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Xerosec™

Omeprazole BP

50049

Presentation

Xerosec 10 capsule : White to off white opaque cap and blue transparent body capsule containing white to off white pellets. Each capsule contains Omeprazole BP 10 mg as enteric coated pellets.

Xerosec 20 capsule : White to off white opaque cap and blue transparent body capsule containing white to off white pellets. Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.

Xerosec 40 capsule : White to off white opaque cap and blue transparent body capsule containing white to off white pellets. Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.

Description

Xerosec capsule (Omeprazole), reduces gastric acid secretion through a unique mechanism of action. It is a specific inhibitor of the gastric acid pump in the parietal cell. It is rapidly acting and it produces reversible control of gastric acid secretion with once daily dosing.

Oral dosing with Xerosec capsule once daily provides rapid and effective inhibition of day time and night time gastric acid secretion with maximum effect being achieved within 4 days of treatment. With Xerosec capsule 20 mg, a mean decrease of approximately 80% in 24 hour intragastric acidity is then maintained in duodenal ulcer patients with the mean decrease in peak acid output after pentagastric stimulation being about 70% twenty four hours after dosing.

Site and mechanism of action: Omeprazole is a weak base and it is concentrated and converted to the active form in the acid environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H+, K+- ATPase- the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for effective inhibition of both basal acid secretion and stimulated acid secretion irrespective of the stimulus.

Helicobacter pylori (Hp) is associated with acid peptic disease including duodenal ulcer (DU) and gastric ulcer (GU) in which about 95% and 80% of patients respectively are infected with this bacterium. Hp is implicated as a major contributing factor in the development of gastritis and ulcers in such patients. Recent evidence also suggests a causative link between Hp and gastric carcinoma.

Eradication of Hp with Omeprazole and antimicrobials is associated with rapid symptom relief, high rates of healing of any mucosal lesion and long term remission of peptic ulcer disease thus reducing complications such as gastrointestinal bleeding as well as the need for prolonged anti-secretory treatment.

During long-term treatment an increased frequency of gastric glandular cysts have been reported in a somewhat increased frequency. These changes are physiological consequences of pronounced inhibition of acid secretion and are benign reversible.

Uses

Treatment of esophageal reflux disease. Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy.

Relief of reflux-like symptoms (e. g, heartburn) and/or ulcer like symptoms (eg. epigastric pain) associated with acid related dyspepsia.

Treatment and prophylaxis of NSAID-associated benign gastric ulcer, duodenal ulcers, and gastroduodenal erosions in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.

Relief of associated dyspeptic symptoms.

Helicobacter pylori eradication: Omeprazole should be used in combination with antibiotics for eradication of *Helicobacter pylori* (Hp) in peptic ulcer disease.

Relief of associated dyspeptic symptoms.

Prophylaxis of acid aspiration

Zollinger-Ellison syndrome.

Dosage and administration

Esophageal reflux disease including reflux esophagitis: 20 mg once daily for 4 weeks: for some patients healing usually occur during a further 4-8 weeks treatment.

Reflux esophagitis refractory to other therapy: 40 mg once daily for 8 weeks. Patients can be continued at a dosage of 20 mg once daily.

Acid reflux disease: For long term management 10mg once daily increasing to 20 mg once daily if symptom returns.

Duodenal ulcer: 20 mg once daily for 4 weeks: in servere or recurrent cases increase to 40 mg once daily.

Benign gastric ulcer: 20mg once daily for 8 weeks: in severe or recurrent cases increase to 40mg daily.

Prevention of replace in duodenal ulcer: 10 mg -20 mg once daily.

Acid related dyspepsia: 10-20mg once daily for 2-4 weeks

NASID associated gastric ulcers, duodenal ulcers or gastroduodenal erosions: 20 mg once daily for 4 weeks: for some patients further 4 weeks treatment is needed.

For prophylaxis of NSAID-associatyed peptic ulcer: 20mg once daily.

Prophylaxis of acid aspiration:

40 mg on the evening before surgery, followed by 40 mg 2-6 hours prior to surgery.

Zollinger-Ellison syndrome:

Initially 60 mg once daily: usual range 20-120 mg daily, if dose is above 80 mg it should be given as twice daily

Eradication of H. pylori:

Omeprazole 40 mg once daily or 20 mg twice daily plus clarithromycin 500 mg plus amoxycillin 500 mg or metronidazole 400 mg both two times a day for one week.

Contra-indications

Known hypersensitivity of omeprazole.

Precautions

In the presence of any alarm symptom (eg significant unintentional weight loss, recurrent vomiting. dysphagia, haematemesis of maelena), and when gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with omeprazole is instituted, as treatment may alleviate symptoms and delay diagnosis.

Effect on ability to drive and use machines:

Omeprazole capsule is not likely to affect the ability to drive or use machines.

Preganancy and lactation: As with most drugs, omeprazole should not be given during pregnancy and lactation unless its use is considered essential. Omeprazole capsule given in doses up to 80mg during 24 hours in women in labour has not revealed any adverse reaction of omeprazole on the child. Animal studies have not shown evidence of any hazard from the administration of omeprazole capsule during pregnancy and lactation and there is no evidence of foetal toxicity or teratogenic effect.

Interactions

The absorptions of some drugs might be altered due to the decreased intragastric acidity. Thus it can be predicted that the absorption of ketoconazole will decrease during omeprazole treatment, as it does during treatment with other acid secretion inhibitors or antacids. No interaction with food or concomitantly administered antacids has been found.

As omeprazole is metabolized in the liver through cytochrome P450 2C19 (CYP2C19), it can prolong the elimination of diazepam, warfairn and phenytoin. Monitoring of patients receiving warfarin and phenytoin is recommended and a reduction of dose may be necessary. However, concomitant treatment with omeprazole 20 mg daily did not change the blood concentration of phenytoin in patients on continuous treatment with this drug. Similarly concomitant treatment with omeprazole 20 mg daily did not change coagulation time in patients on continuous treatment with warfarin.

Plasma conecntration of omeprazole and clarithromycin are increased during concomitant administration.

Adverse Reactions

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. The following events have been reported as adverse events in clinical trials or reported from routine use, but in many cases a relationship to treatment with omeprazole has not been established.

Skin–Rarely rash and/or pruritus. In isolated cases photosensitivity, erythema multiforme, alopecia.

Musculoskeletal–In isolated cases arthralgia, muscular weakness and myalgia.

Central and peripheral nervous system: Headache, rarely dizziness, paraesthesisa, somnolence, insomnia and vertigo, In isolated cases reverisble mental confusion, agitation depression and hallucinations, predominantly in severely ill patients.

Gastrointestinal : Diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence. In isolated cases dry mouth, stomatitis and gastrointestinal candidiasis.

Hepatic : Rarely increased liver enzymes in isolated cases encephalopthy in patients with pre-existing severe liver disease, hepatitis with or without jaundice, hepatic failure.

Endocrine : In isolated cases gynaecomastia.

Haematological : In isolated cases leukopenia, thrombocytopenia, agranulocytosis and pancytopenia.

Other : Rarely malaise, hypersensitivity reactions eg urticaria (rarely) and in isolated cases angioedema, fever, bronchospasm, interstitial nephritis, sweating, peripheral oedema, blurred vision, taste disturbance.

Overdosage

Single oral doses of up to 400 mg of omeprazole have not resulted in any severe symptoms. The rate of elimination was unchanged (first order kinetics) with increased doses and no specific treatment has been needed.

Storage

Store in a cool and dry place, Protect from sunlight.

Package quantities :

Xerosec 10 capsule: Box of 3x10x10 mg in blister packs
Xerosec 20 capsule: Box of 10x10x20 mg in blister packs
Xerosec 40 capsule: Box of 5x6x40 mg in blister packs

Do not use later than the date of expiry
Keep all medicines out of the reach of children
To be dispensed only on the prescription of a registered physician.

Manufactured by:

synovia

Synovia Pharma PLC., Station Road, Tongi, Gazipur.
A Subsidiary of BEXIMCO PHARMACEUTICALS LTD.

516152/1

Direction Slip artwork legend

Product Name	:	Xerosec
Code number	:	516152/1
Dimension	:	L 13.30 x W 2.59 inches
Min. size of text	:	8 pt
Used Colors	:	Black C ■ Pantone 186 C ■