mep® (Omeprazole) Delayed-Release Capsules U.S.P.

20mg
40mg

میپ (اومیپرازول) کیپسولز یو۔ایس۔پی۔

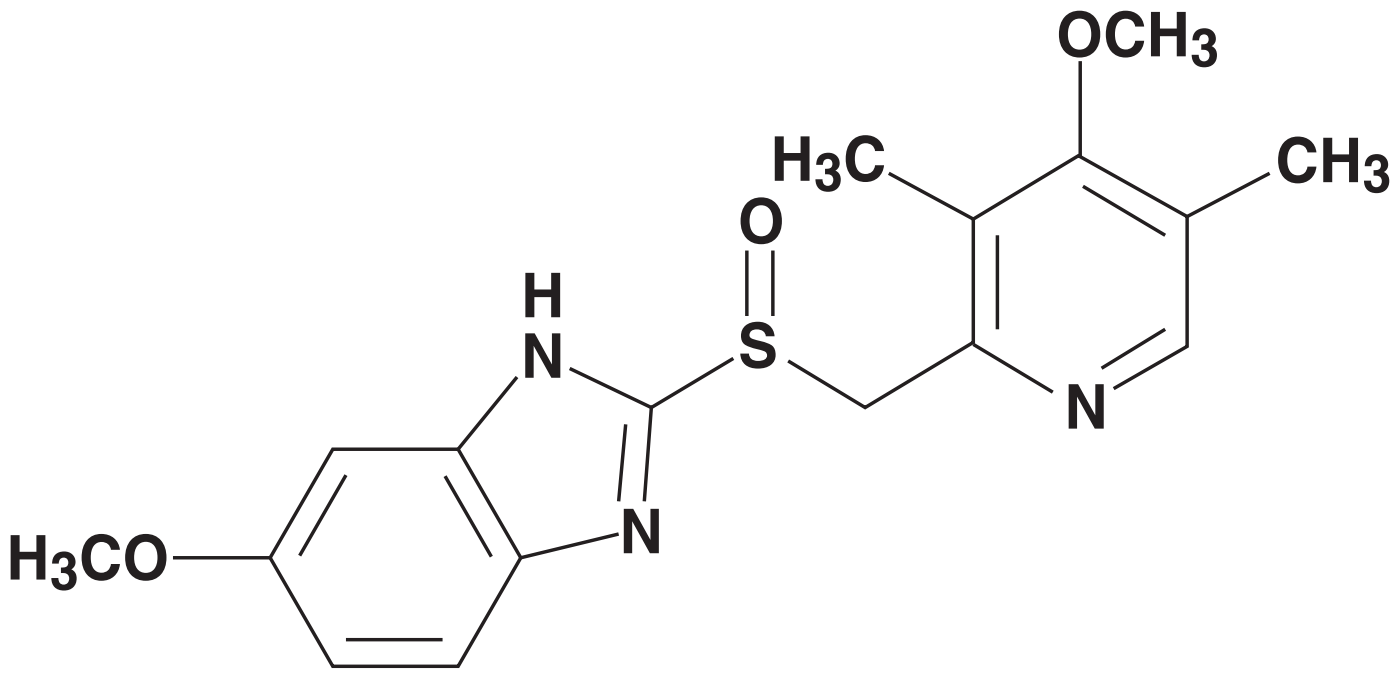
۲۰ ملی گرام
۴۰ ملی گرام

DESCRIPTION:

Mep contains omeprazole which is commonly used to treat the acid peptic diseases.

Structural Formula:

Its empirical formula is $C_{17}H_{19}N_3O_3S$, with a molecular weight of 345.42. The structural formula is:



QUALITATIVE AND QUANTITATIVE

COMPOSITION

mep® 20mg Delayed-Release Capsules U.S.P.

Each delayed-release capsule contains:
Omeprazole enteric-coated pellets eq. to.
Omeprazole 20mg

mep® 40mg Delayed-Release Capsules U.S.P.

Each delayed-release capsule contains:
Omeprazole enteric-coated pellets eq. to.
Omeprazole 40mg

CLINICAL PHARMACOLOGY:

Mechanism of Action:

Omeprazole suppresses gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, omeprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production.

Absorption:

Absorption of omeprazole begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours. Peak plasma concentrations of omeprazole and AUC are approximately proportional to doses up to 40 mg, but be-

cause of a saturable first-pass effect, a greater than linear response in peak plasma concentration and AUC occurs with doses greater than 40 mg. Absolute bioavailability is about 30-40% at doses of 20-40 mg, due in large part to presystemic metabolism. In healthy subjects the plasma half-life is 0.5 to 1 hour, and the total body clearance is 500-600 mL/min.

Distribution:
Protein binding is approximately 95%.

Metabolism:
Omeprazole is extensively metabolized by the cytochrome p450 (cyp) enzyme system.

Excretion: The majority of the dose (about 77%) is eliminated in urine as at least six metabolites. The remainder of the dose is recoverable in feces. This implies a significant biliary excretion of the metabolites of omeprazole.

Hepatic impairment:
In patients with chronic hepatic disease, the bioavailability increased to approximately 100% compared with an I.V. dose, reflecting decreased first-pass effect, and the plasma half-life of the drug increased to nearly 3 hours compared with the half-life in normals of 0.5-1 hour. Plasma clearance averaged 70 ml/min, compared with a value of 500-600 ml/min in normal subjects. Dose reduction, particularly where maintenance of healing of erosive esophagitis is indicated, for the hepatically impaired should be considered.

Renal impairment:
Because urinary excretion is a primary route of excretion of omeprazole metabolites, their elimination slowed in proportion to the decreased creatinine clearance. No dose reduction is necessary in patients with renal impairment.

SIDE EFFECT:

The most common adverse reactions reported ≥ 2% from omeprazole treated patients enrolled in these studies included headache (2.9%), abdominal pain (5.2%), nausea (4.0%), diarrhea (3.7%), vomiting (3.2%), and flatulence (2.7%). Additional adverse reactions reported ≥ 1% included acid regurgitation (1.9%), URTI (1.9%), constipation (1.5%), dizziness (1.5%), rash (1.5%), asthenia (1.3%), back pain (1.1%), and cough (1.1%).

DRUG INTERACTION:

Omeprazole was found to be interfering with atazanavir, saquinavir, ketoconazole, voriconazole, ampicillin esters, iron salts, diazepam, warfarin, phenytoin, theophylline, cyclosporine, disulfiram, benzodiazepines and tacrolimus

OVER DOSAGE:

Doses ranged up to 2400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience. Symptoms were transient, and no serious clinical outcome has been reported when OMEPRAZOLE was taken alone.

DOSAGE & ADMINISTRATION:

Indication	Dose & Duration
Active Duodenal Ulcer	**20mg** OD for 4-weeks
H. pylori associated Duodenal Ulcer (triple therapy)	**20mg** *(Am=1000mg Cl=500mg)* BID for 10-days
H. pylori associated Duodenal Ulcer (double therapy)	**40mg** OD *(Cl=500mg TID)* for 14-days
GERD	**20mg** OD for 4-8 weeks
Maintenance of Healing of Erosive Esophagitis	**20mg** OD
Gastric Ulcer	**40mg** OD for 4-8 weeks
Pathological Hypersecretory Conditions	**60mg** OD

CONTRAINDICATION:

Omeprazole is contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation.

PRECAUTION:

Concomitant Gastric Malignancy Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy.

Atrophic Gastritis:

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole.

Bone Fracture:

The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer).

Pregnancy: Pregnancy Category C:

There are no adequate and well-controlled studies on the use of omeprazole in pregnant women. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers:

Omeprazole is excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:

Use of OMEPRAZOLE in pediatric and adolescent patients 1 to 16 years of age for the treatment of GERD is supported by (a) extrapolation of results, already included in the currently approved labeling, from adequate and well-controlled studies that supported the approval of Omeprazole for adults, and (b) safety and pharmacokinetic studies performed in pediatric and adolescent patients

DOSAGE:

As directed by the physician.

INSTRUCTIONS: Store between 15°C - 30°C.
Preserve in tight, light resistant container.
Keep all medicines out of the reach of children.

PRESENTATION:
mep® (Omeprazole) 20mg capsules are available in Alu-Alu blister pack of 2x7's.
mep® (Omeprazole) 40mg capsules are available in Alu-Alu blister pack of 2x7's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: ۱۵ سے ۳۰ ڈگری سینٹی گریڈ پر رکھیں۔
روشنی سے محفوظ بند کنٹینر میں رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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ISO 9001:2015 ISO 14001:2015 ISO 45001:2018