Axipron®

Capsules
Omeprazole

DESCRIPTION

The active ingredient in Axipron® capsules is omeprazole a compound that inhibits gastric acid secretion. Each oral capsule contains either 10 mg, or 20 mg of omeprazole in the form of enteric-coated granules.

COMPOSITION

Each capsule contains :
Active ingredient : Omeprazole 10mg or 20mg.
Excipients : sugar spheres, lactose anhydrous, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium lauryl sulfate, sodium phosphate dodecahydrate, diethyl phthalate.

CLINICAL PHARMACOLOGY

Axipron® capsules contain an enteric-coated granule formulation of omeprazole, so that absorption begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels occurring within 0.5 to 3.5 hours. The bioavailability of omeprazole increases slightly upon repeated administration of Axipron®.

Omeprazole is an antisecretory compound, that suppresses gastric acid secretion by inhibition of the H^+/K^+ ATPase enzyme system at the secretory surface of parietal cells. It blocks the final step of acid production irrespective of the stimulus.

After oral administration, onset of antisecretory effect of omeprazole occurs within 1 hour, with the maximum effect within 2 hours. Inhibition of secretion is about 50% of maximum at 24 hours and the duration of inhibition lasts up to 72 hours. The inhibitory effect increases with repeated once-daily dosing, reaching a plateau after four days. When the drug is stopped, secretory activity returns gradually, over 3-5 days.

As do other agents that elevate intragastric pH, omeprazole administered for 14 days in healthy subjects produce a significant reversible increase in the intragastric concentrations of viable bacteria.

Serum gastrin levels increase only during the first 1 to 2 weeks of once-daily administration in parallel with inhibition of acid secretion.

INDICATIONS AND USAGE

Duodenal Ulcer
Axipron® is indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks, but some may require an additional four weeks of therapy.

H. pylori eradication
Axipron®, in combination regimens, is indicated for treatment of patients with H. pylori infection and duodenal ulcer, to reduce the risk of duodenal ulcer recurrence.

Gastric Ulcer
Axipron® is indicated for short-term treatment of active benign gastric ulcer (4-8wks).

Treatment of Gastroesophageal Reflux Disease (GERD)
Symptomatic GERD: Axipron® is indicated for the treatment of heartburn and other symptoms associated with GERD.

Erosive Esophagitis: Axipron® is indicated for the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy.

Maintenance of Healing of Erosive Esophagitis

NSAIDS associated gastric and duodenal ulcers or erosions.

Pathological Hypersecretory Conditions
Indicated for long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis).

CONTRAINDICATIONS

Known hypersensitivity to any component of the formulation.

PRECAUTIONS

Symptomatic response to therapy with omeprazole 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.

Information for Patients : **Axipron® should be taken before meals**. The Axipron® Capsule should not be opened, chewed or crushed, and should be swallowed whole.

Drug Interactions
Omeprazole may theoretically interfere with absorption of drugs where gastric pH is important for their bioavailability (e.g., ketoconazole, ampicillin esters, and iron salts).

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin. Patients should be monitored to adjust the dosage of these drugs when necessary.

Co-administration of omeprazole and clarithromycin has resulted in increases in plasma levels of omeprazole, clarithromycin, and 14-hydroxy-clarithromycin.

Pregnancy Category C
There are no adequate studies in pregnant women. Omeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
It is not known whether omeprazole is excreted in human milk; because of the potential for serious adverse reactions in nursing infants from omeprazole, and because of the potential for tumorigenicity shown for omeprazole in rat carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Axipron® is well tolerated and adverse reactions have generally been mild and reversible. The following events have been reported as adverse events, but in many cases a relationship to treatment with omeprazole has not been established.

1- Diarrhea, constipation, abdominal pain, nausea/vomiting and flatulence.
2- Mild and rarely marked elevations of liver enzymes, or overt hepatitis.
3- Hypersensitivity reactions
4- Chest pain, tachycardia, bradycardia, elevated blood pressure, peripheral edema
5- Hyponatremia, hypoglycemia, weight gain
6- Psychic disturbances (such as depression, aggression) and neurological disturbances
7- Rash and, rarely, cases of severe generalized skin reactions
8- Interstitial nephritis, urinary tract infection, urinary frequency, elevated serum creatinine, proteinuria, hematuria, glycosuria, testicular pain, gynecomastia
9- Rare instances of pancytopenia, agranulocytosis (some fatal), thrombocytopenia, neutropenia, anemia, leucocytosis, and hemolytic anemia have been reported.

OVERDOSAGE

Rare reports have been received of overdosage with omeprazole (320-900mg). Reversible manifestations included confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, and dry mouth. No serious clinical outcome has been reported. No specific antidote for omeprazole overdosage is known. Treatment should be symptomatic and supportive.

DOSAGE AND ADMINISTRATION

No dosage adjustment is necessary in renal , hepatic dysfunction or for the elderly.

Short-Term Treatment of Active Duodenal Ulcer
The adult dose of Axipron® is 20 mg once daily for 4 to 8 weeks.

H. pylori Eradication for the Reduction of the Risk of Duodenal Ulcer Recurrence
Triple Therapy (Axipron®/clarithromycin/amoxicillin) : The recommended adult oral dose of Axipron® is 20 mg twice daily for 10 days. In patients with an ulcer present at the initiation of therapy, an additional 18 days of Axipron® 20 mg once daily is recommended.
Dual Therapy (Axipron®/clarithromycin) : The adult dose of Axipron® is 40 mg once daily for 14 days. In patients with an ulcer present at initiation of therapy, an additional 14 days of Axipron® 20 mg once daily is recommended.

Gastric Ulcer
The recommended adult oral dose is 20 - 40 mg once daily for 4 to 8 weeks.

Gastroesophageal Reflux Disease (GERD)
The adult dose for the treatment of symptomatic GERD with no esophageal lesions is 10 mg or 20 mg daily for up to 4 weeks. The adult dose for erosive esophagitis and accompanying symptoms due to GERD is 20 mg once daily for 4 to 8 weeks. For maintenance of healing of erosive esophagitis, the recommended adult oral dose is 10 mg or 20 mg daily.

NSAIDS associated ulceration
20 mg once daily for 4 weeks followed eventually by another 4 weeks course.

Pathological Hypersecretory Conditions
The recommended adult oral starting dose is 60 mg once daily. Doses should be adjusted to individual patient needs (up to 120 mg three times daily) and should continue for as long as clinically indicated (up to 5 years).

PRESENTATION

Capsules 10 mg - Blister pack of 20's
Capsules 20 mg - Blister pack of 14's

STORAGE CONDITIONS

Store in a dry place below 25°C, protected from light.
Do not refrigerate
Do not use after expiry date.

This is a medicament

-A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of children's reach.

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