

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xefo 8 mg film-coated tablets Lornoxicam

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Xefo is and what it is used for
2. Before you take Xefo
3. How to take Xefo
4. Possible side effects
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1. WHAT XEFO IS AND WHAT IT IS USED FOR

Xefo is a non-steroidal anti-inflammatory drug (NSAID) and antirheumatic drug of the oxicam class. It is intended for **short term treatment of acute mild to moderate pain and symptoms of rheumatoid arthritis and osteoarthritis such as pain and inflammation of joints.**

2. BEFORE YOU TAKE XEFO

Do not take Xefo

- if you are allergic (hypersensitive) to lornoxicam or any of the other ingredients of Xefo 8 mg film-coated tablets;
- if you are taking other NSAIDs such as acetylsalicylic acid (for instance, aspirin), ibuprofen and COX-2 inhibitors;
- 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 severe 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 in the last three months of your pregnancy.

Take special care with Xefo

- 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).

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 at the same time Xefo.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken **any other medicines**, including medicines obtained without a prescription.

Do not take Xefo if you are taking other NSAIDs such as **acetylsalicylic acid** (for instance, aspirin), **ibuprofen** and **COX-2 inhibitors**. Ask your doctor or pharmacist if you are uncertain.

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 heparin or phenprocoumon - used to prevent the formation of blood clots;
- Corticosteroids;

- Methotrexate - used in treatment of cancer and immunological diseases;
- Lithium;
- Immunosuppressive agents, such as ciclosporine or tacrolimus;
- Heart medicines, such as digoxin, ACE-inhibitors, beta-adrenergic blockers;
- Diuretics;
- Quinolone antibiotics;
- Anti-platelet agents - medicines used to prevent heart attacks and strokes;
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- 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.

Taking 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.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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

During the first 6 months of pregnancy treatment with Xefo is not recommended, unless explicitly advised by your doctor.

You must not take Xefo during the last three months of your pregnancy.

Breastfeeding

If you are breastfeeding treatment with Xefo is not recommended, unless explicitly advised by your doctor.

Driving and using machines

Xefo has negligible or no influence on the ability to drive or use machinery.

Important information about some of the ingredients of Xefo

Xefo 8 mg tablets contain lactose monohydrate. If you have been told by your doctor that you have **an intolerance to some sugars**, contact your doctor before taking the medicinal product.

3. HOW TO TAKE XEFO

Always take Xefo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults is 8 to 16 mg, divided in two or three doses per day. Do not take more than 16 mg a day.

The dose for **patients with arthritis** is 12 mg, divided in two or three doses per day. Do not take more than 16 mg a day.

If you have a **liver or kidney impairment**, do not take more than 12 mg (taken twice or three times a day) of this medicine.

Xefo tablets must be swallowed with sufficient amounts of liquid. **Do not take Xefo with a meal, as food can reduce the effectiveness of Xefo.**

Xefo is not recommended for children and adolescents below 18 years old, due to lack of data.

If you take more Xefo than you should

Please contact your doctor or the pharmacist if you have taken more Xefo than prescribed.

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).

If you forget to take Xefo

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Xefo can cause side effects, although not everybody gets them.

Medicines such as Xefo may be associated with a small increase in the risk of **heart attack** or **stroke**.

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**.

If you get any of the following side effects, **stop taking this medicine** and **tell your doctor immediately**, or **contact the emergency 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- Johnsons syndrome);

- exceptionally, serious infections of the skin in case of varicella (chickenpox).

Undesirable effects associated with using Xefo are given below.

Common side effects (affect 1 to 10 users in 100)

- mild and passing headache and dizziness,
- nausea, abdominal pain, upset stomach, diarrhoea and vomiting.

Uncommon side effects (affect 1 to 10 users 1 in 1,000)

- weight loss (anorexia), inability to sleep, depression;
- eye discharges (conjunctivitis);
- feeling dizzy, ringing in the ears (tinnitus);
- cardiac failure, irregular heartbeat, rapid heart rate, feeling blushed;
- 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), angioedema (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;
- arthralgia (pain in the joints).

Rare side effects (affects 1 to 10 users in 10,000)

- sore throat;
- anaemia, reduction in the blood cell count (thrombocytopenia and leukopenia), weakness;
- hypersensitivity, anaphylactoid reaction and anaphylaxis (organism reaction characterized usually by face swelling, flushing, difficulties breathing and lightheadedness);
- confusion, nervousness, agitation, feeling sleepy (somnia), 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,
- abnormal liver function;
- 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 (affect less than 1 user in 10,000)

- liver damage, hepatitis (inflammation of the liver), jaundice, cholestasis (interrupted flow of bile from the liver);
- bruising, oedema, severe skin disorder (Stevens-Johnson syndrome, Toxic epidermal necrolysis);
- aseptic meningitis;
- NSAID class effects: neutropenia, agranulocytosis, aplastic anaemia, hemolytic anaemia, kidney toxicity).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE XEFO

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Xefo after the expiry date which is stated on the carton, or on the bottle after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Xefo contains

- The active substance is lornoxicam.
- One film-coated tablet contain 8 mg lornoxicam
- The other ingredients are: Lactose monohydrate, Cellulose, microcrystalline, Povidone, Croscarmellose sodium, Magnesium stearate (*in the core*); Macroglol, Titanium dioxide (E171), Talc, Hypromellose (*in the film*)

What Xefo looks like and contents of the pack

Xefo 8 mg film-coated tablet is a white to yellowish oblong film-coated tablet with the imprint "L08".

Xefo is distributed in pack sizes of 10, 20, 30, 50, 100, 250 and 500 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[See Annex I – To be completed nationally]

{Name and address }

<{tel}>

<{fax}>

<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

DK/H/123/002

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| Austria | Xefo 8 mg - filmtabletten |
| Denmark | Xefo |

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| Estonia | Xefo |
| France | Xefo |
| Greece | Xefo |
| Hungary | Xefo 8 mg filmtabletta |
| Ireland | Xefo |
| Lithuania | Xefo 8 mg pėvele dengtos tabletės |
| Latvia | Xefo 8 mg apvalkotā tablete |
| Poland | Xefo |
| Portugal | Acabel 8 mg |
| Romania | Xefo 8 mg |
| Slovakia | Xefo 8 mg filmom obalené tablety |
| Slovenia | Xefo 8 mg filmsko obložene tablete |
| Spain | Acabel 8 mg comprimidos recubiertos con película |
| Sweden | Xefo |

DK/H/137/002

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|----------|--|
| Denmark | Lornoxicam "TAKEDA" |
| Portugal | BOSPORON 8 mg |
| Spain | BOSPORON 8 mg comprimidos recubiertos con película |

DK/H/137/004

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| Germany | Telos 8 mg filmtabletten |
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This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]