

Pylotrip®

H. pylori Triple Therapy Kit

COMPOSITION

Pylotrip®: Each blister contains one Lansoprazole INN 30 mg capsule, two Amoxicillin BP 500 mg capsules and one Clarithromycin USP 500 mg tablet.

INDICATION

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

DOSAGE AND ADMINISTRATION

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

CONTRAINDICATION AND PRECAUTION

Pylotrip® is contraindicated in patients with known hypersensitivity to any of its component. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on Amoxicillin therapy. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity.

SIDE EFFECT

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

Lansoprazole is metabolized through the cytochrome P450 system, specially through the CYP3A and CYP2C19 isozymes. Studies 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 in healthy subjects.

Use of Clarithromycin in patients who are receiving theophylline may be associated with an 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.

USE IN PREGNANCY AND LACTATION

There were no adequate and well-controlled studies of this combination (Lansoprazole + Amoxicillin + Clarithromycin) in pregnant women. This combination should be used during pregnancy only if the potential benefit justifies the potential risk of the mother. Clarithromycin should not be used in pregnant women except in clinical circumstances where no alternative therapy is appropriate. Amoxicillin is excreted in human milk in very small amounts. Because of the potential for serious adverse reactions in nursing infants from this combination, 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.

USE IN GERIATRICS

Elderly patients may suffer from asymptomatic renal and hepatic dysfunction. Care should be taken when administering this combination to this patient population.

STORAGE CONDITION

Store below 30°C. Protect from light & moisture. Keep out of children's reach.

HOW SUPPLIED

Pylotrip®: Box containing 7 / 14 blister strips of **Pylotrip®**.

SQUARE