

Pylotrip® R

Rabeprazole Sodium+Clarithromycin+Amoxicillin

COMPOSITION

Each **Pylotrip® R** contains one Rabeprazole Sodium 20 mg tablet as Rabeprazole Sodium INN, one Clarithromycin 500 mg tablet as Clarithromycin USP & two Amoxicillin 500 mg capsules as Amoxicillin Trihydrate BP.

INDICATION

Pylotrip® R is indicated for the eradication of *H. pylori* in active chronic gastric, duodenal and gastric ulcers.

DOSAGE & ADMINISTRATION

Each **Pylotrip® R** strip twice daily for 7 days. In case of severity, each **Pylotrip® R** strip twice daily for 14 days.

CONTRAINDICATION

Pylotrip® R is contraindicated in patients with known hypersensitivity to any of its component.

PRECAUTION

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on Amoxicillin therapy. These reactions are more appropriate to occur in individuals with a history of penicillin hypersensitivity. Clarithromycin should not be used in pregnant women except in clinical circumstances where no alternative therapy is appropriate.

ADVERSE REACTION

Adverse reactions which were reported as possibly or probably related to treatment (>3%) in clinical trials when all three components of this therapy were given concomitantly are listed below and divided by body systems.

Digestive system: Nausea, vomiting, diarrhoea, dark stools, dry mouth, glossitis, oral

moniliasis, stomatitis, tongue discoloration ; Musculoskeletal System - myalgia; Nervous System - confusion, headache, dizziness; Skin - skin reactions; Urogenital System - vaginitis, vaginal moniliasis.

DRUG INTERACTION

Clarithromycin use in patients who are receiving theophylline may be associated with increase of serum theophylline concentrations.

There have been reports of interactions of clarithromycin with carbamazepine, cyclosporine, tacrolimus, hexobarbital, phenytoin, alfentanil, disopyramide, lovastatin, bromocriptine, valproate, terfenadine, cisapride, pimozone & astemizole.

USE IN PREGNANCY & LACTATING MOTHER

Pylotrip® R should be used during pregnancy only if the potential benefit justifies the potential risk of the mother. Amoxicillin is excreted in human milk in very small amounts. Because of the potential for serious adverse reactions in nursing infants from **Pylotrip® R** a decision should be made whether to discontinue nursing or to discontinue the drug therapy, taking into account the importance of the therapy to the mother.

GERIATRIC USE

Elderly patients may suffer from asymptomatic renal and hepatic dysfunction. Care should be taken when administering **Pylotrip® R** to these patients.

STORAGE

Store in a cool and dry place, protected from light. Store below 25⁰ C.

HOW SUPPLIED

Box containing 14 **Pylotrip® R** blister strips.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH