

TEpH[®] 20mg Capsules (Omeprazole) 40mg Capsules

DESCRIPTION:

TEpH[®] is a brand of Omeprazole, a proton pump inhibitor which controls gastric acid secretion by inhibiting gastric H⁺ / K⁺ - ATPase, preventing the final step in parietal cell acid secretion. **TEpH[®]** is presented as hard gelatin capsules.

Composition:

TEpH[®] 20mg Capsules:

Each capsule contains:

Enteric coated pellets of Omeprazole MS equivalent to Omeprazole USP.....20mg

TEpH[®] 40mg Capsules:

Enteric coated pellets of Omeprazole MS equivalent to Omeprazole USP.....40mg

CLINICAL PHARMACOLOGY:

Pharmacokinetics:

Each capsule of **TEpH[®]** (Omeprazole) contains an enteric coated pellets formulation of Omeprazole so that absorption of Omeprazole begins only after the pellets leave the stomach. Absorption is rapid, with peak plasma levels of Omeprazole occurring within 1/2 to 3 1/2 hrs. Absolute bioavailability is about 50–60% at doses of 20-40mg. In healthy subjects the plasma half-life is approximately 1 hour. Protein binding is approximately 95%.

Metabolism & Excretion:

Omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole, and to a small extent by CYP3A to form Omeprazole sulfone. The metabolites are inactive, and are excreted mostly in the urine and to a lesser extent in bile. Approximately 77% of the dose eliminated through urine and remaining through feces.

SPECIAL POPULATION:

Paediatric:

In 1 year and older children available data suggested that pharmacokinetic within the recommended doses are similar to adults. Lower plasma levels of Omeprazole were observed in some children at steady state.

Elderly:

Bioavailability may be increased in elderly patients.

Renal impairment:

No significant changes in bioavailability are observed with reduced renal function.

Hence no dose adjustment is needed.

Hepatic impairment:

In patients with impaired liver functions, the area under the plasma concentration time curve is increased but no accumulation of Omeprazole has been found.

THERAPEUTIC INDICATIONS:

TEpH[®] (Omeprazole) is indicated for the treatment of:

- Duodenal ulcer
- Gastric ulcer
- NSAID associated gastric and duodenal ulcers or erosions
- Helicobacter pylori eradication in peptic ulcer disease
- Reflux esophagitis
- Symptomatic gastro-esophageal reflux disease
 - Treatment of erosive reflux esophagitis
 - Long term maintenance therapy to prevent reflux healed esophagitis
- Acid related dyspepsia
- Zollinger-Ellison Syndrome
- Refractory Peptic Ulcer
- Prophylaxis of Acid aspiration

CONTRAINDICATIONS:

Hypersensitivity to Omeprazole.

PRECAUTIONS:

In case of suspected gastric ulcer, exclude malignancy before treatment, as **TEpH[®]** (Omeprazole) may alleviate symptoms and delay diagnosis. Patients with severe hepatic disease should not require more than 20mg daily.

DRUG INTERACTIONS:

TEpH[®] (Omeprazole) can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in liver. No interactions have been reported with theophylline, propranolol, metoprolol, lidocaine or quinidine. Interaction with drugs metabolized by the cytochrome P450 may occur. No interaction with concomitantly administered antacid has been found.

OVER DOSAGE:

None has been reported and no specific treatment can be recommended. Single oral dose up to 160mg has been well tolerated.

EFFECTS ON ABILITY TO DRIVE OR USE MACHINES:

TEpH[®] (Omeprazole) is not likely to affect ability to drive or use machines.

ADVERSE REACTIONS:

TEpH[®] (Omeprazole) is well tolerated. Nausea, vomiting, diarrhoea, constipation and flatulence have been reported occasionally. Skin rashes have been reported in some patients. These events are transient and usually mild and bear no consistent relationship with treatment.

DOSAGE & ADMINISTRATION:

Duodenal ulcer – usually 20mg once daily for 2 weeks, if not fully healed treatment may be extended for further 2 weeks. In refractory cases 40mg once daily for 4 weeks.

Gastric ulcer and Reflux esophagitis – 20mg once daily for 4 weeks, if not fully healed, treatment may be extended for further 4 weeks. In refractory cases 40mg once daily for 8 weeks.

Prevention of relapses in patients with severe reflux esophagitis –20mg once daily. In case of recurrence the dose can be increased to 40mg once daily.

Helicobacter pylori associated peptic ulcer diseases – 40-80mg with Amoxicillin, 1.5 to 3g daily in divided doses for 2 weeks or 40mg daily with Clarithromycin 500mg thrice daily for 2 weeks

Zollinger Ellison Syndrome – 60mg once daily adjusted to response

Usual maintenance – 20 to 120mg daily. Doses over 80mg daily, given in two divided doses

Prophylaxis acid aspiration - Omeprazole 40mg in the evening before surgery and 40mg 2-6 hours before surgery

STABILITY:

See expiry on the pack

PRESENTATION:

TEPAM® 20mg & 40mg capsules are available in Alu-Alu blister pack of 2 x 7 capsules

INSTRUCTION:

Do not chew or crush capsule contents

The capsule should be swallowed whole with water

Keep out of reach of children

Avoid exposure to heat, light and humidity

Store between 15 to 30°C

Improper storage may deteriorate the medicine

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(اوپی پرازول)
۲۰/۴۰ ملی گرام کپسول

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایت: کپسول چبائے بغیر پانی سے نگل لیں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی



Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

210 mm

P000665/S

R.N-08/HA/08/16/Pampac

120 mm