SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Urispas 200 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains as active ingredient: flavoxate hydrochloride 200 mg.

Excipient with known effect:
Each tablet contains 64 mg of lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

White, film-coated tablets with ‘F 200’ embossed.

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 (elderly included)

The recommended adult dosage is one tablet three times a day for as long as required.

Pediatric population

The safety and efficacy of Urispas in children aged <12 years have not yet been established.

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 or to any of the excipients listed 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 has been performed.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data on the effect of flavoxate on 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 200 mg film-coated tablet 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 (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, pruritus 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 the Yellow Card Scheme, website: www.mhra.gov/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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

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

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.

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

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

36 months

6.4 Special precautions for storage

Do not store above 30°C. Keep blister strips in the outer carton.

6.5 Nature and contents of container

PVC / aluminium blister strips in pack sizes of 84, 90, 100 and 250 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Recordati Pharmaceuticals Limited,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 25046/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 May 1997

Date of latest renewal: 14 August 2007

10 DATE OF REVISION OF THE TEXT

26/02/2024