

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**  
This medicine is dispensed with a doctor's prescription only

## Xefo 8 mg Tablets

**Active ingredient and its amount per dosage unit:**

Each tablet contains: Lornoxicam 8 mg

\* For a list of inactive ingredients and allergens in the preparation - see section 6 below.

**Read the package insert carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not usually intended for children under 18 years of age.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

Xefo 8 mg Tablets is used for short-term treatment of mild to moderate pain (e.g., after dental surgery), for back pain and for the treatment of osteoarthritis and rheumatoid arthritis.

**Therapeutic group:** Non-steroidal anti-inflammatory drugs (NSAIDs).

### 2. BEFORE USING THE MEDICINE

**☒ Do not use the medicine if:**

- you are in the third trimester of pregnancy.
- you are sensitive to any of the ingredients contained in the medicine or to other non-steroidal pain-relieving and anti-inflammatory medicines including aspirin (reactions such as difficulty breathing, rash and nasal polyps).
- in case of active duodenal ulcer, severe impairment of liver function, severe impairment of kidney function, thrombocytopenia, gastrointestinal bleeding in the past as a result of using NSAIDs, severe heart failure, gastrointestinal bleeding, bleeding in the brain or other bleeding.

### Special warnings regarding use of the medicine

**You should be especially careful if you suffer, or have suffered in the past, from:**

- impairment of kidney functions.
- hypertension or heart failure.
- colitis or Crohn's disease.
- tendency to bleed.
- asthma.
- systemic lupus erythematosus.
- The doctor may refer you for laboratory tests, if:
  - you suffer from blood coagulation problems.
  - you suffer from impairment of liver functions.
  - you are above the age of 65.
  - you are taking Xefo 8 mg Tablets for more than 3 months.
- You must inform the doctor if you are about to undergo treatment with heparin or tacrolimus.
- If you notice unusual symptoms in the abdomen, such as abdominal bleeding, skin reactions, such as skin rash, damage to the internal mucus membrane of the nostrils, the mouth, eyelids, ears, genitals or anus or other signs of hypersensitivity, stop taking the medicine and refer to the doctor immediately.
- Medicines such as Xefo 8 mg Tablets may slightly increase the risk for heart attack or stroke. The risk increases as the dosage and treatment period increase. **Do not exceed the recommended dose and treatment period.**
- You must consult with the doctor about the treatment if:
  - You suffer from heart diseases.
  - You have had a stroke in the past.
  - You suspect that you have an increased risk of developing these diseases (e.g., you suffer from hypertension, diabetes, high blood cholesterol levels or you smoke).
- Avoid using Xefo 8 mg Tablets if you have chickenpox.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.**

Especially, inform the doctor or pharmacist if you are taking:

- Cimetidine for the treatment of heartburn or stomach ulcer.
  - Anticoagulants such as heparin or phenprocoumon.
  - Corticosteroids.
  - Methotrexate - for treatment of cancer or immune diseases.
  - Lithium.
  - Preparations that depress the immune system, such as ciclosporin and tacrolimus.
  - Medicines for heart diseases and hypertension, such as digoxin, ACE inhibitors, diuretics, beta blockers.
  - Quinolone antibiotics.
  - Medicines that inhibit platelet aggregation for the prevention of heart attacks and stroke.
  - Antidepressants from the SSRI group.
  - Medicines from the sulfonyleurea group for reducing blood sugar level.
  - Medicines that inhibit or induce the enzyme CYP2C9 (e.g., antibiotic - rifampicin or an antifungal medicine - fluconazole).
  - Angiotensin II receptor blockers for the treatment of hypertension, kidney damage due to diabetes, and heart failure.
  - Pemetrexed for the treatment of certain types of lung cancer.
- Do not take Xefo 8 mg Tablets if you are taking other non-steroidal anti-inflammatories such as aspirin, ibuprofen or COX2 inhibitors. Ask your doctor if you are not sure.

### **☒ Use of the medicine and food**

Take the medicine before a meal with a sufficient amount of water. Taking the medicine with food is not recommended since the food may reduce its efficiency.

### **☒ Use of the medicine and alcohol consumption**

Do not drink wine or alcoholic beverages excessively during the period of treatment with the medicine.

### **☒ Fertility, pregnancy and breastfeeding**

**Fertility**

Use of Xefo 8 mg Tablets is not recommended in women trying to get pregnant.

Women with fertility problems or at the testing stage for diagnosis of fertility problems should discuss with the doctor and consider stopping treatment with Xefo 8 mg Tablets.

**Pregnancy**

Use of Xefo 8 mg Tablets during the first 6 months of pregnancy is not recommended, except upon explicit instruction from the doctor.

Do not use Xefo 8 mg Tablets during the last trimester of pregnancy.

**Breastfeeding**

The treatment with Xefo 8 mg Tablets while breastfeeding is not recommended, unless there is a specific instruction from the doctor.

### **☒ Driving and use of machines**

If you feel dizziness and/or sleepiness during the use of the medicine, caution is required when driving, operating dangerous machines and when engaging in activities requiring alertness.

### **☒ Important information regarding some of the ingredients of the medicine**

Xefo 8 mg Tablets contains lactose monohydrate. If you suffer from intolerance to certain sugars, consult the doctor before commencing use of the medicine.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

For treatment of pain - a dosage of 8 mg - 16 mg daily divided into 2-3 doses. The daily dosage must not exceed 16 mg.

For treatment of osteoporosis and rheumatoid arthritis - an initial daily dosage of 12 mg divided into 2-3 doses and then a maintenance dosage not exceeding 16 mg daily.

Dosage in case of kidney or liver function impairment - a maximum daily dosage of 12 mg divided into 2-3 doses.

### **Do not exceed the recommended dose.**

Swallow the medicine with water. Do not take Xefo 8 mg Tablets with a meal since taking with food may reduce the efficiency of the medicine.

The tablets should not be halved, but may be crushed and swallowed immediately.

### **Tests and follow-up**

Your doctor may refer you for periodic follow-up tests for liver and kidney functions, especially if you are being treated with Xefo 8 mg Tablets for more than 3 months, you are over the age of 65 or you suffer from impairment of kidney or liver functions.

### **If you accidentally took a higher dosage**

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. In the case of an overdose, the expected side effects are: nausea, vomiting, effects related to the central nervous system such as dizziness and blurred vision.

**If you forgot to take this medicine** at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

### 4. SIDE EFFECTS

As with any medicine, use of Xefo 8 mg Tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

- Medicines like Xefo 8 mg Tablets may slightly increase the risk for heart attack or stroke.
- If you notice unusual abdominal symptoms, such as abdominal bleeding, skin reactions, such as skin rash, damage to the internal mucus membrane of the nostrils, the mouth, eyelids, ears, genitals or anus or other signs of hypersensitivity, stop taking the medicine and refer to the doctor immediately.
- If you notice any of the following side effects, stop using Xefo 8 mg Tablets and immediately refer to a doctor or hospital emergency room:
  - Shortness of breath, chest pain or appearance/worsening of swelling of ankles.
  - Sharp or prolonged abdominal pain, black stools.
  - Yellowing of the skin and/or whites of the eyes.
  - Allergic reaction manifested by skin problems such as ulcers or blisters, swelling of the face, lips, tongue or throat, which makes breathing difficult.
  - Fever, appearance of blisters or inflammation, especially of the hands, legs or mouth area (Stevens-Johnson syndrome).
  - Severe skin infections during chickenpox.

Additional side effects

- Common side effects (appearing in 1 to 10 patients out of 100)
  - Headaches, dizziness, nausea, abdominal pain, dyspepsia, diarrhea, vomiting.
- Uncommon side effects (appearing in 1 to 10 patients out of 1,000)
  - Insomnia, depression, weight loss.
  - Inflammation of the conjunctiva.
  - Ringing in the ears (tinnitus), dizziness.
  - Rapid heartbeat, irregular heartbeat, heart failure, flushing.
  - Constipation, flatulence, belching, dry mouth, gastritis, gastric or duodenal ulcer, cankers in the mouth.
  - Liver disturbances - increase in liver enzyme levels, feeling unwell.
  - Rash, itching, increased sweating, redness of the skin, angioedema (edema of the deep layers of the skin, especially of the face), urticaria, edema, nasal congestion resulting from allergy (rhinitis).
  - Hair loss, joint pain.
- Rare side effects (appearing in 1 to 10 patients out of 10,000)
  - Sore throat.
  - Anemia, decreased blood count (thrombocytopenia, leukopenia), weakness.
  - Hypersensitivity, anaphylactic reaction or anaphylactic shock (reaction of the body manifested by swelling of the face, flushing, difficulty breathing and dizziness).
  - Confusion, irritability, restlessness, sleepiness, tingling feeling, tremor, taste disturbances, vision disturbances, migraines.
  - High blood pressure, hot flashes.
  - Bleeding, subcutaneous hematomas, prolonged bleeding.
  - Coughing, shortness of breath, bronchospasm.
  - Bleeding ulcer, vomiting blood, bleeding of the digestive system, black stools.
  - Inflammation in the mouth, inflammation of the esophagus, gastroesophageal reflux, difficulty swallowing, mouth ulcers (stomatitis), inflammation of the tongue.
  - Decreased liver functions.
  - Skin problems, such as eczema, rash.
  - Bone pain, muscle pain, muscle spasms.
  - Disturbances in urination, such as needing to urinate during the night, or increase in serum urea and creatinine.
- Very rare side effects (appearing in 1 to 10 patients out of 100,000)
  - Liver damage, hepatitis (liver inflammation), jaundice, biliary tract problems.
  - Wounds, edema, severe skin diseases such as Stevens-Johnson syndrome, toxic epidermal necrolysis.
  - Aseptic meningitis (non-bacterial).
  - Side effects of all non-steroidal anti-inflammatories: neutropenia, agranulocytosis, aplastic anemia and hemolytic anemia, and kidney poisoning.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

### 5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

• Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• Storage conditions:

Do not store at a temperature above 25°C.

Store in the original packaging.

### 6. FURTHER INFORMATION

• In addition to the active ingredient, the medicine also contains:

Magnesium stearate, povidone, croscarmellose sodium, microcrystalline cellulose, lactose monohydrate, macrogol 6000, titanium dioxide, talc, hypromellose.

• What does the medicine look like and what are the contents of the package?

Xefo 8 mg Tablets is film-coated, white to light yellow-colored tablet, rectangular-shaped, with the stamp L08.

Xefo 8 mg Tablets is marketed in packages of 20 tablets.

• License holder/Importer and address: CTS Ltd., 4 Haharash St., Hod Hasharon.

• Manufacturer and address: Takeda Pharma A/S Denmark, Dybdal Alle 10, DK-2630 Taastrup, Denmark.

• This leaflet was checked and approved by the Ministry of Health in April 2013.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1278230632

