**SCHEDULING STATUS**

S2

## 1. NAME OF THE MEDICINE

URISPAS 200, 200 mg film-coated tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 200 mg flavoxate hydrochloride.

Excipient with known effect:

- Contains sugar (lactose monohydrate): 64 mg

For full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film-coated tablets.

White, homogeneous film-coated tablets with “F200” embossed.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

URISPAS 200 is indicated for its antispasmodic action in urological disorders.

### 4.2 Posology and method of administration

**Posology**

Adults - Take one tablet three times a day (600 mg flavoxate hydrochloride) for as long as required.

***Paediatric population***

The safety and efficacy of URISPAS 200 in children aged < 12 years have not been established (see section 4.3).

**Method of administration**

URISPAS 200 is for oral use.

### 4.3 Contraindications

- Hypersensitivity to flavoxate hydrochloride or to any of the excipients of URISPAS 200 (see section 6.1).

- Pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal haemorrhage and obstructive uropathies of the lower urinary tract.
- Safety in pregnancy and lactation has not been established (see section 4.6).
- URISPAS 200 is not recommended for use in children under 12 years of age.
- Urinary retention.
- Glaucoma.
- Myasthenia gravis.

**4.4 Special warnings and precautions for use**

- 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.
- URISPAS 200 should be used with caution in patients with suspected glaucoma, especially narrow angle glaucoma and in patients with serious, uncontrolled, obstructive disorders of the lower urinary tract.
- In the case of drowsiness, the time between the administration of the doses should be extended. See section 4.7 for effects on ability to drive and use machines.

***Lactose***

URISPAS 200 contains lactose. Patients with the rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take URISPAS 200.

**4.5 Interactions with other medicines and other forms of interaction**

No interaction studies have been performed.

**4.6 Fertility, pregnancy and lactation**

***Fertility***

There is no data on the effect of flavoxate on human fertility. Flavoxate has no effect on animal fertility.

***Pregnancy***

There is no or limited amount of data from the use of flavoxate in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of URISPAS 200 during pregnancy.

Safety in pregnancy has therefore not been established.

***Breastfeeding***

It is unknown whether flavoxate (metabolites) is excreted in human milk. A risk to the suckling child cannot be excluded. URISPAS 200 should therefore not be used during breastfeeding.

**4.7 Effects on ability to drive and use machines**

URISPAS 200 may cause drowsiness, blurred vision or vertigo, thus patients should not drive or operate a motor vehicle or machinery, until they are reasonably certain that URISPAS 200 does not affect them adversely. (see section 4.8).

**4.8 Undesirable effects**

***a. Summary of the safety profile***

No data is available.

***b. Tabulated summary of adverse reactions***

| **System Organ Class** | **Frequency** | **Adverse Event** |
|---|---|---|
| **Blood and lymphatic system disorders** | Less frequent | Eosinophilia, leukopenia |
| **Immune system disorders** | Less frequent<br>Frequency unknown | Angioedema<br>Hypersensitivity, anaphylactic reaction, anaphylactic shock |
| **Psychiatric disorders** | Frequency unknown | Confusional state |
| **Nervous system disorders** | Less frequent | Drowsiness, dizziness, headache, mental confusion (especially in the elderly), nervousness, somnolence, vertigo |
| **Eye disorders** | Less frequent<br><br><br>Frequency unknown | Blurred vision, disturbances in eye accommodation, increased ocular tension<br>Glaucoma |
| **Cardiac disorders** | Less frequent | Palpitations, tachycardia |
| **Gastrointestinal disorders** | Frequent<br>Less frequent | Nausea<br>Diarrhoea, dry mouth, dyspepsia, dysphagia, and vomiting |

| | | |
|---|---|---|
| **Hepato-biliary disorders** | Frequency unknown | Jaundice, liver disorder, hepatic enzyme abnormalities |
| **Skin and subcutaneous tissue disorders** | Less frequent<br><br>Frequency unknown | Urticaria, rash, pruritus, and other dermatoses<br>Erythema |
| **Renal and urinary disorders** | Less frequent | Dysuria, urinary retention |
| **General disorders and administration site conditions** | Less frequent | Fatigue and hyperpyrexia |

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of URISPAS 200 is important. It allows continued monitoring of the benefit/risk balance of URISPAS 200. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8

**4.9 Overdose**

The most likely symptoms of overdose are blurred vision, dry mouth, drowsiness, and diarrhoea or constipation. Treatment of overdosage is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: A.18 Medicines acting on genito-urinary system
ATC code: G04BD02.

***Mechanism of action***

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

It acts by inhibiting cAMP-dependent phosphodiesterase, thus producing a cAMP accumulation that reduces the efficiency of the calcium messenger system during smooth muscle contraction. The compound exhibits only weak affinity for α- and β-adrenergic receptors involved either directly or indirectly in voiding.

At active doses with myolitic effects, flavoxate does not influence the parasympathetic system and does not cause any vagolytic-like effects.
Recent findings suggest that it may also act on the micturition center.

**5.2 Pharmacokinetic properties**

Flavoxate is readily adsorbed from the gut, enters the blood, and concentrates rapidly in the tissues where it is metabolized into 3-methylflavon-8carboxylic acid. This metabolite is excreted with the urine partly unmodified and partly conjugated as glucoronide.
Urinary excretion takes place within 4 to 6 hours from administration.

**5.3 Preclinical safety data**

Non-clinical data reveals no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and toxicity to reproduction and development. Carcinogenicity studies have not been performed.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

***Core:***

Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose (Avicel PH-102)
Povidone (Polyvinylpyrollidone K30)
Sodium starch glycolate (Type A)
Talc

***Coating:***

Macrogol 6000
Magnesium stearate
Sepifilm® (coating consisting of: hypromellose, macrogol stearate, microcrystalline cellulose)
Titanium dioxide (CI 77891)

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

36 months.

**6.4 Special precautions for storage**

Store at or below 30 °C.

Protect from moisture and light.

Keep the blister strips in the outer carton until required for use.

**6.5 Nature and contents of container**

Cartons of 15 tablets: Each carton contains 1 blister strip containing 15 tablets.

Cartons of 90 tablets: Each carton contains 6 blister strips containing 15 tablets per blister strip.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

Any unused product or waste material should be disposed of in accordance with local requirements.

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
0860 ADCOCK (232625)

**8. REGISTRATION NUMBER(S)**

29/18/0428

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

06 February 1996

**10. DATE OF REVISION OF THE TEXT**

10 May 2022

Botswana: S2 B9300825

Namibia: NS1 04/18/0744