SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name : **Regurg Tablet**
1.2 Generic Name : Metoclopramide Tablets BP 10mg
1.3 Strength : Metoclopramide Hydrochloride BP 10mg/Tab.
1.4 Pharmaceutical Form : Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each uncoated tablet contains:
Metoclopramide Hydrochloride BP (anhydrous) 10mg

3. PHARMACEUTICAL FORM

Tablet
White coloured round-shaped, biconvex uncoated tablet having central breakline on one face of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Regurg Tablet is indicated in the symptomatic treatment of nausea and vomiting, including that associated with acute migraine, delayed (but not acute) chemotherapy-induced nausea and vomiting, radiotherapy-induced nausea and vomiting, prevention of postoperative nausea and vomiting, Hiccup in palliative care Nausea, and vomiting in palliative care.

4.2 Posology and method of administration

- **Symptomatic treatment of nausea and vomiting including that associated with acute migraine, delayed (but not acute) chemotherapy-induced nausea and vomiting, Radiotherapy-induced nausea and vomiting, prevention of postoperative nausea and vomiting:**
  Adult (body-weight 60 kg and above): 10 mg up to 3 times a day.
- **Hiccup in palliative care:**
  Adult: 10 mg every 6–8 hours.
- **Nausea and vomiting in palliative care:**
  Adult: 10 mg 3 times a day.

4.3 Contraindications

3–4 days after gastrointestinal surgery, gastrointestinal hemorrhage, gastrointestinal obstruction & gastrointestinal perforation, phaeochromocytoma.

4.4 Special warnings and special precautions for use

Asthma, atopic allergy, bradycardia, cardiac conduction disturbances children elderly epilepsy may mask underlying disorders such as cerebral irritation. Parkinson's disease. Uncorrected electrolyte imbalance in young adults (15–19 years old).

MHRA/CHM ADVICE—Metoclopramide: Risk of Neurological:
Adverse Effects—Restricted Dose and Duration of Use:

The benefits and risks of metoclopramide have been reviewed by the European Medicines Agency's Committee on Medicinal Products for Human Use, which concluded that the risk of neurological effects such as extrapyramidal disorders and tardive dyskinesia outweigh the benefits in long-term or high-dose treatment. To help minimize the risk of potentially serious neurological adverse effects, the following restrictions to indications, dose, and duration of use have been made.

In adults over 18 years, metoclopramide should only be used for prevention of postoperative nausea and vomiting, radiotherapy-induced nausea and vomiting, delayed (but not acute) chemotherapy-induced nausea and vomiting, and symptomatic treatment of nausea and vomiting, including that associated with acute migraine (where it may also be used to improve absorption of oral analgesics).

Metoclopramide should only be prescribed for short-term use (up to 5 days); the Usual dose is 10 mg, repeated up to 3 times daily; This advice does not apply to unlicensed uses of metoclopramide (e.g. palliative care).

Hepatic Impairment: Dose adjustments Reduce dose.

Renal Impairment: Dose adjustments Avoid or use small dose in severe impairment; increased risk of extrapyramidal reactions.

4.5 Interaction with other FPPs and Other forms of Interaction

Metoclopramide increases the rate of absorption of Paracetamol. It increases the rate of absorption of Aspirin (enhanced effect); the effects of Metoclopramide on gastrointestinal activity antagonized by analgesic. Increased risk of extrapyramidal side-effects when Amantadine, Tetrabenazine given with Metoclopramide. Antimuscarinics antagonize the effects of Metoclopramide on gastrointestinal activity. Hypoprolactinaemic effect of Bromocriptine antagonized by Metoclopramide. Hypoprolactinaemic effect of Cabergoline antagonized by Metoclopramide. Metoclopramide increases the plasma concentration of Ciclosporin while it decreases the plasma concentration of Atovaquone.

4.6 Pregnancy and lactation

Metoclopramide has long been used in all stages of pregnancy with no evidence of harm to the mother or unborn baby. Metoclopramide is excreted in small amounts in breast milk. Women who are nursing newborn babies should avoid it.

4.7 Effects on ability to drive and use machines

Metoclopramide may cause drowsiness, dizziness, dyskinesia, and dystonias which could affect the vision and also interfere with the ability to drive and operate machinery.

4.8 Undesirable effects

GENERAL SIDE-EFFECTS: Common or very common: Asthenia, depression, diarrhea, drowsiness, hypotension, menstrual cycle irregularities, movement disorders, parkinsonism. **Uncommon:** Arrhythmias, hallucination, hyperprolactinemia. level of consciousness decreased. **Rare or very rare:** Confusion, galactorrhoea, seizure. **Frequency not known:** Atrioventricular block, blood disorders, cardiac arrest, gynaecomastia, hypertension, neuroleptic malignant syndrome, QT interval prolongation, shock, syncope.

SIDE EFFECTS, FURTHER INFORMATION: Metoclopramide can induce acute dystonic reactions involving facial and skeletal muscle spasms and oculogyric crises. These dystonic effects are more common in the young (especially girls and young women) and the very old; they usually occur shortly after starting treatment with metoclopramide and subside within 24 hours of stopping it. Injection of an antiparkinsonian drug such as procyclidine will abort dystonic attacks.

4.9 Overdose & Treatment

Extrapyramidal disorders, drowsiness, decreased level of consciousness, confusion, hallucination, and cardio-respiratory arrest may occur. In case of extrapyramidal symptoms related or not to overdose, the treatment is only symptomatic (benzodiazepines in children and/or anticholinergic antiparkinsonian medicinal products in adults). Symptomatic treatment and continuous monitoring of the cardiovascular and respiratory functions should be carried out according to clinical status.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dopamine receptor antagonist, antiemetic.

Mechanism of action:

Metoclopramide hydrochloride is an anti-emetic and accelerator of gastric emptying. It is a dopamine D2 receptor antagonist with a dual action, i.e. it sedates the chemo-receptor trigger zone (CTZ) and inhibits vomiting, including induced by copper sulphate (peripheral action).

5.2 Pharmacokinetic properties

Metoclopramide is rapidly and almost completely absorbed from the GI tract (oral); peak plasma concentrations after 1-2 hours. It is widely distributed; crosses the blood-brain barrier and placenta; enters breast milk. It shows extensively hepatic metabolism. Excretion of Metoclopramide via urine (as unchanged drug, sulphate or glucuronide conjugates and metabolites), faeces; 4-6 hours (terminal elimination half-life).

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Maize Starch	BP
02.	Calcium Hydrogen Phosphate	BP
03.	Microcrystalline Cellulose	BP
04.	Sod. Methyl Hydroxybenzoate	BP
05.	Sod. Propyl Hydroxybenzoate	BP
06.	Purified Talc	BP
07.	Magnesium Stearate	BP
08.	Sodium Starch Glycolate	BP
09.	Sodium Lauryl Sulfate	BP
10.	Croscarmellose Sodium	BP
11.	Colloidal Anhydrous Silica	BP
12.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep away from moisture. Keep out of reach of children.

6.5 Nature and contents of container

i. 10 blisters of 10 tablets packed in an inner carton. (10'sx10)
ii. 10 blisters of 20 (i.e.10x2) tablets packed in an inner carton (20's x10).

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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Country	:	INDIA

8. MARKETING AUTHORISATION NUMBER

AMD/12/2002 & AMD/6/2002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

a) Date of first authorization: 21/01/1989.

b) Date of latest renewal: 01/01/2018.

10. DATE OF REVISION OF THE TEXT

01/01/2023