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 because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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. What you need to know before you take Xefo

Do not take Xefo
- if you are allergic to lornoxicam or any of the other ingredients of this medicine (listed in section 6);
- 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.

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).

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.

Other medicines and Xefo
Tell your doctor or pharmacist if you are taking, have recently taken or might **take any other medicines**.

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;
- Immunosuppresive 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.

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, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking thismedicine.

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.

Breast-feeding
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.

Xefo contains lactose monohydrate 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 this medicine exactly as your doctor has told you. 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, this medicine 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 (may affect up to 1 in 10 people)
- mild and passing headache and dizziness,
- nausea, abdominal pain, upset stomach, diarrhoea and vomiting.

Uncommon side effects (may affect up to 1 in 100 people)
- 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), 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;
- arthralgia (pain in the joints).

Rare side effects (may affect up to 1 in 1,000 people)
- 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 (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,
- 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 (nocturnia) 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, oedema, severe skin disorder (Stevens-Johnson syndrome, Toxic epidermal necrolysis);
- aseptic meningitis;
- NSAID class effects: neutropenia, agranulocytosis, aplastic anaemia, hemolytic anaemia, kidney toxicity).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xefo

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xefo contains

- The active substance is lornoxicam.
- One film-coated tablet contains 8 mg lornoxicam
- The other ingredients are: Lactose monohydrate, Cellulose, microcrystalline, Povidone, Croscarmellose sodium, Magnesium stearate (*in the core*);
  Macrogol, 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

Takeda UK Limited
Building 3
Glory Park
Glory Park Avenue
Wooburn Green
BUCKS
HP10 0DF
UK

Manufacturer

Takeda GmbH
Plant Oranienburg
Lehnitzstrasse 70-98
DE-16515 Oranienburg
Germany

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

DK/H/123/002

Austria	Xefo 8 mg - filmtabletten
Denmark	Xefo
Estonia	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
Slovakia	Xefo 8 mg filmom obalené tablety
Slovenia	Xefo 8 mg filmsko obložene tablete
Spain	Acabel 8 mg comprimidos recubiertos con película

DK/H/137/002

Denmark	Lornoxicam "Takeda"
Portugal	BOSPORON 8 mg
Spain	BOSPORON 8 mg comprimidos recubiertos con película

DK/H/137/004

Germany	Telos 8 mg filmtabletten

This leaflet was last revised in 01/2015.