xefo 8 mg-
Film-coated tablets

Active Substance: Lornoxicam

Composition
1 film-coated tablet contains 8 mg lornoxicam, magnesium stearate, polyvidone K 25, croscarmellose sodium, cellulose, lactose, polyethylene glycol 6000, titanium dioxide, talcum and hydroxypropylmethylcellulose.

Pharmaceutical Form
Film-coated tablets

Package Size
10, 20, 30, 50, 100, 250 film-coated tablets

Therapeutic Group
"How do XEFO 8 mg - film-coated tablets work?"
XEFO is a medicinal product for the treatment of pain and inflammatory diseases.

Marketing Authorization Holder and Manufacturer
NYCOMED Austria GmbH, Linz

Indications
"When are XEFO 8 mg - film-coated tablets used?"
Short-term treatment of mild to moderate pain associated with inflammation.
Treatment of rheumatic joint diseases and inflammation of the joints.

Contraindications
"In the following situations XEFO 8 mg - film-coated tablets should not be taken:"
- known hypersensitivity/allergy to the constituents of the product, acetylsalicylic acid (e.g. aspirin) and other anti-inflammatory or pain-relieving medication,
- acute gastric/intestinal bleedings, active gastric ulcers or ulcers in the small intestine,
- impaired formation of blood cells,
- conditions with increased tendency to bleed,
- cirrhosis of the liver,
- severe heart failure,
- severe kidney disease,
- pregnancy,
- lactation,
- patients under 18 years.

Special Warnings for Safe Administration
"Attention: This drug may impair the reactivity and the ability for active participation in traffic."
The combination with alcohol intensifies this effect. Therefore alcohol should be avoided during the treatment with XEFO.
Inform your physician immediately if you become pregnant.
Keep out of the reach of children!
XEFO 8 mg - film-coated tablets are to be administered under special care in the following conditions:
- liver disease,
- kidney disease or impaired kidney

Dosage, Mode and Duration of Application

Dosage:
"How many XEFO 8 mg - film-coated tablets should you take?"
Mild to moderate pain associated with inflammation:
A dosage of 8 – 16 mg/day is recommended which preferably is taken as 1 XEFO 8 mg - film-coated tablet once or twice daily.
The maximum daily dose is 16 mg.
The dose prescribed by your physician has to be followed exactly.
Treatment of rheumatic joint diseases and of inflammations of the joints:
A dose of 12 – 16 mg/day is recommended which preferably is taken as 1 XEFO 8 mg - film-coated tablet 2 times a day. In long-term treatment the recommended maximum daily dose is 16 mg.
The dose prescribed by your physician has to be followed exactly.
Dosage in elderly patients:
A dose adjustment for older patients is not necessary provided the kidney or liver function is not impaired. In these cases the daily dose should be reduced. The dose prescribed by your physician has to be followed exactly.
Dosage in patients with impaired renal and hepatic function:
For patients with impaired renal and hepatic function a maximum daily dose of 12 mg is recommended which preferably is taken as 1 film-coated tablet XEFO 4 mg 3 times a day.

Method of Application
XEFO 8 mg - film-coated tablets should be swallowed with a glass of liquid before meals.

Duration of Treatment
"How long should you take XEFO 8 mg - film-coated tablets?"
Your doctor will instruct you about this. Ask your doctor regularly and follow exactly his advice about diet, lifestyle and exercise.

Overdosage: if you have accidently taken too many XEFO 8 mg - film-coated tablets:
Although no experience with an acute overdosage of Lornoxicam exists it can be expected that the symptoms and complaints cited in the section "Adverse Effects" occur to a greater degree.
In the event of a real or suspected overdose, no further medication must be taken and a physician must be informed immediately.

What should you do if you have accidently forgotten to take the drug:
If you have accidently forgotten to take XEFO, do not take a double dose next time, but continue the treatment as prescribed by your doctor.

Adverse Effects

- liver disease,
- kidney disease or impaired kidney function,
- a history of gastrointestinal bleeding or gastrointestinal ulcers, patients with mild or moderate cardiac insufficiency
- "Systemic Lupus Erythematoses" (congenital skin disease).

As with other antiinflammatory drugs, the treatment with XEFO may cause gastrointestinal ulcers and bleeding. In case of gastrointestinal bleeding, the treatment with XEFO has to be stopped. Special care has also to be taken in patients with gastrointestinal diseases who experience their first treatment with XEFO. Please inform your physician if you experience stomach or intestinal disturbances.

With XEFO it should be taken into consideration that patients with chronic respiratory infections, bronchial asthma, swelling of the nasal mucosa or hay fever are more susceptible to develop hypersensitivity reactions.

In the case of a prolonged treatment with XEFO, regular blood count controls and controls of the liver and kidney function should be performed.

Please adhere to the controls arranged by your physician.

Interactions

"Which drugs may influence each other in their action or their adverse effects?"

Interactions of XEFO 8 mg - film-coated tablets with other drugs may occur. If you visit another doctor (or specialist) do not forget to inform them that you take XEFO.

The following concomitant therapies should be avoided if you take XEFO:

- treatment with substances which impair blood clotting,
- treatment with methotrexate (drug for the impairment of cellular proliferation).

Special care has to be taken if you undergo the following additional treatments:

- treatment with drugs which have an anticoagulant or hemodiluting effect,
- treatment of diabetes with tablets,
- treatment with other pain-relieving drugs or antiinflammatory drugs,
- treatment with diuretic drugs,
- treatment of psychiatric disorders with lithium,
- treatment with cimetidine (medicinal product which reduces the acid production in the stomach),
- treatment with digoxin (medicinal product for the treatment of certain cardiac arrhythmias and cardiac insufficiency),
- treatment with β-receptor-blocking agents (medicinal product for the treatment of elevated blood pressure or of heart complaints),
- treatment with cyclosporine (medicinal product to avoid rejections of organ transplants),
- treatment with ACE-inhibitors (blood pressure decreasing medicinal product).

Adverse Effects

"Which undesirable effects, which, however, must not occur in every patient, can be caused by XEFO 8 mg - film-coated tablets?"

The most common adverse effects are stomach pain and indigestion.

Rare adverse effects:

Headache, dizziness, changes in appetite, somnolence, sweating, loss of weight, edemas, anemia, bleedings of the skin, palpitation, diarrhea, nausea, vomiting, dysphagia, flatulence, constipation, dryness of the mouth, inflammation of the oral mucosa, sour eructation, gastric ulcers with or without bleeding, allergic skin reactions, itching of the skin, loss of hair, dyspnea, muscle cramps, muscle pain, migraine, perception disorders (tingling, formication), taste disturbances, ringing in the ears, trembling, depression, sleep disturbances, inflammation of the conjunctiva of the eye, visual disturbances.

Isolated adverse effects:

Allergic reactions, weakness, weight gain, prolonged duration of bleeding, changes in blood pressure, inflammation of the esophagus, bleeding hemorrhoids or bleeding from the rectum, irritation of the upper airways, disturbances in urine output.

Comment on Expiry Date and Storage

"How should XEFO 8 mg - film-coated tablets be stored?"

For the package sizes of 10, 20, 30, 50, and 100 film-coated tablets (in blister packs):
Store below 25° C! Store protected from humidity!

For the package size of 250 film-coated tablets (in bottles):
Store below 25° C! Store protected from humidity!
Store tightly closed!

Please note the expiry date given on the outer package. After that date XEFO 8 mg - film-coated tablets may not be taken!
In case of uncertainty, seek professional advice.

NYCOMED Austria GmbH
Linz, Austria
Austria's Leading Manufacturer of Pharmaceuticals

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