PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

XEFO® 8 IV/IM

Lornoxicam

Contains sugar: 100,0 mg/vial mannitol

Read all of this leaflet carefully before you receive 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.

What is in this leaflet

1. What XEFO is and what it is used for

XEFO is a non-steroidal anti-inflammatory drug and antirheumatic drug (NSAID) of the oxicam class. It is intended for treatment of short-term mild to moderate pain when oral administration is inappropriate.

2. What you need to know before you receive XEFO

XEFO should not be administered to you

- 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
- if you suffer from hypovolemia or dehydration
- if you suffer from gastro-intestinal bleeding, cerebrovascular bleeding or other bleeding disorders
- if you have a history of gastrointestinal bleeding, ulceration, or perforation, related to previous NSAIDs therapy
- if you suffer from an active or have a history of recurrent peptic ulcer
- if you suffer from severe liver impairment
- if you suffer from severe renal impairment
- if you suffer from thrombocytopenia
- if you suffer from severe heart failure.
- if you are pregnant or breastfeeding
- if you are under the age of 18 years old
- if you are elderly (> 65 years)

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have impaired kidney or liver function

- If you have had a recent operation

- if you have a history of hypertension and/or heart failure as fluid retention and oedema may occur

- if you suffer from gastric ulcers and gastric bleeding

- if you are taking other medication that might cause gastric ulcers and gastric bleeding

- if you suffer from any gastric diseases such as ulcerative colitis or Crohn’s disease

- if you have a history of bleeding tendency

- If you suffer from blood coagulation disorder, impaired liver function, such as liver cirrhosis, are elderly or you will be treated with XEFO for more than 3 months, your doctor may monitor you by laboratory test on a frequent basis.

- If you are going to be treated with heparin or tacrolimus concomitantly with XEFO, please inform your doctor about your current medicine.

- XEFO should not be used concomitantly with other NSAIDs such as acetylsalicylic acid, ibuprofen and COX-2 inhibitors. Ask your doctor or pharmacist if you are uncertain.

- If you experience any unusual abdominal symptoms such as abdominal bleeding, skin reactions such as skin rash, mucosal lesions or other signs of hypersensitivity, you should stop taking XEFO and contact you doctor immediately.
- Medicines such as XEFO may be associated with a small increased 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 of duration of treatment.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Children and adolescents

XEFO is contraindicated in children under the age of 18 years.

Other medicines and XEFO

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

XEFO may interfere with other medicines. Particular care should be taken if you are receiving any of the following substances:

- Cimetidine
- Digoxin
- Anticoagulant such as heparin, warfarin, phenprocoumon
- Corticosteroids
- Methotrexate
- Lithium
- Immunosuppressive agents as cyclosporine, tacrolimus
- Heart medicine such as digoxin, ACE-inhibitors, beta-adrenergic blockers
- Diuretics
- Quinolone antibiotics
- Anti-platelet agents
- NSAIDs such as aspirin, ibuprofen, acetylsalicylic acids

- SSRI
- Sulphonylureas (e.g., glibenclamide)
- Inducer and inhibitors of CYP2C9-isoenzymes

XEFO with food and drink and alcohol

Not Applicable

Pregnancy and 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.

XEFO must not be taken if you are pregnant or breastfeeding.

The use of XEFO may impair fertility and is not recommended in women attempting to fall pregnant. In women who have difficulties conceiving, or who are undergoing investigation of infertility, withdrawal of XEFO should be considered.

Driving and using machines

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

Patients showing dizziness and/or sleepiness under treatment with XEFO should refrain from driving or operation machinery.

3. How to receive XEFO

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

Adults: The recommended dose is 8 mg I.V. or I.M.

The maximum daily dose should not exceed 16 mg. Some patients may need further 8 mg within the first day of treatment.

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

You will not be expected to give yourself XEFO. It will be given to you by a person who is qualified to do so.

If you receive more XEFO than you should

Since a healthcare provider will administer XEFO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Please contact your doctor or the pharmacist if you have received more XEFO than prescribed.

In case of an overdose the following symptoms may be expected: Nausea, vomiting, cerebral symptoms (dizziness, disturbances in vision).

If you forget to receive XEFO

Since a health care provider will administer XEFO, it is unlikely that the dose will be missed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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.

Medicines such as XEFO may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

The most common side effects of XEFO include nausea, dyspepsia, indigestion, abdominal pain, vomiting, and diarrhoea.

Tell your doctor if you notice any of the following:

Frequent side effects

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

Less frequent side effects:

- Pharyngitis, anaemia, thrombocytopenia, leukopenia, hypersensitivity, confusion, nervousness, agitation, somnolence, paraesthesia, dysgeusia, tremor, migraine, visual disturbances, hypertension, hot flush, haemorrhage, haematoma, dyspnoea, cough, melaena, haematemesis, stomatitis, oesophagitis, gastrooesophageal reflux, dysphagia, aphthous stomatitis, glossitis, hepatic function abnormal, dermatitis, bone pain, muscle spasms, myalgia, nocturia, micturition disorders, asthenia, prolonged bleeding time, purpura, bronchospasm, increase in blood urea nitrogen and creatinine levels, perforated peptic ulcer
- Anorexia, insomnia, depression, conjunctivitis, vertigo, tinnitus, palpitations, tachycardia, flushing, constipation, flatulence, eructation, dry mouth, gastritis, gastric ulcer, abdominal pain upper, duodenal ulcer, mouth ulceration, increase in liver function tests, SGPT (ALT) or SGOT (AST), rash, pruritus, hyperhidrosis, rash erythematous, urticaria, alopecia, arthralgia, malaise, face oedema, weight changes, oedema, rhinitis.
- Hepatocellular damage, ecchymosis, oedema and bullous reactions, Stevens-Johnson syndrome, Toxic epidermal necrolysis.

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 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.You can also report side effects 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.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems.
- Keep out of the reach and sight of children.
- Store at room temperature at or below 25 ºC.
- Keep the vial in the outer carton

6. Contents of the pack and other information

What XEFO contains

The vial:

- The active substance is lornoxicam.
- One vial with powder contains 8 mg lornoxicam
- Reconstituted solution: One ml contains 4 mg lornoxicam
- The other ingredients are mannitol, trometamol, disodium edetate.

What XEFO looks like and contents of the pack

XEFO 8 IV/IM: Freeze-dried powder in an amber-coloured glass vial.

XEFO Water for Injection: A clear, colourless liquid in a clear glass ampoule.

When reconstituted the medicine is a yellow, clear liquid free of visible particles

A vial containing freeze-dried powder and a 2 ml glass ampoule with Water for Injection packed as a set in one pack: or a vial containing freeze dried powder only.

Package sizes available: 1 set, 5 sets Vial only: 5 vials per pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

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