substance is lornoxicam:

  XEFO 4 tablets: Each film-coated tablet contains 4 mg lornoxicam.

  XEFO 8 tablets: Each film-coated tablet contains 8 mg lornoxicam.

- The other ingredients are:

  Core: Lactose monohydrate, microcrystalline cellulose, povidone K 30,

  croscarmellose sodium, magnesium stearate;

  Film: Macrogol 6 000, titanium dioxide (E171), talc, methylhydroxypropyl cellulose 5.

What XEFO looks like and contents of the pack

XEFO 4: White to yellowish oblong film-coated tablet with imprint “L04”

XEFO 8: White to yellowish oblong film-coated tablet with imprint “L08”

XEFO 4 film-coated tablets: blister pack of opaque PVC foil with silver-coloured aluminium foil. Each blister strip contains 10 film-coated tablets.

XEFO 8 film-coated tablets: blister pack of opaque PVC foil with gold-coloured aluminium foil. Each blister strip contains 10 film-coated tablets.

Pack sizes: packs with 20 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

ACINO PHARMA (PTY) LTD.

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1685

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