Summary of Product Characteristics (SPC)

1. Name of the medicinal product
Mef-Spas (Drotaverine Hydrochloride Tablets 80 mg)

1.1 International Non-Proprietary Name (INN)
Drotaverine Hydrochloride

1.2 Strength
80 mg / Tablets

1.3 Pharmaceutical form
Film Coated Tablets

2. Qualitative and quantitative composition
Each film coated tablet contains
Drotaverine Hydrochloride ……. 80 mg
Excipients ……. q.s.
Colour: Approved colour used

3. Pharmaceutical form
Film Coated Tablets
Light yellow to yellow colour, round shaped, biconvex, film coated tablets, plain on both sides.

4. Clinical particulars
4.1 Therapeutic indications
Drotaverine HCl effectively treats twitches or spasm of the smooth muscles generally found in the stomach and heart. It is effective in relieving pain triggered due to irritable bowel syndrome, headache, menstrual periods and cervical spasm during labor. It is also effective in abdominal pain, chest pain, gallstones pain in the kidneys, pain in renal colic and a few other conditions. Spasm of smooth muscles of inner organs (cardio- and pylorospasm), chronic gastroduodenitis, stomach and duodenum ulcer, cholelithiasis (biliary colic), chronic cholecystitis, post cholecystectomy syndrome, hypermotoric biliary track dyskinesia, spasmodic intestines dyskinesia, intestines colic caused by gas retard after intervention, colitis, proctitis, tenesmus, meteorism, urolithiasis (renal colic), pyelitis. spasm of brain vessels, of coronary and peripheral arteries, necessary abatement uterus traction in parturition and reversal of spasm of neck of uterus in parturition, spasm of smooth muscles in instrumental intervention.

4.2 Posology and method of administration
Dosage: As directed the physician.
Mode of Administration: Oral use only

4.3 Contraindications

Hypersensitivity, glaucoma. Drotaverine Hydrochloride is not recommended in patients with severe heart, liver, and kidney disease. Drotaverine HCI should be used with caution in patients suffering from a genetic disorder of the skin and blood. People who have allergic reactions, are pregnant or are breastfeeding are also advised to avoid taking this medicine. Drotaverine HCl may interact with a few other drugs like atropine, diclofenac, levodopa and diazepam, Inform your doctor about taking any other medications, before starting the course of Drotaverine Hel is not recommended for use if you suffer from a condition that impairs the normal blood pumping ability of the heart.

4.4 Special warnings and precautions for use

Before using Drotaverine HCl inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Appearance of Blood clots in the body
- Avoid direct sunlight or ultraviolet light
- Breathlessness
- Discoloration of the skin on the face or neck
- Hereditary swelling in lips and face
- Irregular heartbeat Pain and swelling under the skin
- Pregnancy
- Systemic lupus erythematosus

4.5 Interaction with other medicinal products and other forms of interaction

Enhances the affect of other spasmolytics (cholinergic antagonist inclusive), hypotensia caused by tricyclic antidepressants, by quinidine, by procainamide hydrochloride. The secure spasm elimination is enhanced by phenobarbital. It inhibits spasmogenic action of morphine. antiparkinsonian activity of levodopa.

- Atropine (MODERATE): Report the use of any medicine taken for pain to the doctor. You may require a dose adjustment and more frequent monitoring to use these medicines together.
- Diclofenac (MODERATE): Report the use of any medicine taken for pain to the doctor. You may require a dose adjustment and more frequent monitoring to use these medicines together.
- Levodopa (MAJOR): Use of this medicine in a patient taking levodopa should be avoided. The risk of adverse effects are significantly high and the symptoms might worsen after taking these medicines together. Use of an alternative medicine that is safer for use is recommended in such cases.
- Diazepam (MODERATE): Report the use of any medicine taken for pain to the doctor. You may require a dose adjustment and more frequent monitoring to use these medicines together Report any incidence of adverse effects to the doctor on priority.

4.6 Pregnancy and lactation
As with most drugs, the use of Drotaverine Hydrochloride should be avoided during pregnancy and lactation unless essential.

4.7 Effects on ability to drive and use machines
No relevant studies have been conducted. The use of tablet may cause undesirable effects such as dizziness and vertigo. Affected patients should refrain from driving a vehicle or using machines until the undesirable effect has subsided.

4.8 Undesirable effects
Heat sensation, vertigo, arrhythmia, hypotensia, tachycardia, hyperhidrosis (often in parenteral introduction), allergic dermatitis. The possible side-effects that may occur on using Drotaverine HCI are nausea, vomiting, fainting, dry mouth, sleep disorders, constipation, flushing, allergic dermatitis, swelling of face, lips, eyelids, tongue, hands and feet, falling of blood pressure and change in pulse rate.

4.9 Overdose
AV block, cardiac arrest, paralysis of respiratory center. In case of an overdose, doctor should be consulted immediately. The overdose symptoms are restlessness, confusion and dizziness. As per the severity of the symptoms, the supportive measures like gastric lavage are initiated.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacological Group: Vasodilators, Myothropic, spasmolytics.
ATC code: A03AD02

Drotaverine HCl has 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 bloof-filling. Practically it does not influence vegetative nervous system and does not penetrate to CNS.

5.2 Pharmacokinetic properties
Rapid and total absorption by gastrointestinal tract. Bioavailability is about 100%. Absorption half-life is 12 minutes. Smooth distribution in tissues of plain muscle cells. Drotaverine Hydrochloride is bound with plasma proteins to 95-98%

5.3 Preclinical safety data
Based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, reproductive toxicity and carcinogenic potential, the non-clinical data reveal no special hazard for humans.
• Based on in vitro and in vivo studies, drotaverine did not cause a delay in ventricular repolarisation.

• In in vitro and in vivo genotoxicity studies (e.g. Ames test, mouse lymphoma assay, micronucleus assay), drotaverine showed no indication of genotoxicity.
• Drotaverine had no impact on fertility in rats and on embryonic/foetal development in rats and rabbits.
It has been observed that drotaverine acts as a cytostatic agent in various human tumour cell lines and non-malignant mouse fibroblasts. In SRB assays, EC50 values of up to 3.0 mM were observed for human HT-29 colorectal cancer cells. The clinical consequences of this effect are not known and no relevant undesirable effects in children, adolescents or adults have been observed during five decades of use in humans.

6. Pharmaceutical particulars
6.1 List of excipients

Maize starch	BP
Microcrystalline Cellulose	BP
Lactose Monohydrate	USP
Povidone (K-30)	BP
Purified Water	BP
Magnesium Stearate	BP
Sodium Starch	USP
Colloidal Silicon Dioxide	USP
Purified Talc	BP
Croscarmellose Sodium	USP/NF
DRA COAT FCUAY 502	IH
Isopropyl alcohol	BP
Methylene chloride	BP

6.2 Incompatibilities
None known

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C in a cool & dry place, protected from light.

6.5 Nature and contents of container
10 Tablets Alu-Alu Blister is packed in the carton along with leaflet. Such 10 mono cartons are packed in an outer carton.

6.6 Special precautions for disposal and other handling
None

7. Manufactured By

Scott-Edil Pharmacia Limited. Unit-II,
Plot No. 21-22, EPIP, Phase-I, Jharmajri, Baddi,
Distt. Solan (H.P.), 173205 INDIA

8. Marketed By

M/s Ncure Healthcare Ltd.

9. Date of revision of the text

04/2023

10. DOSIMETRY (IF APPLICABLE)

Not applicable

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable