

زیکسم®

ایس اومپیدازول ۲۰ اور ۴۰ ملی گرام

علامات:

زیکسم کیپسول معدے کے مختلف امراض کیسٹرو وائیڈ پیپٹین ریفلکس، ہیپلی کوئیکٹر یا نیکوری کے باعث ڈیوڈنل السرا اور ایسڈ (NSAID) کے مستقل استعمال کے باعث معدے کے السر سے بچاؤ کے لئے مفید ہے۔

خوراک:

زیکسم ۲۰ ملی گرام یا ۴۰ ملی گرام روزانہ ایک مرتبہ ۸ ہفتوں کے لئے۔ (علامات برقرار رہنے کی صورت میں خوراک مزید ۸ ہفتوں تک بڑھائی جاسکتی ہے)	کیسٹرو وائیڈ پیپٹین ریفلکس
زیکسم ۲۰ ملی گرام کیپسول روزانہ ایک مرتبہ ۸ دن کے لئے۔ ایکوی کیپسول ۱۰۰۰ ملی گرام روزانہ دو مرتبہ ۸ دن کے لئے۔ کلیریتھرو ماسین ۵۰۰ ملی گرام روزانہ دو مرتبہ ۸ دن کے لئے۔	ہیپلی کوئیکٹر یا نیکوری کے باعث ڈیوڈنل السر (ٹریپل تھراپی)
زیکسم ۲۰ ملی گرام یا ۴۰ ملی گرام کیپسول روزانہ ایک مرتبہ ۶ ماہ کے لئے۔	ایسڈ (NSAID) کے باعث السر

زیکسم کیپسول کھانے سے کم از کم ایک گھنٹہ قبل یا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

- * کیپسول کو کھولے یا چبانے بغیر پانی سے نگل لیں۔
- * دو کوکھڑی اور شش گھبر چکیں۔
- * دو کوکھڑی، روشنی اور نمی سے محفوظ رکھیں۔
- * تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش: زیکسم ۲۰ ملی گرام کیپسول (۵x۳) - ایلو - ایک پیکیٹ میں دستیاب ہیں۔
زیکسم ۴۰ ملی گرام کیپسول (۵x۳) - ایلو - ایک پیکیٹ میں دستیاب ہیں۔



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

ZEXUM®

Esomeprazole 20 and 40 mg

COMPOSITION:

Each Zexum 20mg capsule contains:

Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole..... 20mg

Each Zexum 40mg capsule contains:

Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole..... 40mg

CLINICAL PHARMACOLOGY:

Mechanism of action:

Esomeprazole is a proton pump inhibitor that suppresses the gastric acid secretion by specific inhibition of the H⁺/K⁺ ATPase in the gastric parietal cell. The S- and R-isomers of omeprazole are protonated and converted in the acidic compartment of the parietal cell forming the active inhibitor, the achiral sulphenamide. By acting specifically on the proton pump, esomeprazole blocks the final step in acid production, thus reducing gastric acidity. This effect is dose related up to a daily dose 20 to 40 mg and leads to inhibition of gastric acid secretion.

Esomeprazole works by binding irreversibly to the H⁺/K⁺ ATPase in the proton pump. As the proton pump is the final pathway for secretion of hydrochloric acid by the parietal cells in the stomach, its inhibition dramatically decreases the secretion of hydrochloric acid into the stomach and alters gastric pH.

Pharmacokinetics:

Absorption:

After oral administration peak plasma levels (C_{max}) occur at approximately 1.5 hours (T_{max}). The C_{max} increases proportionally when the dose is increased, and there is a three-fold increase in the area under the plasma concentration-time curve (AUC) from 20 to 40mg.

The AUC after administration of a single 40mg dose of esomeprazole is decreased by 43-53% after food intake compared to fasting conditions. Esomeprazole should be taken at least one hour before meals. Food delays and decreases the absorption of esomeprazole, but this does not significantly change its effect on the intragastric acidity.

Distribution:

Esomeprazole is 97% bound to plasma proteins. Plasma protein binding is constant over the concentration range of 2-20μmol/L.

Metabolism:

Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (CYP) enzyme system. The metabolites of esomeprazole lack antisecretory activity. The major part of esomeprazole's metabolism is dependent upon the CYP2C19 isoenzyme, which forms the hydroxy and desmethyl metabolites. The remaining amount is dependent on CYP 3A4 which forms the sulphone metabolite.

Excretion:

The plasma elimination half life of esomeprazole is approximately 1-1.5 hours. Less than 1% of the parent drug is excreted in the urine. Approximately 80% of an oral dose of esomeprazole is excreted as inactive metabolites in the urine, and the remainder is found as inactive metabolites in the feces.

INDICATIONS:

Zexum is indicated for the:

Treatment of Gastroesophageal Reflux Disease (GERD)

- Healing of Erosive Esophagitis
- Maintenance of Healing of Erosive Esophagitis
- Symptomatic Gastroesophageal reflux disease

Helicobacter pylori Eradication to reduce the risk of duodenal ulcer recurrence

As a triple therapy (esomeprazole plus amoxicillin and clarithromycin)

For the treatment of patients with H. Pylori infection and duodenal ulcer disease to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

Risk reduction of NSAID associated gastric ulcer

Reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk for developing gastric ulcer. Patients are considered at risk due to their age (≥ 60) and history of gastric ulcer.

DOSAGE AND ADMINISTRATION:

The recommended adult dosages are outlined in the table below. Zexum (esomeprazole) capsules should be swallowed whole and taken atleast one hour before meals.

Recommended Adult Dosage Schedule		
Indication	Dose	Frequency
Gastroesophageal Reflux Disease Healing of erosive esophagitis	20mg or 40mg	Once daily for 4 to 8 weeks (an additional 4-8 weeks treatment may be considered if symptoms persist or esophagitis does not heal)
Maintenance of healing of erosive esophagitis	20mg	Once daily
Symptomatic gastroesophageal reflux disease without esophagitis	20mg	Once daily for 4 weeks (an additional 4-8 weeks treatment may be considered if symptoms does not resolve completely)
H. Pylori eradication to reduce the risk of duodenal ulcer recurrence (Triple therapy) Zexum Amoxicillin Clarithromycin	40mg 1000mg 500mg	Once daily for 10 days Twice daily for 10 days Twice daily for 10 days
Risk reduction of NSAID associated gastric ulcers	20mg or 40mg	Once daily for up to 6 months

CONTRA-INDICATIONS:

Zexum is contra-indicated in patients with known hypersensitivity to esomeprazole or any other component of this product or to substituted benzimidazoles.

PRECAUTIONS AND WARNINGS:

- Before giving esomeprazole to patients with gastric ulcers the possibility of malignancy should be considered since these drugs may mask the symptoms and delay diagnosis.
- Symptomatic response to therapy with Zexum does not preclude the presence of gastric malignancy.
- Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which esomeprazole is an enantiomer.
- Esomeprazole should be used with caution in hepatic impairment.
- When prescribing esomeprazole for on demand therapy the implications for interaction with other pharmaceuticals, due to fluctuating plasma concentrations of esomeprazole

should be considered.

- Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- When prescribing esomeprazole for eradication of Helicobacter pylori infection possible drug interactions for other components in the triple therapy should be considered.

Pediatric use:

Safety and effectiveness in pediatric patients have not been established.

Pregnancy:

There are no adequate and well-controlled studies in pregnant woman. Esomeprazole should be used during pregnancy only if clearly needed.

Nursing Mothers:

Because esomeprazole is likely to be excreted in human milk a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of drug to the mother due to potential for serious adverse reactions in nursing infants from esomeprazole.

DRUG INTERACTIONS:

Esomeprazole, a proton pump inhibitor is metabolized by the cytochrome P450 system, primarily by isoenzyme CYP2C19, and may alter the metabolism of some drugs metabolized by these enzymes. Esomeprazole may prolong the elimination of diazepam, phenytoin, and warfarin. Esomeprazole can reduce the absorption of drugs such as ketoconazole and possibly itraconazole, whose absorption is dependant on an acid gastric pH. With voriconazole, the plasma concentration of both drugs may be increased and a reduced dose of esomeprazole is recommended.

SIDE EFFECTS:

The following adverse drug reactions have been reported during therapy of esomeprazole. None found to be dose related.

Common: Headache, diarrhea, flatulence, nausea/vomiting, constipation, dry mouth.

Body as a whole: Abdomen enlarged, allergic reaction, asthenia, back pain, chest pain, edema, fatigue, fever.

Cardiovascular: Flushing, hypertension, tachycardia.

Endocrine: Goiter

Gastrointestinal: Bowel irregularity, constipation aggravated, dyspepsia.

Hematological: Leucopenia, thrombocytopenia, anemia, leukocytosis.

Hepatic: Bilirubinemia, hepatic function abnormal.

Skin: Acne, angioedema, dermatitis, rash, skin inflammation, sweating.

Nervous system: Anorexia, apathy, appetite increased, confusion, depression aggravated.

OVER DOSAGE:

The clinical manifestations of over dosage are confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache and dry mouth.

TREATMENT:

No specific antidote for esomeprazole is known. Since esomeprazole is extensively protein bound, it is not expected to be removed by dialysis. In the event of over dosage treatment should be symptomatic and supportive.

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:

Zexum 20mg capsules are available in (3x5) Alu-Alu blister pack.

Zexum 40mg capsules are available in (3x5) Alu-Alu blister pack.