

Summary of Product Characteristics for Pharmaceutical Products

1. NAME OF THE MEDICINAL PRODUCT

ACL KIT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACL Kit strip contains: Two Amoxicillin 1000mg Tablets, Two Clarithromycin 500mg and Two Lansoprazole 30mg capsules

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Amoxicillin Tablets 1000mg – Each film coated tablet contains: Amoxicillin trihydrate BP equivalent to Amoxicillin 1000mg

Clarithromycin Tablets 500mg

Each film coated tablet contains Clarithromycin USP 500mg

Lansoprazole 30mg capsules

Each capsule contains Lansoprazole USP 30mg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ACL Kit is indicated for the eradication of H. Pylori in active chronic gastric, duodenal and gastric ulcers

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 bacteria ribosome and thus inhibits the translation of peptides.

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

4.2 Posology and method of administration

The recommended daily dose is Amoxicillin 1000mg (1 tablet), Clarithromycin 500mg (1 tablet) and Lansoprazole 30mg (1 capsule) to be taken twice a day, in the morning and evening

4.3 Contraindications

ACL Kit is contraindicated in patients with known hypersensitivity to any of its components

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

There have been reports of interaction of Amoxicillin with drugs like Probenecid, tetracyclines, oral anticoagulants, methotrexate.

Lansoprazole is metabolized through the cytochrome P450 system specially through the CYP3A and CYP219 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, indomethacin, ibuprofen, phenytoin. Lansoprazole may interfere with the absorption of drugs like Atazanavir, Ketoconazole, Itraconazole, digoxin. Lansoprazole may increase plasma concentrations of drugs that are metabolized by CYP3A4 like theophylline, tacrolimus

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, phenytoin,

4.6 Pregnancy and lactation

Pregnancy

ACL Kit should be used during pregnancy only if the potential benefit justifies the potential risk to the mother as there are no controlled studies of ACL Kit in pregnant women.

ACL Kit should be used with caution in breast feeding mothers since Amoxicillin is excreted in human milk in very small quantities

Geriatric uses

Elderly patients may suffer from asymptomatic renal and hepatic dysfunction. Care should be taken when administering ACL Kit to these patients.

4.7 Effects on ability to drive and use machines

Side effects are not expected to affect attention or reduce co-ordination but undesirable effects such as dizziness may occur, in which case patients should not drive or use machines.

4.8 Undesirable effects

Digestive system: Nausea, vomiting, diarrhea, dark stools, dry mouth, tongue discolouration, stomatitis

Musculoskeletal system: Myalgia,

Arthralgia Nervous system: Confusion, headache, dizziness Skin: Skin reactions

Urogenital: Vaginitis

Eye: Visual disturbances

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

Symptoms: headache, anorexia, nausea, vomiting, agitation

Treatment: the patient should be urgently transferred to a specialised unit for close monitoring and supportive therapy including, where appropriate, activated charcoal and fluid administration; Liver and renal function should be monitored

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacokinetic properties

Amoxicillin is resistant to inactivation of gastric acid. About 20% is bound to plasma proteins and plasma half-lives of 1 to 1.5 hours have been reported. Amoxicillin is widely distributed at varying concentrations in body tissues and fluids. It crosses the placenta; small amounts are distributed into breast milk.

Clarithromycin is rapidly absorbed from the gastrointestinal tract and undergoes first-pass metabolism; the bioavailability of the parent drug is about 55%. Peak plasma concentrations occur 2 to 3 hours after an oral dose.

Lansoprazole is rapidly absorbed after oral doses and peak plasma concentrations occur about 1.5 to 2 hours. Lansoprazole is about 97% bound to plasma protein. It is extensively metabolized in the liver.

Metabolites are excreted mainly in faeces via the bile; only about 15 to 30% of a dose is excreted in urine

6. PHARMACEUTICAL PARTICULARS

6.1 List of

excipients

Amoxicillin Tablets

1000mg

Microcrystalline cellulose, PVP K 30, IPA, Talcum, Magnesium Stearate, Ac di sol Clarithromycin Tablets 500mg

Lactose, Starch. PVP K 30, Magnesium stearate, Ac di sol, Aerosil, Talcum, Sodium Starch glycolate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from light and moisture Store the tablets in blisters in the provided box or carton. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton or blister card, after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

6.5 Nature and contents of container

Primary Packing:

Tablets are packed in Alu/PVC blisters. 2 tablets of Amoxicillin 1000mg, 2 tablets of Clarithromycin 500mg and 2 capsules of Lansoprazole 30mg

Secondary pack size:

7 blisters in a carton

6.6 Special precautions for disposal

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

7. Marketing Authorisation Holder

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8. Marketing Authorisation Number

H2022/CTD9112/21014

9. Date of first registration / Renewal of the authorization

September 12,2022.

10. Date of revision of the text

07/01/2022