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Espra® Capsule

(Esomeprazole)

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COMPOSITION:

Espra 20 mg Capsule:

Each capsule contains:

Enteric coated pellets of Esomeprazole Magnesium trihydrate equivalent to Esomeprazole USP ..... 20 mg.

Product Specs.: USP

Espra 40 mg Capsule:

Each capsule contains:

Enteric coated pellets of Esomeprazole Magnesium trihydrate equivalent to Esomeprazole USP ..... 40 mg.

Product Specs.: USP

THERAPEUTIC INDICATIONS & DOSAGE:

Esomeprazole is indicated for:

Adults: Gastro-esophageal Reflux Disease (GORD):

– **Treatment of erosive reflux esophagitis** 40 mg once daily for 4 weeks. An additional 4 weeks treatment is recommended for patients in whom esophagitis has not healed or who have persistent symptoms.

– Long-term management of patients with healed esophagitis to prevent relapse 20 mg once daily.

– **Symptomatic treatment of gastro-esophageal reflux disease (GORD):**

20 mg once daily in patients without esophagitis. If symptom control has not been achieved after 4 weeks, the patient should be further investigated.

In combination with an appropriate antibacterial therapeutic regimen for the eradication of Helicobacter pylori

– ***Healing of Helicobacter pylori associated duodenal ulcer and***

– **Prevention of relapse of peptic ulcers in patients with *Helicobacter pylori*-associated ulcers.**

20 mg Esomeprazole with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days.

Patients requiring continued NSAID therapy:

– Healing of gastric ulcers associated with NSAID therapy

The recommended dose is 20 mg once daily. The treatment duration is 4-8 weeks.

– Prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk 20 mg once daily.

Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers: 40 mg once daily for 4 weeks after IV induced prevention of rebleeding of peptic ulcers.

Treatment of Zollinger Ellison Syndrome: The recommended initial dosage is Esomeprazole 40 mg twice daily. The dosage should then be individually adjusted and treatment continued as long as clinically indicated.

Special populations:

Impaired renal function: Dose adjustment is not required in patients with impaired renal function. Due to limited experience in patients with severe renal insufficiency, such patients should be treated with caution.

Impaired hepatic function: Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a maximum dose of 20 mg Esomeprazole should not be exceeded.

Elderly: Dose adjustment is not required in the elderly.

Pediatric population: Adolescents from the age of 12 years

Gastroesophageal Reflux Disease (GERD):

– Treatment of erosive reflux esophagitis 40 mg once daily for 4 weeks.

An additional 4 weeks treatment is recommended for patients in whom esophagitis has not healed or who have persistent symptoms.

– **Long-term management of patients with healed esophagitis to prevent relapse:** 20 mg once daily.

– **Symptomatic treatment of gastroesophageal reflux disease (GERD):**

20 mg once daily in patients without esophagitis. If symptom control has not been achieved after 4 weeks, the patient should be further investigated. Once symptoms have resolved, subsequent symptom control can be achieved using 20 mg once daily.

Treatment of duodenal ulcer caused by Helicobacter pylori

Weight	Posology
30 - 40 kg	***Combination with two antibiotics:*** esomeprazole 20 mg, amoxicillin 750 mg and clarithromycin 7.5 mg/kg body weight are all administered together twice daily for one week.
>40 kg	***Combination with two antibiotics:*** esomeprazole 20 mg, amoxicillin 1 g and clarithromycin 500 mg are all administered together twice daily for one week.

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METHOD OF ADMINISTRATION: For oral use. The capsules should be swallowed whole with liquid. The capsules should not be chewed or crushed.

CONTRAINDICATIONS: Hypersensitivity to esomeprazole, substituted benzimidazoles or to any of the excipients. Esomeprazole should not be used concomitantly with nelfinavir.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

In the presence of any alarm symptom and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with Esomeprazole may alleviate symptoms and delay diagnosis.

Helicobacter pylori eradication: When prescribing esomeprazole for eradication of Helicobacter pylori possible drug interactions for all components in the triple therapy should be considered.

Gastrointestinal infections: Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

Absorption of vitamin B_{12}: Esomeprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B_{12} (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients on long-term therapy.

Hypomagnesaemia: Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like esomeprazole for at least three months, and in most cases for a year.

Risk of fracture: Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognized risk factors.

Serious cutaneous adverse reactions (SCARs): Serious cutaneous adverse reactions (SCARs) such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening, have been reported very rarely in association with esomeprazole treatment.

Subacute cutaneous lupus erythematosus (SCLE): Proton pump inhibitors are associated with very infrequent cases of SCLE.

DRUG INTERACTIONS:

Methotrexate: When given together with PPIs, methotrexate levels have been reported to increase in some patients. In high-dose methotrexate administration a temporary withdrawal of esomeprazole may need to be considered.

Tacrolimus: Concomitant administration of esomeprazole has been reported to increase the serum levels of tacrolimus. The absorption of medicinal products such as ketoconazole, itraconazole and erlotinib can decrease and the absorption of digoxin can increase during treatment with esomeprazole. When esomeprazole is combined with drugs metabolized by CYP2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin etc., the plasma concentrations of these drugs may be increased and a dose reduction could be needed.

Warfarin: Monitoring is recommended when initiating and ending concomitant esomeprazole treatment during treatment with warfarin or other coumarin derivatives.

Clopidogrel: As a precaution concomitant use of clopidogrel should be discouraged.

Pregnancy & Lactation:

For esomeprazole, clinical data on exposed pregnancies are insufficient. Caution should be exercised when prescribing to pregnant women. It is not known whether esomeprazole is excreted in human breast milk. Therefore Esomeprazole should not be used during breast-feeding.

Effects on ability to drive and use machines: Esomeprazole has minor influence on the ability to drive and use machines. Adverse reactions such as dizziness (uncommon) and blurred vision (rare) have been reported.

ADVERSE EFFECTS:

Headache, abdominal pain, diarrhea and nausea are among those adverse reactions that have been most commonly reported in clinical trials and also from post-marketing use. In addition, the safety profile is similar for different formulations, treatment indications, age groups and patient populations. No dose-related adverse reactions have been identified.

OVERDOSE:

No specific antidote is known. Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

Pharmacodynamic properties:

Pharmacotherapeutic group: Drugs for acid-related disorders, Proton pump inhibitors. **ATC Code:** A02B C05

Esomeprazole is the S-isomer of omeprazole and reduces gastric acid secretion through a specific targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. Both the R- and S-isomer of omeprazole have similar pharmacodynamic activity.

INSTRUCTIONS:

– Store below 30°C.
– Protect from heat, sunlight & moisture.
– Keep out of the reach of children.
– To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Espra 20 mg Capsule	:	Pack of 2 x 7 capsules.
Espra 40 mg Capsule	:	Pack of 2 x 7 capsules.

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
Plot No. 710, Sundar Industrial Estate, Raiwind Road Lahore, Pakistan.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL

Manufactured for:
CCL Pharmaceuticals (Pvt.) Ltd.
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