PACKAGE INSERT

SCHEDULING STATUS: **S2**

PROPRIETARY NAME: **URISPAS 200**

(AND DOSAGE FORM) **TABLETS**

COMPOSITION:

Each film-coated tablet contains flavoxate hydrochloride 200 mg.

Contains: Lactose monohydrate 64 mg.

List of excipients: Sodium starch glycolate Type A, Povidone, Talc, Magnesium stearate, Cellulose Microcrystalline, Hypromellose, Macrogol 6000, Macrogol stearate, Titanium dioxide (E171).

PHARMACOLOGICAL CLASSIFICATION:

A.18 Medicines acting on genito-urinary system

PHARMACOLOGICAL ACTION:

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

INDICATIONS:

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

CONTRAINDICATIONS:

Hypersensitivity to flavoxate hydrochloride or to any of the excipients of **URISPAS 200.** 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. **URISPAS 200** tablets are not recommended for use in children under 12 years of age.

WARNINGS:

In the event of drowsiness, blurred vision or vertigo, patients should not drive or operate a motor vehicle or machinery.

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

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

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

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Adverse reactions noted include:

Side effects:

Blood and lymphatic disorders:

Less frequent: Eosinophilia and leukopenia.

Cardiac disorders:

Less frequent: Palpitations and tachycardia.

Eye disorders:

Less frequent: Blurred vision, disturbances in eye accommodation and increased ocular tension.

Gastrointestinal disorders:

Less frequent: Diarrhoea, dry mouth, dyspepsia, dysphagia, nausea and vomiting.

General disorders:

Less frequent: Fatigue and hyperpyrexia.

Immune system disorders:

Less frequent: Angioedema.

Nervous system disorders:

Less frequent: Drowsiness, dizziness, headache, mental confusion (especially in the elderly) nervousness, and vertigo.

Renal and urinary disorders:

Less frequent: Dysuria.

Skin and subcutaneous tissue disorders:

Less frequent: Urticaria and other dermatoses.

Special precautions:

URISPAS 200 tablets 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.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

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

IDENTIFICATION:

White, film-coated tablets embossed with “F 200”.

PRESENTATION:

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.

STORAGE INSTRUCTIONS:

Store below 25 °C. Protect from moisture. Keep the blister strips in the outer carton.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

29/18/0428

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