6ª BOZZA (04/04/2019)

LINEA GAMMA

RECORDATI

LEAFLET (f.ill.)

URISPAS 200 mg - tablets

GUEST (cliente): RECORDATI

COUNTRY (nazione): SINGAPORE

SIZE (formato): 150 x 215

CODE (codice): 41894515

PROOF-READING (revisione): A

ISSUE DATE (data creazione f.ill.): 03/10/2018

VISUAL CODE (codice visivo): 9-20

PHARMACODE (Laetus): 300

INVERSE PHARMACODE (Laetus inverso): 435

WORK N. (n. lavoro): 0705

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Helvetica Neue

Font minimum size: 7 pt

Urispas® 200

Flavoxate hydrochloride

Presentation: Each tablet contains 200mg flavoxate hydrochloride.

Manufactured by: Recordati Industria Chimica E Farmaceutica, Milan, Italy.

The white, film-coated tablets are embossed with "F 200".

Uses: 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, urethrocystitis 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.

Dosage and administratlon:
Adults (including the elderly): The recommended adult dosage is 200mg three times a day for as long as required.
Children: Not recommended for children under 12 years of age.

Contra-indications, warnings etc:
Contra-indications:
- Hypersensitivity to the active substance or to any of the excipients;
- Gastrointestinal obstructive conditions or ileus;
- Gastro-intestinal haemorrhage
- Achalasia
- Urinary retention
- Glaucoma.
- Myasthenia gravis.

Special precautions: 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.
As the tablets contain lactose, its use is not recommended in patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption. In the event of drowsiness and blurred vision, the patient should not drive a motor vehicle or operate machinery.

Side-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

Use in pregnancy and breast-feeding: 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 Preclinical safety data). As a precautionary measure, it is preferable to avoid the use of Urispas during pregnancy.

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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.

Symptoms and treatment of overdosage: No risk following overdose has been identified in the post-marketing experience.

Drug interactions: None known.

Pharmacodynamic properties:
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 pressure 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.

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 100mg), the following parameters were calculated for flavoxate:
T1/2 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 200mg and 400mg flavoxate, almost no free flavoxate was detected in the plasma. The peak level of MFCA was attained at 30-60 mins after the 200mg dose and at around two hours following the 400mg dose. The AUC for the 400mg dose was approximately twice as large as the AUC for the 200mg 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 (200mg, TDS, 7 days) the cumulative excretion of metabolites stabilised at 60% of the dose on the third day remaining almost unchanged after one week.

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.

Pharmaceutical precautions: Do not store above 30ºC. Keep the blister strips in the outer carton in order to protect from light.

This medicine should not be used after the expiry date shown on the pack.

Package quantities: Urispas 200mg tablets are supplied in packs of 90 tablets.

Date of preparation: November 2018.

Manufactured by Recordati Industria Chimica e Farmaceutica S.p.A., Milan, Italy
FOR RECORDATI IRELAND LTD.
Rahees East, Ringaskiddy, Co. Cork, Ireland