1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

FLOSPASM film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg flavoxate hydrochloride.

Contains sugar: Lactose monohydrate 64 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

FLOSPASM is a white to off white, round, film-coated tablet with "D 93" on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

FLOSPASM is indicated for its antispasmodic action in urological disorders.

4.2. Posology and method of administration

Posology

Adult:

One tablet three times a day (600 mg flavoxate hydrochloride daily) for as long as required.

Paediatric population

FLOSPASM is not recommended for use in children (see section 4.3).

Method of administration

Oral administration.

FLOSPASM should be taken after a meal in order to prevent nausea.

4.3. Contraindications

FLOSPASM is contraindicated in:

- Patients with hypersensitivity to flavoxate hydrochloride or to any excipients in FLOSPASM (see section 6.1).
- Patients with pyloric or duodenal obstruction, obstructive intestinal lesions, ileus, achalasia or other gastrointestinal obstructive conditions.
- Patients with gastrointestinal haemorrhage.
- Patients with obstructive uropathies of the lower urinary tract or urinary retention.
- Patients with glaucoma
- Patients with myasthenia gravis.
- Children under 12 years of age.
- Pregnancy and lactation (see section 4.6).

4.4. Special warnings and precautions for use

Renal impairment

Since the renal clearance of the active metabolite accounts more than 50 % of the dose, renal impairment may significantly affect the product kinetics. Caution is therefore required in patients with renal impairment (see section 4.3).

Glaucoma

FLOSPASM is contraindicated in patients with suspected glaucoma, especially narrow angle glaucoma (see section 4.3).

Urinary tract disorders

FLOSPASM should be used with caution in patients with serious, uncontrolled, obstructive disorders of the lower urinary tract (see section 4.3).

Drowsiness

If a patient experiences drowsiness, the time between administration of doses should be extended.

Paediatric population

The use in children below the age of 12 years is contraindicated (see sections 4.2 and 4.3).

Excipients

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

4.5. Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (see section 4.3).

Pregnancy

There are no or a limited amount of data for the use of flavoxate in pregnant woman. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. FLOSPASM should not be used during pregnancy (see section 4.3).

Breastfeeding

It is unknown whether flavoxate (metabolites), as contained in FLOSPASM, is excreted in human milk. A risk to the suckling child cannot be excluded. FLOSPASM should not be used during breastfeeding (see section 4.3).

Fertility

There are no data on the effect of flavoxate, as contained in FLOSPASM, on human fertility. Flavoxate has no effect on animal fertility.

4.7. Effects on ability to drive and use machines

Since adverse reactions such as drowsiness, somnolence, vertigo and blurred vision have been reported in patients receiving FLOSPASM, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that FLOSPASM does not adversely affect their ability to do so (see sections 4.4 and 4.8).

4.8. Undesirable effects

a. Tabulated list of adverse reactions for FLOSPASM

System organ class	Frequent	Less frequent	Frequency unknown
Blood and lymphatic disorders		Eosinophilia, leukopenia	
Immune system disorders		Angioedema	Hypersensitivity, anaphylactic reaction, anaphylactic shock

Psychiatric disorders		Mental confusion (especially in the elderly), nervousness	
Nervous system disorders		Somnolence, drowsiness, dizziness, headache	
Eye disorders		Visual impairment, blurred vision, disturbances in eye accommodation, increased ocular tension	Glaucoma
Ear and labyrinth disorders		Vertigo	
Cardiac disorders		Palpitations, tachycardia	
Gastrointestinal disorders	Nausea	Vomiting, dry mouth, dyspepsia, diarrhoea, dysphagia	
Hepatobiliary disorders			Jaundice, liver disorder, abnormal hepatic enzyme
Skin and subcutaneous tissue disorders		Urticaria and other dermatoses, rash, pruritus,	Erythema
Renal and urinary disorders		Urinary retention, dysuria	
General disorders and administration site conditions		Fatigue, hyperpyrexia	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

The most likely symptoms of overdose are blurred vision, dry mouth, drowsiness and diarrhoea or constipation.

Treatment

Treatment of overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A 18 Medicines acting on genito-urinary system

Pharmacotherapeutic group: Drugs for urinary frequency and incontinence

ATC code: G04BD02

Mechanism of action

Flavoxate hydrochloride is a non-specific, direct-acting, smooth muscle relaxant.

5.2. Pharmacokinetic properties

Absorption

Oral studies have indicated that flavoxate is readily absorbed from the intestine and converted, to a large extent, almost immediately to MFCA.

Distribution

Following an IV dose (equimolar to 100 mg), the following parameters were calculated for flavoxate: $T_{½}$ was 83,3 mins and the apparent volume of distribution was 2,89 L/kg. The apparent distribution of MFCA was 0,20 L/kg. No free flavoxate was found in urine (24 hours). However, 47 % of the dose was excreted as MFCA.

Following single oral dosing of 200 mg and 400 mg flavoxate, almost no free flavoxate was detected in the plasma. The peak level of MFCA was attained at 30 to 60 mins after the 200 mg dose and at around two hours following the 400 mg dose. The AUC for the 400 mg dose was approximately twice as large as the AUC for the 200 mg dose.

Elimination

About 50 % of the dose was excreted as MFCA within 12 hours; most being excreted within the first 6 hours. After repeated oral dosing (200 mg, three times per day for 7 days) the cumulative excretion of metabolites stabilised at 60 % of the dose on the third day remaining almost unchanged after one week.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Anatase titanium dioxide (E171), hypromellose (E464), lactose monohydrate, magnesium stearate, macrogol, macrogol stearate, povidone, microcrystalline cellulose (E460), sodium starch glycolate.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 °C.

6.5. Nature and contents of container

PVC/PVDC/Aluminium or PVC/PE/Aluminium blisters with either 10 or 15 tablets per blister strip.

Pack size of 10 tablets consists of 1 blister strip of 10 tablets in a carton.

Pack size of 15 tablets consists of 1 blister strip of 15 tablets in a carton.

Pack size of 90 tablets consists of 9 blister strips of 10 tablets or 6 blister strips of 15 tablets in a carton.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

49/18/0064

9. DATE OF FIRST AUTHORISATION

10 August 2022

10. DATE OF REVISION OF TEXT

10 August 2022

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

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