Summary of Product Characteristics

1 Name of Medicinal Product

Regulix 80
INN: Drotaverine Hydrochloride Tablets 80 mg

2 Qualitative and Quantitative Composition

Each Film Coated Tablet Contains:
- Drotaverine HCl (In House) (80 mg)
- Tartrazine (In House)

Excipient know effect Each tablet contain : lactose

3 Pharmaceutical form

Oral Tablets

Yellow colored circular, biconvex film coated tablets with embossed as '80' on one side and plain on other side

4 Clinical Particulars

4.1 Therapeutic Indications

- Primary & Secondary Dysmenorrhoea
- Post Surgical Uterine Spasm
- Uterine irritability and pain associated with IUCD insertion, dilatation and curettage, pelvic inflammatory disease or HSG
- Gastro-intestinal colic, renal colic, biliary colic

4.2 Posology and Method of administration:

Route of Administration : Oral route administration

Method of administration and posology

Adult: 1 to 2 tablets, three times a day.

Children (over 6 years): ½ or 1 tablet, 1 - 2 times daily.

Children (1-6 years): ¼ or ½ tablet, 1-2 times daily.

4.3 Contraindications

- Hypersensitivity to mefenamic acid or drotaverine
- Pre-existing renal disease
- Rhinitis, urticaria, asthma, or allergic reactions to aspirin or other anti-inflammatory agents
- Ulceration or chronic inflammation of the upper or lower GI tract Porphyria
- Neonates.

4.4 Special Warning and Precautions for use:

Use with caution in patients with renal/hepatic/ cardiac dysfunction, and elderly people. Reproduction toxicology studies conducted in animals shows no teratogenic and embrytoxic effects. Drotaverine has been widely in labour induction in pregnant women. According to data from surveillance of congenital anomalies in Hungary (1980 - 1991), whose analysis focuses on 30,663 pregnant women, no detectable teratogenic effect was observed during the administration of drotaverine. However, the use of Drotaverine should be avoided during pregnancy and lactation.

This medicine contains lactose

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

4.5 Interaction with other medicinal products and other forms of interaction

Drotaverine intensifies the effect of other spasmolytics, hypotension caused by tricyclic antidepressants, quinidine and novocainamid. Reduces spasmogenic morphine activity, antiparkinsonian levodopa activity. When administered together with levodopa it decreases its antiparkinsonian effect, rigidity and tremor increase. Concurrent use of analgesics, antimuscarinics or benzodiazepines has additive beneficial effects.

4.6 Pregnancy and Lactation

Pregnancy: There is no evidence of teratogenicity and embryotoxicity from retrospective human and animal studies by oral route. Nevertheless, caution should be taken when prescribed during pregnancy.

Lactation: There are no adequate data on the use of Drotaverine in lactation women, this medicine should not recommended for prescribing in these subjects.

4.7 Effects on ability to drive and use machines

In therapeutic doses, Drotaverine has no effect on ability to drive or operate machinery during oral treatment. Patients should be instructed that if they experience vertigo, they should avoid potentially hazardous task such as driving or operating machines.

4.8 Undesirable effects

- Cardiovascular: Hypotension, Tachycardia

- CNS: Headache and Vertigo

- Metabolic effects: Acute attacks of Porphyria have been associated with Drotaverine use.

4.9 Overdose

Based on the data available in published literature and based on reports of side effects, an overdose of Drotaverine may cause weakness, malaise, dizziness, vomiting, headache, a drop in blood pressure and sleepiness. Heart rhythm and conduction disorders, incl. potentially fatal complete bundle block and cardiac arrest have also been reported. In the case of accidental or intentional overdose, contact your doctor immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Drotaverine, a benzylisoquinoline derivative, is an analogue of papaverine with smooth muscle relaxant properties. Its antispasmodic activity is by phosphodiesterase enzyme IV inhibition. It is a nonanticholinergic antispasmodic. It causes smooth muscle relaxation by increasing intracellular levels of cyclic adenosine monophosphate (cAMP) secondary to inhibition of phosphodiesterase. Drotaverine has been shown to inhibit platelet aggregation in a dose dependent manner.

5.2 Pharmacokinetic properties

Absorption:
Although therapeutic serum levels have not been established, peak concentrations occur approximately 1 to 3 hours after an oral dose. Oral bioavailability of drotaverine ranges from 25% to 91%.
Distribution:
Drotaverine and its metabolites are 80% to 95% protein bound and it has a volume of distribution of 193 to 195 litres.
Metabolism:
Drotaverine appears to undergo extensive first-pass metabolism. It is readily metabolized in the liver by O-deethylation to mono- and di-phenolic compounds and their corresponding glucuronic acid derivatives.
Excretion:
Drotaverine is extensively metabolized in the liver and it is excreted in the urine and faeces. The half-life of drotaverine ranges from 7 to 12 hours.

1.6 PHARMACEUTICAL PARTICULARS

6.1List of Excipients

- Microcrystalline cellulose
- Starch
- Lactose
- Sodium Starch Glycolate
- Polyvinyl Pyrrolidone (PVP K-30)
- Croscarmellose sodium
- Aerosil
- Purified talc
- Magnesium Stearate
- Cross povidone
- Fine coat
- Isopropyl alcohol
- Methylene chloride
- Tartrazine Lake
- PEG-6000

6.2. Incompatibilities

None Known

6.3. Shelf Life

36 Months from the date of manufacture.

6.4. Special precautions for Storage

Store in a dry place at temperature not exceeding 30 ^{o}C.

Keep out of reach of children.

Store in the original package to protect from light and moisture.

Store the blisters in the outer carton until required for use.

6.5 Nature and content of Container

2 x10 tablets in ALU-PVC Blister pack.

6.6 Special precaution for disposal and other handling

No Special Requirements

7. MARKETING AUTHORISATION HOLDER

BDA HEALTHCARE PVT. LTD.,

Plot No.: B-1, B-2, B-3, Near Gov. ITI MIDC, Parseoni – 441105,

Taluka: Parseoni, District: Nagpur, M.S., India.

8. MARKETING AUTHORISATION NUMBER(S)

06431/08067/NMR/2020

9. MEDICAL PRESCRIPTION STATUS:

Prescription Only Medicinal Product (POM)

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26.07.2021

11. DATE OF REVISION OF THE TEXT

07 July 2023