**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. Name of the Medicinal Product:

RABICOR PLUS CAPSULES

[Rabeprazole Sodium (Enteric Coated) and Itopride Hydrochloride (Sustain Release) Capsules.]

## 2. Quality and Quantitative Composition

Each hard gelatin capsule contains:

Rabeprazole Sodium 20 mg

(As enteric coated pellets)

Itopride Hydrochloride 150 mg

(As sustained release pellets) Excipients q.s.

Colour: Red Oxide of Iron and Titanium Dioxide Each hard gelatin capsule contains approved colours.

## 3. Pharmaceutical Form:

"0" Size Hard Gelatin Capsules with Black Colored Cap and Red Colored Body containing Brick Red and White colored pellets.

## 4. Clinical Particulars

### 4.1 Therapeutic indications:

RABICOR PLUS CAPSULE is indicated for relief from:

• Symptoms of dysmotility associated with acid peptic disorders.

• GERD

• Dyspepsia

• Chronic gastritis

**4.2 Posology and method of administration** :

One capsule once a day or as directed by the Physician. Swallow the medication whole. Do not chew, divide or crush the capsules.

**4.3 Contraindications**

Hypersensitivity to any component of the formulation. ltopride should not be used in patients in whom an increase in gastrointestinal motility could be harmful, e.g. gastrointestinal hemorrhage, mechanical obstruction or perforation.

**4.4 Special warning and precautions for use:**

Symptomatic response to the therapy with rabeprazole does not preclude the presence of gastric malignancy. Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis - related fractures of the hip, wrist or spine. The risk of fracture was increased in patients who received high dose, defined as multiple daily doses, and long term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis related fractures should be managed according to the established treatment guidelines.
Pediatric Use: The safety and efficacy of rabeprazole and itopride in patients below 12 years of age have not been established.

**4.5 Drug Interaction:**

There have been reports of increased INR and prothrombin time in patients receiving rabeprazole and warfarin concomitantly which may lead to abnormal bleeding and even death. In normal subjects co-administration of rabeprazole resulted in decrease in the bioavailability of ketoconazole and increases AUG & Cmax for digoxin. Therefore, patients may need to be monitored when such drugs are taken concomitantly with rabeprazole. Concomitant use of atazanavir and proton pump inhibitors is not recommended as it is expected to substantially decrease atazanavir plasma concentration and thereby reduce its therapeutic effect. Combined administration consisting of rabeprazole, amoxicillin and clarithromycin resulted in increase in plasma concentration of rabeprazole and 14-hydroxyclarithromycin. Anticholinergic agents may reduce the action of itopride.

**4.6 Pregnancy and lactation:**

Pregnancy category B There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Since many drugs are excreted in milk, and because of the potential for adverse reactions to the nursing infants from rabeprazole, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. ltopride is excreted with the breast milk in lactating rats. Treatment with itopride should be avoided during breast-feeding.

**4.7 Effect on ability to drive and use machines**

Not Known.

**4.8 Undesirable effects:**

Adverse events with rabeprazole are mild to moderate in intensity and included malaise, diarrhoea, nausea, skin eruptions, headache and dizziness. Symptoms such as diarrhoea, constipation, abdominal pain, increased saliva, headache, irritated feeling, sleep disorder, dizziness, increased prolactin, leucocytopenia, chest or back pain, fatigue, increase in BUN and creatinine may occur infrequently with itopride. Allergic reactions have rarely been reported.

**4.9 Overdose:**

There has been no experience with large overdoses with rabeprazole. There were no clinical signs or symptoms associated with any reported overdose. No specific antidote for rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive. There have as yet been no reports of itopride overdose in humans. The oral single dose LD50 was > 2000 mg/kg in mice and rats and about 600 mg/kg in dogs. In case of excessive overdosage the usual measures of gastric lavage and symptomatic therapy should be applied. ltopride does not cause QT prolongation.

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: Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

## 5.PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Rabeprazole prevents the production of acid in the stomach. It reduces symptoms and prevents injury to the esophagus or stomach in patients with gastroesophageal reflux disease (GERD) or ulcers. Rabeprazole is also useful in conditions that produce too much stomach acid such as Zollinger-Ellison syndrome. Rabeprazole may also be used with antibiotics to get rid of bacteria that are associated with some ulcers. Rabeprazole is a selective and irreversible proton pump inhibitor, suppresses gastric acid secretion by specific inhibition of the H+, K+ -ATPase, which is found at the secretory surface of parietal cells. In doing so, it inhibits the final transport of hydrogen ions (via exchange with potassium ions) into the gastric lumen.

Itopride has three way action. It inhibits the dopamine D2 receptor at the parasympathetic nerve ends. It increases the release of acetycholine and decreases the metabolism of acetylcholine by inhibiting the enzyme acetylcholinesterase (AChE). By maintaining higher acetylcholine levels, itopride increases the oesophageal and gastrointestinal peristalsis, increases the lower oesophageal sphincter pressure, stimulates gastric motility, accelerates gastric emptying and improves gastro-duodenal coordination. Itopride exerts anti-emetic actions because of its dopamine D2 receptor antagonistic action at CTZ.

### 5.2 Pharmacokinetic properties

For Rabeprazole Sodium

Absorption: Rabeprazole sodium is well absorbed after oral administration and its bioavailability is about 50% since it undergoes first pass metabolism.

Distribution: It is widely distributed in the body in protein bound form. Metabolism: Rabeprazole sodium is extensively metabolised in the liver. Excretion:

It is excreted mainly in the urine and small amount in faeces. For Itopride Hydrochloride

Absorption: it is orally well absorbed after oral administration. Metabolism: Itopride undergoes extensive hepatic metabolism

### 5.3 Preclinical safety Data:

None

## 6. Pharmaceutical Particulars:

### 6.1 List of excipients:

Excipients are not included in this formulation.

**6.2 Incompatibilities**: None

**6.3 Shelf life**: 24 Months

**6.4 Special precautions for storage**:

Store below 30$^{o}$C. Protect from light.

### 6.5 Nature and contents of container:

10 capsules to be packed in Alu- Alu Blister. Such 3 blisters to be packed in carton along with pack insert.

### 6.6 Special precautions for disposal

None

## 7. Marketing Authorization Holder:

**Signature Healthcare Limited**

Cape Business Park,

Along Thika Super Highway,

P.O. Box 66172-00800,

Nairobi, KENYA.

**8. Marketing Authorization Numbers:**
**H2025/CTD9677/20706**

**9. Date of first authorization/renewal of the authorization: ---**

**10. Date of revision of the text:**

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