۵×۳ کیپسولز

ذوپرول®

اومیپرازول یو ایس پی

Acid pump inhibitor

Zoprol®

3x5 Capsules

Omeprazole U.S.P. 20 mg

ذوپرول کیپسول معدے کی رطوبت (معدے کے تیزاب) کو ایک خاص طریقے سے کم کرتا ہے۔ ذوپرول کیپسول کی خاص مقدار معدے کی تیزابیت کو پیدا کرنے والے خامرے کو روکتی ہے جو السر پیدا کرنے کا باعث بنتے ہیں۔

علامات:

* معدے کے السر، ایسوفیگس کی سوزش اور ڈیوڈنل السر۔
* معدے کے السر اور ڈیوڈنل السر جو انسیڈ (NSAID) کے باعث ہو۔
* بیلی کو بیکٹر پائلوری جو پیپٹک السر (Peptic Ulcer) کے امراض کا باعث ہو۔

خوراک:

ڈیوڈنل السر:	ذوپرول کیپسول ۲۰ ملی گرام دن میں ایک مرتبہ دو ہفتوں کے لیے۔
معدے کے السر:	ذوپرول کیپسول ۲۰ ملی گرام دن میں ایک مرتبہ چار ہفتوں کے لیے۔
ایسوفیگس کی سوزش	ذوپرول کیپسول ۲۰ ملی گرام دن میں ایک مرتبہ چار ہفتوں کے لیے۔
انسیڈ (NSAID) کے باعث السر:	ذوپرول کیپسول ۲۰ ملی گرام دن میں ایک مرتبہ چار ہفتوں کے لیے۔
(بیلی کو بیکٹر پائلوری) پیپٹک السر:	ذوپرول کیپسول ۲۰ ملی گرام دن میں دو مرتبہ ایک ہفتے کے لیے۔
امراض جگر میں:	ذوپرول کیپسول ۲۰ ملی گرام دن میں ایک مرتبہ۔
امراض گردہ میں:	ذوپرول کیپسول کی دوا میں ردوبدل کی ضرورت نہیں۔
بچوں کے لئے:	بچوں میں ذوپرول کیپسول کا استعمال ثابت شدہ نہیں ہے۔

یا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

* کیپسول کو کھولے یا چبائے بغیر پانی سے نگل لیں۔
* دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش: ذوپرول ۲۰ ملی گرام کیپسولز (۵×۳) ایلو۔ایلو پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

COMPOSITION:

Each capsule contains:
Omeprazole U.S.P. 20 mg as enteric coated pellets.

CLINICAL PHARMACOLOGY:

Zoprol capsules contain enteric-coated pellets of (Omeprazole) reduces gastric acid secretion through a highly targeted mechanism of action. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dose.

Omeprazole is a weak base and is concentrated and converted to the active form in the intracellular canaliculi within the parietal cell, where it inhibit the enzyme H^+, K^+, ATPase the acid pump.This effect is dose dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus. All pharmacodynamic effects observed can be explained by the effect of omeprazole on acid secretion. Omeprazole is almost completely metabolized in the liver and rapidly eliminated mostly in the urine.

The elimination half life from plasma is short being reported to be about 0.5-3 hrs. Its duration of action with regard to inhibition of acid secretion is much longer allowing to the tissues & particularly to the gastric parietal cells, accounts for this action. Omeprazole is highly bound about 95 % to plasma protein.

Oral dosing with **Zoprol** once daily provides for rapid and effective inhibition of day time and night time gastric acid secretion with maximum effect being achieved within 4 days of treatment. Oral dosing with **Zoprol** 20 mg maintains an intragastric pH of ≥3 for a mean time of 17 hours of the 24 hours period in duodenal ulcer patient. As a consequence of reduced acid secretion and intragastric acidity, Omeprazole dose dependently reduce/normalizes acid exposure of the oesophagus in patients with gastro-oesophageal reflux disease.

INDICATIONS:

- Zoprol is indicated for the treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis.
- Helicobacter pylori associated peptic ulcer disease.
- NSAID associated gastric and duodenal ulcer.
- Zollinger-Ellison Syndrome.

CONTRA-INDICATIONS:

Known hypersensitivity to omeprazole.

PRECAUTIONS:

Before giving omeprazole to patients with gastric ulcers the possibility of malignancy should be excluded since omeprazole may mask the symptoms and delay diagnosis.

Omeprazole inhibits the metabolism of drug metabolised by the hepatic cytochrome P450 enzyme system & may increase plasma concentration of diazepam, phenytoin and warfarin.

Use in Pregnancy:
As with all new drugs **Zoprol** should not be given during pregnancy and lactation unless its use is considered essential. Animal studies have not shown evidence of any hazard from the administration of omeprazole during pregnancy and lactation and there is no evidence of foetal teratogenic effect.

SIDE EFFECTS:

Zoprol is well tolerated. The following events have been reported, but in the great majority cases a consistent relationship between these events and treatment with Omeprazole has not been established.

Headache, diarrhoea, constipation, abdominal pain, nausea/ vomiting, and flatulence have been reported rarely.

Rarely: Increased liver enzymes, rash urticaria and or pruritus, dizziness, parasthesia, somnolence, insomnia, vertigo and malaise.

DOSAGE & ADMINISTRATIONS:

The dose of **Zoprol** is recommended to be given in the morning-swallowed whole with liquid. Capsule should not be chewed or crushed.

Duodenal ulcer:
The recommended dosage for an active duodenal ulcer is **Zoprol** 20 mg once daily. Symptom relief is rapid and in most of patient healing occur within 2 weeks. For those patient who may not healed after the initial course, healing usually occur during further 2 weeks treatment periods.

In patients with poorly responsive duodenal ulcer **Zoprol** 40 mg once daily has been used and healing is usually achieved within 4 weeks treatment period.

For the prevention of relapse in duodenal ulcer the recommended dose is 10 mg once daily, if needed the dose can be increased to **Zoprol** 2 x 20 mg once daily.

Gastric ulcer:
The recommended dosage is **Zoprol** 20 mg once daily Symptoms relief is rapid and in most patients healing occurs within 4 weeks. For those patients who may not have fully healed after the initial course, healing usually occurs during further 4 weeks treatment period.

In patients with poorly responsive gastric ulcer **Zoprol** 2 x 20 mg once daily has been used and healing is usually achieved within 8 weeks.

For the prevention of relapse in patients with poorly responsive gastric ulcer the recommended dose is **Zoprol** 20 mg once daily. If needed the dose can be increased to **Zoprol** 2 x 20 mg once daily.

The effectiveness of **Zoprol** is not affected by concomitant NSAID treatment and the usual duration of treatment is recommended.

NSAID Associated gastric ulcer:
The recommended dose is **Zoprol** 20 mg once daily. Symptom is rapid in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period.

Helicobacter pylori associated peptic ulcer disease:

Triple therapy regimens:
Zoprol 20 mg, amoxicillin 1 gm and clarithromycin 500 mg, all twice a day for one week.

Zoprol 20 mg , clarithromycin 250 mg and metronidazole 400 mg (or tinidazole 500 mg), all twice a day for one week.

Zoprol 2 x 20 mg , amoxicillin 500 mg and metronidazole 400 mg all a day for one week.

Dual therapy regimens:
Omeprazole 40 –80 mg with amoxicillin 1.5 gm daily in divided doses for two weeks. In clinical studies daily doses of 1.5 – 3 gm of amoxicillin have been used or **Zoprol** 2 x 20 mg once daily and clarithromycin 500 mg three times a day for two weeks.

To ensure healing in patients with active peptic ulcer disease, see further dosage recommendations for Duodenal and Gastric ulcer.

In each regimen if the patient is still Hp positive, therapy may be repeated.

Reflux Oesophagitis:
The recommended dosage is **Zoprol** 20 mg once daily. Symptom relief is rapid and in most patients healing occurs within 4 weeks. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period. In patients with severe reflux oesophagitis **Zoprol** 2 x 20 mg once daily has been used and healing is usually achieved within 8 weeks.

For the long term management of patients with healed reflux oesophagitis the recommended dose of **Zoprol** is 10mg once daily. If needed the dose can be increased to **Zoprol** 2 x 20 mg once daily.

Zollinger-ellison syndrome:
The recommended initial dosage is 3 x 20 mg **Zoprol** once daily. The dosage should be adjusted individually and treatment continued as long as clinically indicated. All patients with severe disease and inadequate response to other therapies have been effectively controlled and more than 90 % of the patients maintained on doses of 20-120 mg daily. With doses above 80 mg daily, the dose should be divided and given twice daily.

Impaired hepatic function
As bioavailability and plasma half life of omeprazole are increased in patients with impaired hepatic function a daily dose of 20 mg is generally sufficient.

Impaired renal function
No dose adjustment is required in patients with impaired renal function.

Children
There is no experience with **Zoprol** in children.

INTERACTIONS:

Zoprol can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. Monitoring of patients also receiving warfarin or phenytoin is recommended and a reduction of dose of phenytoin and warfarin may be necessary. However, concomitant treatment with **Zoprol** 20 mg daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. Similarly concomitant treatment with **Zoprol** 20 mg daily did not change coagulation time in patients on continuous treatment with warfarin. Plasma concentrations of **Zoprol** and clarithromycin are increased during concomitant medication. No interaction with propanolol, metoprolol, theophylline, lidocaine, quinidine and amoxicillin has been found, but interaction with other drugs also metabolized via the cytochrome P450 enzyme system cannot be excluded. No interaction with concomitantly administered antacids or food has been found.

DIRECTIONS:

- Use on Physician's prescription only.
- The capsule should be swallowed with liquid.
- Do not chew or crush the capsule contents.

OVER DOSAGE:

Single oral doses of up to 400 mg of **Zoprol** have not resulted in any severe symptoms and no specific treatment has been needed. No information is available on the effects of higher doses in man and specific recommendations for treatment cannot be given.

SPECIAL WARNINGS & SPECIAL PRECAUTIONS FOR USE:

When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and delay diagnosis.

STORAGE CONDITIONS:

* Store in a cool and dry place.
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

PACKING:

Zoprol 20 mg Capsules are available in (3 x 5) Alu-Alu pack.