Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Ilapraz 20mg gastro-resistant tablets

2. Qualitative and quantitative composition

Each enteric coated tablet contains:
Ilaprazole 20 mg
Excipients QS
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film Coated Tablet
Pink coloured, round shaped, biconvex, film-coated tablet, plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Ilaprazole is indicated for the treatment of duodenal ulcer and reflux esophagitis.

4.2 Posology and method of administration

Dosage

For the treatment of duodenal ulcer: 10 mg once daily for consecutive 4 weeks.
For the treatment of reflux esophagitis:10 mg once daily for consecutive 4 weeks. If not healed, patients are recommended to take an additional 4-week treatment; if healed but still have persistent symptoms, patients are recommended to adjust the dosage to 5 mg daily for additional 4-week.

Food(before/after)

Ilaprazole should be taken at least 30 minutes before food intake.

4.3 Contraindications

It is contraindicated m patients with known hypersensitivity to any component of the formulation.
It is contraindicated m patients with known hypersensitivity to Ilaprazole and other benzimidazoles. Ilaprazole is contraindicated in pregnancy and breast feeding.

4.4 Special warnings and precautions for use

Pregnancy

This medicine is not recommended for use in pregnant women unless absolutely necessary. All the risks and benefits should be discussed with the doctor before taking this medicine.

Breast-feeding

This medicine is not recommended for use in breastfeeding women unless absolutely necessary. All the risks and benefits should be discussed with the doctor before taking this medicine.

Geriatric Use

Ilaprazole should be used with caution in elderly patients whose capacity of gastric acid secretion and other physiological functions of elderly patient may be reduced generally. The clinical trial results indicate that there is no significant difference in safety and efficacy between elderly patients and general population.

General warnings

Hypomagnesemia

Ilaprazole should be used with caution in patients who are prone to magnesium level imbalances. Regular monitoring of magnesium levels is recommended while using this medicine. Any imbalance of magnesium levels and any symptoms such as seizures, spasms, or arrhythmias should be reported to the doctor on priority. Appropriate corrective measures, dose adjustments, or replacement with a suitable alternative may be required based on the clinical condition.

Pediatric use

Ilaprazole is not recommended for use in children.

4.5 Interaction with other medicinal products and other forms of interaction

Drug-Drug Interactions: ILAPRAZOLE may have interaction with a pain killer (aspirin, naproxen), osteoporosis medication (ibandronate, etidronic acid, alendronic acid, clodronic acid), antifungal drugs such as fluconazole, ketoconazole and itraconazole, iron supplements such as ferrous sulphate anhydrous, anti-sleeping drugs (dextroamphetamine, amphetamine), anti-cancer drugs (dacomitinib) and anti-inflammatory drugs (budesonide).

Food-Drug Interactions: Avoid smoking and alcohol consumption. Alcohol intake leads to increased production of stomach acid, thereby increases acidity and heartburn.

Drug-Disease Interactions: ILAPRAZOLE may have interactions with kidney disease, liver disease, bone fractures, and hypomagnesemia.

4.6 Pregnancy and Lactation

Pregnancy

ILAPRAZOLE is not recommended for use in pregnant women unless absolutely necessary. All the risks and benefits should be discussed with the doctor before taking this medicine.

Lactation

ILAPRAZOLE is not recommended for use in breastfeeding women unless absolutely necessary.

4.7 Effects on ability to drive and use machines

There is no interaction between driving and consuming this drug. So, dose alteration

4.8 Undesirable effects

Diarrhea, headache and dizziness, abnormal hepatic function: alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevation, rash, urticaria, low back pain, abdominal distension, dry mouth and bitter taste.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

If over-exposure occurs accidentally, symptomatic and supportive treatment should be carried out immediately.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ilaprazole is an irreversible proton pump inhibitor, which belongs to the benzimidazole. After oral administration, Ilaprazole selectively enters the gastric parietal cells and is converted to the active metabolite sulfonamide which will react with the sulphydryl on the H+ /K+ -ATPase to form the disulfide bond and inhibits the H+/K +-ATPase to further play the role of gastric acid inhibition.

5.2 Pharmacokinetic properties

After oral administration, the drug is rapidly absorbed. The drug is extensively metabolized to Ilaprazole sulfone via the CYP450 enzymes. The drug is primarily excreted in the urine as drug metabolites and unchanged drug to some extent. The pharmacokinetics results showed that 5 mg, 10 mg, 20 mg single oral dose of the product was given to the subjects in the morning before meals, as a result, Cmax and AUC increased with the dose increasing, and the process of Ilaprazole in the human body basically complied with linear dynamic characteristics. No prototype drug was detected in the urine of subjects.

The subjects were orally given the products for consecutive 7 days with 10 mg daily. It is indicated that pharmacokinetic parameters of llaprazole after multiple dose administration have no significant change compared to single dose administration, and there is no accumulation in vivo. After oral administration for consecutive more than 4 days, the concentration of llaprazole in plasma will reach a steady state. Compared with fasting, feeding will delay the T max of plasma

5.3 Preclinical safety data

The toxicological effects of this product have not been thoroughly studied.

Acute toxicity, Oral (Category 4), H302

Acute aquatic toxicity (Category 1), H400

Chronic aquatic toxicity (Category 1), H410

6. Pharmaceutical Particulars

6.1 List of Excipients

Tablet core

Magnesium Stearate
Purified Talc
Sodium Stearyl Fumarate
Cross Povidone (XL 10)
Colloidal Anhydrous Silica
Polacrilin Potassium
Light Magnesium Oxide
Microcrystalline Cellulose
Mannitol
Hydroxypropyl cellulose
Sodium Carbonate

Seal coating
Hypromellose (E-15)
Purified Talc
Colour: Titanium Dioxide
Iso Propyl Alcohol
Dichloromethane
Light Magnesium Oxide
Enteric coating
Hypromellose Phthalate (HP-55)
Polysorbate 80 (Tween-80)
Colour: Yellow oxide of Iron
Iso Propyl Alcohol
Dichloromethane
Dibutyl Phthalate

6.2 Incompatibilities
Not applicable.
6.3 Shelf-Life
3 years
6.4 Special Precautions for storage
Store at a temperature not exceeding 30oC. Protect from light.
6.5 Nature and Content of container
Ten tablets are packed in an Alu - Alu blister and 1 such blister is packed in a carton along with package insert.
6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder
GALAXY PHARMACEUTICAL LTD.
1st Floor, Doctors Park, 3rd Parkland Avenue,
P.O.BOX 39107 - 00623,
Nairobi (Kenya).
8. Marketing Authorization Number
CTD9288
9. Date of first authorization/renewal of the authorization
18/04/2024

10. Date of revision of the text
05/05/2025