Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Urispas 200 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Urispas tabletcontainsflavoxate hydrochloride200 mg.

Excipient with known effect:
Each tablet contains 64 mg of lactosemonohydrate.

Forthe full list ofexcipients, seesection 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
White, film-coated tablets embossed with 'F200'.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Urispas is indicated for the symptomatic relief of dysuria, urgency, nocturia, vesical supra-pubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethro-cystitis and urethrotrigonitis.

In addition, the preparation is indicated for the relief of vesico-urethral spasms due to catheterisation, cystoscopy or indwelling catheters; prior to cystoscopy or catheterisation; sequelae of surgical intervention of the lower urinary tract.

4.2 Posology and method of administration

Posology

Adults(including elderlypatients)

Onetablet threetimes aday.

Paediatricpopulation:

Urispasshould not beused in children youngerthan 12 yearsofage.

Method of administration
Oral administration
The tablets should be taken after a meal in order to prevent nausea.

4.3 Contraindications

- Hypersensitivity to the active substance orto any oftheexcipientslisted in section 6.1.
- Gastrointestinal obstructive conditions or ileus
- Gastro-intestinal haemorrhage
- Achalasia
- Urinary retention
- Glaucoma
- Myasthenia gravis

4.4 Special warnings and precautions for use

The use in children below the age of <12 years is not recommended.

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 contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Urispas contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Fertility.There are no data on the effect of flavoxate in human fertility. Flavoxate has no effect on animal fertility.

Pregnancy
There are 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 during pregnancy.
Lactation.
It is unknown whether flavoxate (metabolites) is excreted in human milk. A risk to the suckling child cannot be excluded. Urispas should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Urispas has minor influence on the ability to drive and use machines.
Patients should be informed that if somnolence or blurred vision occur they should not drive or use machines.

4.8 Undesirable effects

The source of the below ADRs frequencies is represented by data collected through clinical trials, observational studies and spontaneous reporting.
In the table below, adverse reactions are reported and listed by MedDRA system organ class and frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (frequency cannot be estimated from available data). Within each frequency grouping the observed adverse reactions are presented in order of decreasing seriousness.

System Organ Class	***Frequency***	***Preferred Terms***
Immune system disorders	Not known	Hypersensitivity, anaphylactic reaction, anaphylactic shock*
Psychiatric disorders	Not known	Confusional state*
Nervous system disorders	Uncommon	Somnolence
Eye disorders	Uncommon Not known	Visual impairment Glaucoma*
Cardiac disorders	Not known	Palpitations
Gastrointestinal disorders	Uncommon Common	Vomiting, dry mouth, dyspepsia Nausea
Hepatobiliary disorders	Not known	Jaundice, liver disorder, hepatic enzyme abnormal*

Skin and subcutaneous tissue disorders	Uncommon Rare Not known	Rash Urticaria, pruritis Erythema*
Renal and urinary disorders	Rare	Urinary retention
General disorders and administration site conditions	Rare	Fatigue

*Adverse reactions from spontaneous reporting in the worldwide post-marketing experience.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

4.9 Overdose

No risk following overdose has been identified in the post-marketing experience.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Urinary antispasmodics – Flavoxate
ATC Code: G04BD02

Mechanism of action
Flavoxate hydrochloride (and its main metabolite methyl flavone carboxylic acid, MFCA) is an antispasmodic, selective to the urinary tract. In animal and human studies, flavoxate hydrochloride has been shown to have a direct antispasmodic action on smooth muscle fibres.

The mechanism of action involves intracellular cyclic AMP accumulation and calcium blocking activity. It inhibits bladder contractions induced by various agonists or by electrical stimulation and inhibits the frequency of bladder voiding contractions. It increases bladder volume capacity, reduces the threshold and micturition pressure.

In addition, animal studies have shown flavoxate hydrochloride to have analgesic and local anaesthetic properties.

Flavoxate does not significantly affect cardiac or respiratory functions.

5.2 Pharmacokinetic properties

Absorption
Oral studies in man 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: $T_{½}$ 83.3 mins: apparent volume of distribution 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.

Elimination
Following single oral dosing to volunteers of 200 mg and 400 mg flavoxate, almost no free flavoxate was detected in the plasma. The peak level of MFCA was attained at 30-60 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. 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, TDS, 7 days) the cumulative excretion of metabolites stabilised at 60% of the dose on the third day remaining almost unchanged after one week.

5.3 Preclinical safety data

Non clinical data reveal 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

Tablet Core:
Lactose Monohydrate
Sodium starch glycolate Type A
Povidone
Talc
Magnesium stearate
Cellulose, Microcrystalline

Tablet Coating:
Hypromellose
Cellulose, Microcrystalline
Macrogol 6000
Macrogol stearate
Magnesium stearate
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C. Keep blister strips in the outer carton in order to protect from light.

6.5 Nature and contents of container

PVC/aluminium foil blisters packed in cartons in pack sizes of 250, 100, 90 or 6 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Recordati Ireland Limited
Raheens East
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1404/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 October 1990

Date of last renewal: 15 October 2010

10 DATE OF REVISION OF THE TEXT

July 2024