

# Pylotrip®

Lansoprazole + Clarithromycin+ Amoxicillin

## COMPOSITION

Each **Pylotrip®** contains one Lansoprazole 30 mg capsule as Lansoprazole USP, one Clarithromycin 500 mg tablet as Clarithromycin USP & two Amoxicillin 500 mg capsules as Amoxicillin Trihydrate BP.

## PHARMACOLOGY

Lansoprazole is a proton-pump inhibitor which inhibits the stomach's production of gastric acids.

Amoxicillin is a penicillin antibiotic. It acts by inhibiting the synthesis of bacterial cell walls. It inhibits cross-linkage between the linear peptidoglycan polymer chains that make up a major component of the cell walls of both Gram-positive and Gram-negative bacteria.

Clarithromycin is a macrolide antibiotic. It prevents bacteria from growing by interfering with their protein synthesis. It binds to the subunit 50S of the bacterial ribosome and thus inhibits the translation of peptides.

## INDICATION

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

## DOSE & ADMINISTRATION

One **Pylotrip®** strip twice daily for 7-14 days or as per the physician's advice.

## USE IN PREGNANCY & LACTATING MOTHER

There were no adequate and well-controlled studies of **Pylotrip®** in pregnant women. **Pylotrip®** 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®** 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®** to these patients.

## CONTRAINDICATION

**Pylotrip®** 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.

## DRUG INTERACTION

Lansoprazole is metabolized through the cytochrome P450 system, specially through the CYP3A and CYP2C19 isozymes. Studies in healthy subjects have shown that Lansoprazole does not have clinically significant interactions with other drugs metabolized by the cytochrome P450 system, such as warfarin, antipyrine, indomethacin, ibuprofen, phenytoin, propranolol, prednisolone, diazepam, clarithromycin or terfenadine. Clarithromycin use in patients who are receiving theophylline may be associated with increase of serum theophylline concentrations.

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

## 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 devided by body systems.

Digestive system: Nausea, vomitng, 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.

## STORAGE

Store in a cool and dry place, protected from light. Store below 30 °C.

## HOW SUPPLIED

Each box contains 14 **Pylotrip®** in blister strips.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH