



품명	크린세이트정-설명서		
작업자	삼천당제약		
규격	(전) 90×260mm	(후) 180×190mm	
수출 국가	싱가포르	완료 일자	
인쇄	  	별색 3도	

Improvement of dysuria

CLEANXATE Tablet

■ Composition

Each tablet contains

Flavoxate HCl ----- 200mg

■ **Description** : White, sugar coated tablet

■ Pharmacology/Pharmacokinetics

Flavoxate exerts a direct spasmolytic(papaverine-like) action on smooth muscle. It is described as a smooth muscle relaxant but it also has antimuscarinic effects. In vitro, the spasmolytic effect has been demonstrated on the small intestine, gall bladder, uterus, seminal vesicle and colon of various animals.

Flavoxate is readily absorbed from the gastrointestinal tract and rapidly metabolised, about 50-60% of a dose being excreted in the urine within 24hours as methyl flavone carboxylic acid.

■ Indications

Symptomatic relief of dysuria, urgency, nocturia, vesical suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis and urethrotrigonitis.

■ Dosage and Administration

Adults(including the elderly) : 1 tablet 3 times daily.

■ Precautions

Cleanxate should be used with caution in patients with suspected glaucoma. In the event of drowsiness and blurred vision, the patient should not operate a motor vehicle or machinery.

■ 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 should be avoided in pregnancy unless there is no safer alternative.

■ Use in children

Not yet recommended for children under 12 years since safety and efficacy studies in this age group are not completed.

■ Use in lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when flavoxate is administered to a nursing woman.

■ Side Effects

In clinical trials comparing Flavoxate with other spasmodic agents, the incidence of side effects was low. The following adverse reactions were observed :

Gastrointestinal : Nausea, vomiting, dry mouth, diarrhoea

CNS : Vertigo, headache, mental confusion.

Ophthalmic : Disturbance in eye accommodation

Cardiovascular : Tachycardia and palpitations

Allergic : Urticaria and other dermatoses, eosinophilia and hyperpyrexia

■ Contraindications

Patients who have any of the following obstructive conditions : Pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal haemorrhage and obstructive uropathies of the lower urinary tract.

■ **Drug Interactions** : None reported so far.

■ Overdosage

Patients who have taken an overdosage of Cleanxate should have gastric lavage performed within 4 hours of the overdosage occurring.

If overdosage is extreme, or there is a delay in removing the drug from the stomach, administration of a parasyntomimetic drug should be considered.

■ Pack Size

1)50 tablets in a plastic bottle.

2)10x10tablets in a printed box.

■ **Storage** : Store below 25°C

■ **Shelf life** : 3 years from manufacture date

SIN9677P



Manufactured by
SAMCHUNDANG PHARM.CO.,LTD.
Seoul, Korea

PRODUCT REGISTRANT :

Zyfas Pharma Pte. Ltd.

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