**Summary of Product Characteristics of pharmaceutical product**

## 1. Name of the medicinal product

Ilaprazole Gastro-resistant Tablets (Ilapraz-20)

## 2. Qualitative and quantitative composition

Each enteric coated tablet contains:

Ilaprazole……20 mg

Excipient (s) with known effect:

Mannitol

For 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 helpful in treating the below provided problems:

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

### 4.2 Posology and method of administration

Dosage

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

Food(before/after)

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

### 4.3 Contraindications

- 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

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.

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 unless prescribed by a pediatrician.

## 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 (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 Fertility, 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.

Breast-feeding

ILAPRAZOLE 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.

## 4.7 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
- Rash
- Back Pain

**Reporting of suspected adverse reactions**

Reporting of suspected adverse reactions: Healthcare professionals are requested 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

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

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 contents 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**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. Marketing authorisation holder**

GALAXY PHARMACEUTICAL LTD.

1st Floor, Doctors Park, 3rd Parkland Avenue, P.O.BOX 39107 - 00623,

Nairobi (Kenya).

**8. Marketing Authorisation Number**

H2024/CTD9288/21426

**9. Date of First (Registration) / Renewal of the (Registration)**

22/5/2024

**10. Date of Revision of the Text:**

22/5/2024