



Pylotrip®

Lansoprazole, Amoxicillin, Clarithromycin
Antiulcerants

COMPOSITION

Pylotrip® : 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, duodenal and gastric 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, alfetanyl, disopyramide, lovastatin, bromocriptine, valproate, terfenadine, cisapride, pimizide & astemizole.

USE IN PREGNANCY AND LACTATION

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. 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 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.

USE IN GERIATRICS

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

STORAGE CONDITION

Store in a cool and dry place.

HOW SUPPLIED

Pylotrip® : Box containing 7 strips of Pylotrip® in blister pack.

