

150mm.

UROXATE TABLET 100 MG

CONTENT

Each **UROXATE** Tablet contains 100 mg Flavoxate hydrochloride.

DESCRIPTION

White round biconvex film-coated tablet embossed with "SPS" on one side and plain on the other.

PHARMACODYNAMICS

Flavoxate hydrochloride is an antispasmodic selective to the urinary tract. 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. Flavoxate does not significantly affect cardiac or respiratory functions.

PHARMACOKINETICS

There are very limited published reports on the pharmacokinetic data on flavoxate hydrochloride. In a single study of 11 normal male subjects, the time to onset of action is 55 minutes after oral administration. Peak plasma concentration was observed at 112 minutes and 57% of the flavoxate hydrochloride was excreted via the kidneys within 24 hours in this particular study. It has also been reported that 10-30% of a 100 mg dose is excreted in urine within 6 hours after oral administration.

INDICATIONS

UROXATE is used as an antispasmodic to provide symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence that may occur in patients with cystitis, prostatitis, urethritis, urethrocystitis and urethrotrigonitis.

RECOMMENDED DOSAGE

Adults and children over 12 years old: One or two 100 mg tablets to be taken three or four times daily. The dose may be reduced with improvement in symptoms.

CONTRAINDICATIONS

UROXATE is contraindicated in patients who have hypersensitivity to flavoxate hydrochloride or to any of the excipients, gastrointestinal obstructive conditions or ileus, gastrointestinal haemorrhage, achalasia, urinary retention, glaucoma and myasthenia gravis.

WARNINGS AND PRECAUTIONS

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.

Paediatric population

The safety and efficacy of flavoxate hydrochloride in children below the age of 12 years have not been established. As such **UROXATE** is not recommended for use in infants and children in this age group.

Effects on ability to drive and use machines

Patients should be informed that if somnolence or blurred vision occur, they should not drive or use machines.

PREGNANCY AND LACTATION

Use in pregnancy: Since there is no evidence of the drug's safety in human pregnancy, nor is there any evidence from animal work that it is free from hazard, flavoxate hydrochloride should be avoided in pregnancy unless there is no safer alternative.

Use in lactation: It is not known whether flavoxate hydrochloride is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **UROXATE** is administered to a nursing woman.

DRUG INTERACTIONS

Flavoxate hydrochloride has antimuscarinic effects, concomitant use of two or three such drugs potentiate the side effects such as dry mouth, urine retention and constipation. Concomitant use with other antimuscarinic drug may also lead to confusion in the elderly.

SIDE EFFECTS

Immune system disorders

Not known: Hypersensitivity, anaphylactic reaction, anaphylactic shock

Psychiatric disorders

Not known: Confusional state

Nervous system disorders

Uncommon: Somnolence

Eye disorders

Uncommon: Visual impairment

Not known: Glaucoma

Cardiac disorders

Not known: Palpitations

Gastrointestinal disorders

Uncommon: Vomiting, dry mouth, dyspepsia

Common: Nausea

Hepatobiliary disorders

Not known: Jaundice, liver disorder, hepatic enzyme abnormal

Skin and subcutaneous tissue disorders

Uncommon: Rash

Rare: Urticaria, pruritus

Not known: Erythema

Renal and urinary disorders

Rare: Urinary retention

General disorders and administration site conditions

Rare: Fatigue

OVERDOSAGE AND TREATMENT

Symptoms of overdosage developing soon after ingestion of the drug include: tachycardia, palpitation, dry mouth, blurred vision, speech disturbance, drowsiness, difficulty in swallowing, restlessness, diarrhoea or constipation, dry hot skin and fever.

Treatment: Gastric lavage and other measures to limit intestinal absorption should be initiated without delay. Administration of parasympathetic drugs should also be considered.

PACK SIZES

Box of (10 x 10) & (50 x 10) tablets.

STORAGE

Store in a cool dry place, below 30°C.

Protect from light.

Keep medicines out of reach of children.

Jauhi daripada kanak-kanak.

Shelf life: Please refer to the outer box label.

Manufactured by:

SPS SRIPRASIT PHARMA CO., LTD.
216 Moo 6 Suanluang, Krathum Baen,
Samut Sakhon 74110, Thailand.

Date of revision: April 2022

PIU0003 Rev: 5

210mm.

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Artist	ยศ	Job Name	(PIU0003)UROXATE LEAFLET (MALAYSIA) (Rev:5)	
Date	05/04/2567			รับรองงานถูกต้องสิ่งพิมพ์ได้
Modify				

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