Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Ilapraz 20mg Tablet

2. Qualitative and quantitative composition

Each enteric coated tablet contains: Ilaprazole 20 mg

Excipient with known effect

Mannitol

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Enteric coated tablet Light Yellow coloured, round biconvex, plain on both side, enteric coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

Ilaprazole is useful in treating the following;

- Gastroesophageal Reflux Disease
- Zollinger-Ellison Syndrome
- Duodenal Ulcer
- Helicobacter Pylori Infection
- Erosive Esophagitis

4.2 Posology and method of administration

Posology

The recommended adult dosage of Ilaprazole is 5-20 mg/day.

Method of administration

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

4.3 Contraindications

It is contraindicated in;

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pregnancy.
- Breast feeding.

4.4 Special warnings and precautions for use

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

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

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, palindromic acid, colonic acid), antifungal drugs (fluconazole), iron supplements (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 (low levels of magnesium)

4.6 Pregnancy and Lactation

Currently, no clinical data is available for pregnant and lactating women. It is not recommended for pregnant and lactating women to use this product. If there is a clear need to a nursing woman, breast-feeding should cease during the treatment.
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.
Ilaprazole is not recommended for use in children unless prescribed by a paediatrician

4.7 Effects on ability to drive and use machines

There is no interaction between driving and consuming this drug. So, dose alteration is not needed.

4.8 Undesirable effects

Side effects of Ilaprazole are as follows:

- Abdominal Pain
- Fever
- Joint Pain
- Sore Throat
- Loss Of Appetite
- Constipation
- Diarrhoea
- Difficulty In Breathing
- Dizziness
- Muscle Pain
- Drowsiness
- Back pain

Reporting of suspected adverse reactions: 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

Experience to date with deliberate or accidental overdose is limited.
As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC CODE A02BC11

Mode of Action

This medication belongs to the class of proton-pump inhibitor which works by suppressing the secretion of gastric acid by specifically inhibiting the H+/K+-ATPase enzyme in the gastric parietal cells. Inhibition of this enzyme and blocking of the proton pump blocks the acid formation pathway, reducing gastric acid production.

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.

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

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
Hypromellose (E-15)
Titanium Dioxide
Iso Propyl Alcohol
Dichloromethane
Hypromellose Phthalate (HP-55)
Polysorbate 80 (Tween-80)
Yellow oxide of Iron Iso Propyl Alcohol
Dichloromethane
Dibutyl Phthalate

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

36 months

6.4 Special Precautions for storage

Store at a temperature not exceeding 30C. Protect from light.

6.5 Nature and Content of container

10 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

Not Applicable

7. Marketing Authorization Holder

GALAXY PHARMACEUTICAL LTD

8. Marketing Authorization Number

CTD9288

9. Date of first authorization/renewal of the authorization

18/04/2024

10. Date of revision of the text

09/05/2025