

Nexprazole®

(Esomeprazole)

20 mg, 40mg capsule

نیکسپرازول
کپسول
(ایسومپرازول)

DESCRIPTION

Nexprazole (Esomeprazole) capsules are an enteric coated pellet formulation of Esomeprazole Magnesium which is a compound that inhibits gastric acid secretion.

COMPOSITION

Nexprazole (Esomeprazole) capsules are available for oral administration as:

1. Nexprazole.....20mg capsule
Each capsule contains:
Esomeprazole Magnesium Trihydrate (Enteric coated pellets) equivalent to Esomeprazole 20 mg
2. Nexprazole.....40mg capsule
Each capsule contains:
Esomeprazole Magnesium Trihydrate (Enteric coated pellets) equivalent to Esomeprazole 40 mg

INDICATIONS

Nexprazole (Esomeprazole) is indicated for:

1. Gastroesophageal Reflux Disease (GERD)
 - Treatment of erosive reflux esophagitis
 - Long term management of patients with healed esophagitis to prevent relapse.
 - Symptomatic treatment of gastroesophageal reflux disease (GERD) without esophagitis.
2. As a triple therapy (Esomeprazole plus amoxicillin and clarithromycin) for the eradication of *helicobacter pylori*
 - Healing of duodenal ulcer associated with helicobacter pylori infection.
 - Prevention of relapse of peptic ulcers in patients with helicobacter pylori associated ulcers.

Note: In patients who failed the therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

DOSAGE AND ADMINISTRATION

The recommended adult dosages are outlined in the table below. Nexprazole (Esomeprazole) capsules should be swallowed whole and taken at least one hour before meals.

Recommended Adult Dosage Schedule

Indication	Dose	Frequency
I. Gastroesophageal Reflux Disease	20 mg or 40 mg	Once daily 4 to 8 weeks (an additional 4-8 weeks treatment may be considered if symptoms persist or esophagitis does not heal)
Healing of erosive esophagitis		
Maintenance of healing erosive esophagitis	20 mg	Once daily
Symptomatic gastroesophageal reflux disease without esophagitis	20 mg or 40 mg	Once daily for 4 weeks (an additional 4-8 weeks treatment may be considered if symptoms does not resolve completely)
II. H. Pylori eradication to reduce the risk of duodenal ulcer recurrence		
Nexprazole	40 mg	Once daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

For patients with severe liver impairment (Child Pugh Class C), a dose of 20 mg of Nexprazole (Esomeprazole) should not be exceeded.

DOSAGE IN SPECIAL POPULATIONS

Dosage in renal dysfunction: No dosage adjustment is required in patients with renal dysfunction. However, patients with severe renal dysfunction should be treated with caution.
Dosage in hepatic dysfunction: No dosage adjustment is required except in patients with severe liver dysfunction where maximum allowed daily dose is Nexprazole capsules 20 mg.
Dosage in children and adolescents: Since no data is available in children, Nexprazole capsules should not be used in these patients.
Dosage in old patients: No dose adjustment is required.
Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

CONTRA-INDICATIONS

Nexprazole capsules are contraindicated in patients with known hypersensitivity to the drug or any of its constituents.

Pregnancy & Lactation

There are no adequate and well-controlled studies in pregnant women. Esomeprazole should be used during pregnancy only if clearly needed. 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 importance of the drug to the mother due to the potential for serious adverse reactions nursing infants from Esomeprazole.

SIDE EFFECTS

- **Common:** headache, abdominal pain, diarrhoea, flatulence, nausea/vomiting and constipation.
- **Uncommon:** dermatitis, pruritus, urticaria, dizziness, dry mouth and blurred vision.
- **Rare:** Hypersensitivity reactions e. g. angioedema and anaphylactic reaction, increased liver enzymes, Stevens Johnson syndrome, erythema multiforme and myalgia.

DRUG INTERACTIONS

- When combined with Nexprazole capsule, absorption of ketoconazole or itraconazole may be reduced.
- Dose reduction may be required when Nexprazole capsules are co-administered with diazepam, citalopram, imipramine, clomipramine, phenytoin and other drugs which are metabolised by CY2C19. In such cases, serum levels of these drugs should be monitored when Nexprazole capsules are started or discontinued.
- Similarly, serum level monitoring should be done when initiating and ending concomitant treatment with warfarin.

INSTRUCTIONS

- To be sold on the prescription of a registered medical practitioner only.
- Store at room temperature.
- Protect from sunlight and moisture.
- Keep out of the reach of children.

ہدایات:
صرف مشورہ اکثر کے لئے پر فروخت کریں۔
کمرے کے درجہ حرارت پر رکھیں۔
دوا کو روپ اور روش سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔

PRESENTATION

Nexprazole (Esomeprazole) 20 mg capsules in blister pack of 14's (2 x 7's).
Nexprazole (Esomeprazole) 40 mg capsules in blister pack of 14's (2 x 7's).



Manufactured by:
OBS Pakistan (Pvt) Ltd.
C-14, S.I.T.E., Karachi - 75700.

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