Important Information. Please read carefully.

Xepamet®

Film-Coated Tablets 200mg / 400mg

COMPOSITION

Xepamet Film-Coated Tablets 200mg:
Each film-coated tablet contains Cimetidine 200mg

Xepamet Film-Coated Tablets 400mg:
Each film-coated tablet contains Cimetidine 400mg

PHARMACODYNAMICS

Cimetidine is a H2-receptor antagonist. It inhibits gastric acid secretion and reduces pepsin output. It is therefore used to heal peptic ulcers, particularly duodenal ulcers and also in conditions whereby gastric acid reduction is beneficial.

PHARMACOKINETICS

It is readily absorbed after oral administration. The bioavailability is about 60% to 70% but varies considerably with individuals. Peak plasma concentrations are obtained in an hour if taken on an empty stomach, two hours if taken with food. The duration of action is prolonged with the latter.
Plasma half-life is about 2 hours. About 20% are protein bound in plasma. About 50% are excreted unchanged in the urine along with the sulphoxide metabolite and the hydroxymethylcimetidine. It is also eliminated in the faeces. Cimetidine crosses the placental barrier and is excreted in breast milk.

INDICATIONS

Xepamet is used for the treatment of duodenal & benign gastric ulcer, oesophageal reflux, non-ulcer acid-related persistent dyspepsia, Zollinger-Ellison syndrome, NSAID-induced lesions (ulcers, erosions) and symptoms in the upper gastrointestinal tract and prevention of their recurrence in patients needing continued NSAID therapy. It is also used for the prevention of recurrence of duodenal ulcer or benign gastric ulcer, at reduced dosage, in patients who have demonstrated a history of recurrence or complications; for the prevention of stress ulcer in patients at risk of gastrointestinal haemorrhage; reducing the risk of pulmonary damage caused by aspirating gastric contents in patients undergoing general anaesthesia including caesarean section. It can also be used to reduce malabsorption and fluid loss in patients with the short bowel syndrome and as an adjunct to enzyme supplement therapy to patients with pancreatic insufficiency to reduce the degradation of the enzyme. In addition, it can be indicated for heartburn and indigestion.

DOSAGE AND ADMINISTRATION

For oral administration only.
The usual oral dose is 400mg twice daily (in the morning and at bedtime); other regimes are 200mg or 400mg, three times daily with 400mg taken at bedtime.
For the treatment of duodenal and gastric ulcer: 800mg daily at bedtime for at least 4 weeks (6 weeks for gastric ulcer).
Prevention of recurrent ulcer: In patients with recurrent duodenal ulcer and benign gastric ulceration, a maintenance dose of 400mg may be given once at bedtime or both in the morning and at bedtime.
Gastro-oesophageal reflux disease (including conditions ranging from heartburn to peptic oesophagitis): 400mg four times a day with meals and at bedtime, for 4 to 8 weeks.
Zollinger-Ellison Syndrome and other cases of high acid secretions: Doses should be adjusted to individual patient needs. Suggested dosage: 400mg four times a day, occasionally increased to a total of 2.4g daily.
Management of patients at risk from stress-related ulceration of upper gastrointestinal tract: 200mg or 400mg every 4 to 6 hours.
In patients at risk of developing the acid aspiration syndrome during general anaesthesia: 400mg may be given 90 to 120 minutes before the induction of anaesthesia or at the start of labour.
As an adjunct to enzyme supplement therapy in pancreatic insufficiency:
0.8g -1.6g daily in 4 divided doses before meals.
Non-ulcer related dyspepsia: 200mg twice a day after breakfast and at bedtime.
Treatment of NSAID-induced lesions: 800mg daily, as 800mg at bedtime or 400mg twice a day (at breakfast and at bedtime).Treatment should be given for at least 4 weeks.
For patients who responded to the initial course, recurrence of lesion may be prevented by continuing treatment.The usual maintenance dosage is 400mg at bedtime.
Children over 1 year: 25 - 30mg/kg daily in divided doses.

In patients with impaired renal function, dosage should be reduced according to creatinine clearance.The following dosages are suggested.

Creatinine Clearance	Dosage
0 - 15 ml/min	200mg twice a day
15 - 30 ml/min	200mg three times a day
30 - 50 ml/min	200mg four times a day
> 50 ml/min	Normal dosage

CONTRAINDICATION

Contraindicated in patients with known hypersensitivity to the drug.

PRECAUTIONS

It is vital to establish during treatment that a gastric ulcer is not malignant as cimetidine may give symptomatic relief in gastric ulcer and temporarily heal the lesion.

Use with care in those with hepatic disease or with a history of peptic ulcer, particularly the elderly. Avoid use of cimetidine during pregnancy and lactation, unless essential. Avoid abrupt withdrawal of treatment. Dosage should be reduced in patients with impaired renal function.

DRUG INTERACTIONS

Cimetidine may cause clinically significant changes in the metabolism of some drugs such as anticoagulants, phenytoin, theophylline, certain benzodiazepines or beta-blockers, by delaying their elimination and increasing or prolonging blood concentrations of these drugs. Dosage adjustment may be necessary.

SIDE EFFECTS

Xepamet is usually well tolerated. Side effects are generally infrequent and are usually reversible following a reduction of dosage or withdrawal of therapy.
Occasionally diarrhoea, dizziness and rashes may occur. Gynaecomastia has been reported in men receiving relatively high dosage for conditions such as Zollinger-Ellison Syndrome. Other side effects reported rarely may include tiredness, allergic reactions, interstitial nephritis, headache, hepatoxicity, pancreatitis, mental confusion (usually in the elderly and in patients with renal disease), joint and muscular pain, impotence in men, blood disorders such as agranulocytosis or granulocytopenia and thrombocytopenia.

OVERDOSAGE AND TREATMENT

Acute overdosage of up to 20g has been reported several times with no significant ill effects.
Treatment should consist of gastric lavage, provided that not more than 4 hours elapsed since ingestion of the drugs, followed by supportive measures and symptomatic treatment only.

SHELF-LIFE

The expiry date is indicated on the packaging.

PRESENTATION

Xepamet Film-Coated Tablets 200mg: Light green, round, normal convex with embossed crown logo, film-coated tablet, 10 mm in diameter in box of 60's (in blister pack of 10 tablets).
Xepamet Film-Coated Tablets 400mg: Light green, oval shaped, film-coated tablet and symbol of crown on one side in box of 60's (in blister pack of 10 tablets).

STORAGE

Protect from light. Store below 30°C.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder
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