## SUMMARY OF PRODUCT CHARACTERISTICS

**1. NAME OF THE MEDICINAL PRODUCT**: **PRAZOMED- D**
**(Rabeprazole and Domperidone Capsules)**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each Hard Gelatin Capsule Contains:
Rabeprazole Sodium BP 20mg
(As enteric coated pellets)
Domperidone BP 30mg
(As substained release pellets)
Approved colour used in hard gelatin capsule shell.

**3. PHARMACEUTICAL FORM**

Capsules

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Rabeprazole 20mg Gastro-resistant Tablets are indicated for the treatment of:

• Active duodenal ulcer

• Active benign gastric ulcer

• Symptomatic erosive or ulcerative gastro-oesophageal reflux disease (GORD).

• Gastro-Oesophageal Reflux Disease Long-term Management (GORD Maintenance)

• Symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD)

• Zollinger-Ellison Syndrome

Domepridone is indicated for the relief of the symptoms of nausea and vomiting.

**4.2 Posology and method of administration**
**Rabeprazole:**

Posology

*Adults/elderly*

*Active Duodenal Ulcer and Active Benign Gastric Ulcer:* The recommended oral dose for both active duodenal ulcer and active benign gastric ulcer is 20 mg to be taken once daily in the morning.

Most patients with active duodenal ulcer heal within four weeks. However a few patients may require an additional four weeks of therapy to achieve healing. Most patients with active benign gastric ulcer heal within six weeks. However again a few patients may require an additional six weeks of therapy to achieve healing.

*Erosive or Ulcerative Gastro-Oesophageal Reflux Disease (GORD):* The recommended oral dose for this condition is 20 mg to be taken once daily for four to eight weeks.

*Gastro-Oesophageal Reflux Disease Long-term Management (GORD Maintenance)*: For long-term management, a maintenance dose of Rabeprazole 20 mg or 10 mg once daily can be used depending upon patient response.

*Symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD):* 10 mg once daily in patients without oesophagitis. If symptom control has not been achieved during four weeks, the patient should be further investigated. Once symptoms have resolved, subsequent symptom control can be achieved using an on-demand regimen taking 10 mg once daily when needed.

**Domperidone:**

Domperidone should be used at the lowest effective dose for the shortest duration necessary to control nausea and vomiting.

It is recommended to take oral domperidone tablets before meals. If taken after meals, absorption of the drug is somewhat delayed.

Patients should try to take each dose at scheduled time. If a scheduled dose is missed, the missed dose should be omitted and the usual dosing schedule resumed. The dose should not be doubled to make up for a missed dose.

Usually, the maximum treatment duration should not exceed one week.

See section 4.4. for further information.

*Adults and adolescents (12 years of age and older and weighing 35 kg or more)*

One 10mg tablet up to three times per day with maximum dose of 30 mg per day.

Hepatic Impairment

Domperidone is contraindicated in moderate or severe hepatic impairment (see section 4.3). Dose modification in mild hepatic impairment is however not needed (see section 5.2).

Renal Impairment

Since the elimination half-life of domperidone is prolonged in severe renal impairment, on repeated administration, the dosing frequency of Domperidone

tablets should be reduced to once or twice daily depending on the severity of the impairment, and the dose may need to be reduced. Such patients on prolonged therapy should be reviewed regularly

## 4.3 Contraindications

**Rabeprazole**

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

**Domperidone**

Domperidone is contraindicated in the following situations:
• In patients with moderate or severe hepatic impairment
• In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure.
• Co-administration with QT-prolonging drugs, at the exception of apomorphine
• Co-administration with potent CY3A4 inhibitors (regardless of their QT prolonging effects)

## 4.4 Special warnings and precautions for use

**Rabeprazole**

Symptomatic response to therapy with rabeprazole sodium does not preclude the presence of gastric or oesophageal malignancy, therefore the possibility of malignancy should be excluded prior to commencing treatment with Rabeprazole.Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance.

**Domperidone**

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Neurological side effects are rare (see "Undesirable effects" section). Since metabolic functions and the blood-brain barrier are not fully developed in the first months of life the risk of neurological side effects is higher in young children.Overdosing may cause extrapyramidal symptoms in children, but other causes should be taken into consideration.

## 4.5 Interaction with other medicinal products and other forms of interaction

Warfarin: Increased INR and prothrombin time in patients receiving PPIs, including rabeprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death.
Methotrexate: Concomitant use of rabeprazole with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its

metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities. No formal drug interaction studies of methotrexate with PPIs have been conducted

**Domperidone**

The main metabolic pathway of domperidone is through CYP3A4. *In vitro* data suggest that the concomitant use of drugs that significantly inhibit this enzyme may result in increased plasma levels of domperidone.
Increased risk of occurrence of QT-interval prolongation, due to pharmacodynamic and/or pharmacokinetic interactions.

## 4.6 Fertility, pregnancy and lactation

**Pregnancy**

There are no data on the safety of rabeprazole in human pregnancy.
Reproduction studies performed in rats and rabbits have revealed no evidence of impaired fertility or harm to the foetus due to rabeprazole sodium, although low foeto-placental transfer occurs in rats. Rabeprazole is contraindicated during pregnancy.
There are limited post-marketing data on the use of domperidone in pregnant women. A study in rats has shown reproductive toxicity at a high, maternally toxic dose.

**Lactation**

It is not known whether rabeprazole sodium is excreted in human breast milk. No studies in lactating women have been performed. Rabeprazole sodium is however excreted in rat mammary secretions. Therefore, Rabeprazole must not be used during breast feeding.
Domperidone is excreted in human milk and breast-fed infants receive less than 0.1% of the maternal weight-adjusted dose. Occurrence of adverse effects, in particular cardiac effects cannot be excluded after exposure via breast milk.

## 4.7 Effects on ability to drive and use machines:

Based on the pharmacodynamic properties and the adverse events profile, it is unlikely that Rabeprazole 20mg + domperidone 30mg Gastro-resistant capsules would cause an impairment of driving performance or compromise the ability to use machinery. If however, alertness is impaired due to somnolence, it is recommended that driving and operating complex machinery be avoided.

## 4.8 Overdose

Experience to date with deliberate or accidental overdose is limited. The maximum established exposure has not exceeded 60 mg twice daily, or 160 mg once daily. Effects are generally minimal, representative of the known adverse event profile and reversible without further medical intervention. No specific antidote is known. Rabeprazole sodium is extensively protein bound and is,

therefore, not dialysable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

*Symptoms*
Overdose has been reported primarily in infants and children. Symptoms of overdosage may include agitation, altered consciousness, convulsions, disorientation, somnolence and extrapyramidal reactions.

*Treatment*
There is no specific antidote to domperidone, but in the event of overdose, standard symptomatic treatment should be given immediately. Gastric lavage as well as the administration of activated charcoal, may be useful. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Close medical supervision and supportive therapy is recommended.

Anticholinergic, anti-parkinson drugs may be helpful in controlling the extrapyramidal reactions.

**Reporting of suspected adverse reactions:**
Healthcare professionals are requested to report any suspected adverse reactions via the national Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alimentary tract and metabolism. Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD),PPIs. ATC code: A02B C04

**Mechanism of Action:**

***Rabeprazole***

Rabeprazole sodium belongs to the class of anti-secretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or $H_2$ histamine antagonist properties but suppress gastric acid secretion by the specific inhibition of the $H^+/K^+$-ATPase enzyme (the acid or proton pump). The effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

Domperidone is a dopamine antagonist with anti-emetic properties domperidone does not readily cross the blood-brain barrier. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema.

## 5.2 Pharmacokinetic properties

***Rabeprazole***

Rabeprazole is an enteric-coated pellet formulation of rabeprazole sodium. This presentation is necessary because rabeprazole is acid-labile. Absorption of rabeprazole therefore begins only after the pellet leaves the stomach. Absorption is rapid, with peak plasma levels of rabeprazole occurring approximately 3.5 hours after a 20 mg dose.

***Domperidone***

Domperidone is rapidly absorbed after oral administration with peak plasma concentrations occurring at approximately 1 hr after dosing.. The Cmax and AUC values of domperidone increased proportionally with dose in the 10 mg to 20 mg dose range. A 2- to 3-fold accumulation of domperidone AUC was observed with repeated four times daily (every 5 hr) dosing of domperidone for 4 days.

## 5.3 Preclinical safety data

Non-clinical effects were observed only at exposures sufficiently in excess of the maximum human exposure that make concerns for human safety negligible in respect of animal data.

# 6.0 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

| SR. NO. | INGREDIENTS | SPECIFICATION |
|---|---|---|
| 1 | Microcrystalline Cellulose | BP |
| 2 | Lactose | BP |
| 3 | HPMC | BP |
| 4 | Citric acid | BP |
| 5 | Povidone 30 | BP |
| 6 | Purified water | BP |
| 7 | Magnesium Stearate | BP |
| 8 | Purified Talc | BP |

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

36 months from date of manufacturing.

## 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

**6.5 Nature and contents of container**

10 tablets are packed in one Alu-Alu blister such 3 blister are packed in a carton with insert.

**6.6 Special precautions for disposal and other handling**

This medicinal product does not require any special storage conditions.

**7. MARKETING AUTHORIZATION HOLDER**

**MANUFACTURED BY:**
**BRUSSELS LABORATORIES PVT. LTD.,**
33, CHANGODAR IND. ESTATE,
SARKHEJ –BAVLA ROAD,
CHANGODAR - 382210,
DIST – AHMEDABAD, GUJARAT, INDIA.

**MARKETED BY:**
**PROMED PHARMACEUTICALS LTD.**
P.O.BOX 22953-00100
NAIROBI, , KENYA

**8. MARKETING AUTHORIZATION NUMBER**
H2026/CTD9994/22296

**9. DATE OF REGISTRATION/RENEWAL**
February 18 2026

**10. DATE OF REVISION OF THE TEXT**
February 18 2026