**Summary Product Characteristics for Pharmaceutical products .**

## 1.Name of the medicinal product

Spasmorid ,80mg tablets

## 2.Qualitative and quantitative composition

Each uncoated tablet contains:

Drotaverine Hydrochloride 80 mg Excipients QS

**Excipients with known effect**

Lactose

For the full list of excipients, see section 6.1.

## 3.Pharmaceutical form

Uncoated tablet

Light yellow colour, biconvex, round shaped plain on both sides uncoated tablet.

## 4.Clinical particulars

### 4.1 Therapeutic indications

Spasmorid is used to treat:

Muscle spasms of the abdomen caused by gall stones and kidney stones

Genitourinary smooth muscle spasms

Spastic pain caused by cystitis

### 4.2 Posology and method of administration

| | | |
|---|---|---|
| **Children Between 1 And 6 Years** | : | The usual daily dose is 40-120 mg (in 2-3 divided doses). |
| **Children over 6 years** | : | The usual daily dose is 80-200mg (in 2-5 divided doses). |
| **Adults** | : | The usual dose is 120-240mg daily (in 2-3 divided doses). |

**Directions for Use**

Take drotaverine tablet with or without food.

Swallow drotaverine tablet as a whole with a glass of water; do not chew, or break the tablet.

### 4.3 Contraindications

Hypersensitivity to the active component or to an excipient

Drotaverine tablet is contraindicated in patients: Severe hepatic or renal failure, severe heart failure, AV blockade II and III grades, cardiogenic shock, arterial hypotension.

## 4.4 Special warnings and precautions for use

In case of hypotension the administration of this drug needs increased caution.

Due to the presence of lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

Phosphodiesterase inhibitors like papaverine decrease the antiparkinsonian effect of levodopa. When Drotaverine is administered together with levodopa, rigidity and tremor may therefore become aggravated.

## 4.6 Pregnancy and lactation

**Pregnancy:**

Pregnant women do not take this drug unless absolutely necessary and the benefits outweigh the risks.

**Breastfeeding:**

If patient is breastfeeding, this drug is not recommended because the chances of adverse effects on the baby are very high.

## 4.7 Effects on ability to drive and use machines

Drotaverine causes dizziness. Do not drive or operate machinery unless you are alert.

## 4.8 Undesirable effects

Some of the common and serious side effects of Drotaverine are:

-Nausea
-Vomiting
-Dry mouth
-Change in pulse rate
-Dizziness
-Headache
-Difficulty in breathing
-Skin allergic
-Swelling of face, lips, eyelids and tongue
-Fall in Blood pressure
-Vertigo
-Constipation
-Sleep disorders
-Dermatitis

**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. Healthcare professionals are asked to report any suspected adverse reactions via*: Pharmacy and Poisons Board*

*Pharmacovigilance Electronic Reporting System (PvERS);*

*https://pv.pharmacyboardkenya.org*

### 4.9 Overdose

No case of drotaverine overdose has been reported. In case of overdose, the patient should be closely monitored, and managed by symptomatic and supportive care. Suggested measures include emesis and/ or gastric lavage.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Mechanism of action

Drotaverine hydrochloride is of spasmolytic, myotropic, vasodilation, hypotensive action.

It decreases ionized active calcium supply to smooth muscle cells due to inhibition of phosphoesterase and intracellular accumulation of adenosine monophosphate. It is of apparent and prolonged action on smooth muscles of inner organs and vessels, it decreases moderately arterial pressure, increases minute volume of heart, is of some antiarrhythmic action. It decreases tone of cerebral vessels and increases their blood-filling. Practically it does not influence vegetative nervous system and does not penetrate to CNS.

### 5.2 Pharmacokinetic properties

Drotaverine has rapid and total absorption by gastrointestinal tract. Bioavailability is about 100%. Half-absorption is 12 min. Smooth distribution in tissues of plain muscle cells. Drotaverine is bound with plasma proteins to 95-98%.

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.

### 5.3 Preclinical safety data

No data available

## 6.Pharmaceutical particulars

### 6.1 list ofexcipients

Microcrystalline

Cellulose Lactose

Maize Starch

Povidone (As PVPK-30)
Colour Tartrazine
Supra Magnesium
Stearate Purified Talc
Sodium Starch Glycollate
Crospovidone
Colloidal Anhydrous Silica
Polacrilin Potassium (As Kyron-T-314)
Purified Water

**6.2 Incompatibilities**
Not applicable

**6.3 Shelf life**
36 months

**6.4 Special precautions for storage**
Stored at a temperature not exceeding 30ºC, in a cool and dark place, protect from direct sunlight.

**6.5 Nature and contents of container**
**3 x 10 pack:** 10 tablets packed in alu-alu blister and such 3 blisters are packed in single carton along with pack 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 Authorization Number**

CTD10091

**9.Date of authorization /renewal of the authorization**

30/05/2024

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

07/05/2025