

# Xyzine<sup>®</sup> Tab.

(Levocetirizine 5mg)

## ■ COMPOSITION

Each tablet contains

Levocetirizine HCl ..... 5mg.

## ■ DESCRIPTION

A oval-shaped, white or slight yellow Film Coating tablet.

## ■ INDICATIONS AND USAGE

1. The relief of symptoms associated with seasonal and perennial allergic rhinitis
2. The treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria

## ■ DOSAGE & ADMINISTRATION

Adults and children 6 years of age : 1 tablet (Levocetirizine 5mg) once daily

• Renal Impairment

Adjust the dose with decreased renal function (CLcR (mL/min))

Creatinine Clearance CLcR (mL/min)		Dosage and Frequency
Mild	$50 \leq \text{CLcR} < 80$	1 tablet once daily
Moderate	$30 \leq \text{CLcR} < 50$	1 tablet twice daily
Severe	$10 \leq \text{CLcR} < 30$	1 tablet three times daily

## ■ PRECAUTIONS

### 1. Contraindication

- 1) Patients with known hypersensitivity to Hydroxyzine or any of the ingredients of XYZINE
- 2) Patients with end-stage renal disease
- 3) Pregnancy and Breast-feeding
- 4) Children less than 6 years of age
- 5) Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

### 2. Caution

- 1) Patients with Renal impairment (It can maintain high plasma concentration)
- 2) Patients with Hepatic impairment (It can maintain high plasma concentration)
- 3) Elderly (It can maintain high plasma concentration)

### 3. Adverse reactions

- 1) Nervous System: Drowsiness, Sometimes Malaise, Headache, Feeling paralysis, Rare slight temporary weary, fatigue, Dizziness, Heavy, Excitation
- 2) Digestive: Dry mouth, Nausea, rare vomiting, Anorexia, Stomachache, dyspepsia, gastrointestinal disturbance, diarrhea, stomatitis, dysgeusia
- 3) Cardiovascular: tachycardia, hypertension, arrhythmia, palpitation
- 4) Blood: capillaritis, sometimes leucopenia, Neutropenia, lymphocytosis, acidophilia, monocytosis, thrombocytosis, thrombocytopenia
- 5) Anaphylaxis: light hypersensitive, anaphylaxis shock, sometimes edema, rare eruption, Pruritus, vascular edema
- 6) Eye: visual clouding, conjunctival congestion
- 7) Liver: sometimes AST, ALT, A1-P, Total Bilirubin synergistic action
- 8) Kidney: sometimes Bun synergy action, Diabete mellitus, urine occult blood
- 9) others: pharyngitis, cough, congestion, Bronchus spasm, paracosis, dysopsia, sometimes chest pain, rare dysmenorrheal, tinnitus

### 4. Precautions

- 1) Symptoms of overdose may include drowsiness
- 2) stop to take, when the patients appear Hypersensitivity reactions

3) Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, and motor coordination such as operating machinery or driving a motor vehicle

**5. Drug Interactions**

- 1) Concurrent use of XYZINE with alcohol should be avoided
- 2) A small decrease in the clearance of cetirizine was observed in a multiple dose study with theophylline (400mg once a day)

**6. Pregnancy and lactation**

- 1) For XYZINE no clinical data on exposed pregnancies are available,
- 2) Because XYZINE is also expected to be excreted in human milk, use of XYZINE in nursing mothers is not recommended.

**7. Pediatric Use**

The safety and effectiveness of XYZINE in pediatric patients under 6 years of age have not been established.

**8. Elderly use**

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function

**9. Effect of Clinical test result**

Should not administrate XYZINE before 3~5 days to operate allergen intraderma test because XYZINE inhibit the reaction.

**10. Overdosage**

Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children. There is no known specific antidote to XYZINE. Should overdose occur, symptomatic or supportive treatment is recommended. XYZINE is not effectively removed by dialysis, and dialysis will be ineffective unless a dialyzable agent has been concomitantly ingested.

■ **STORAGE**

Store at 1 - 30°C in air tight containers.

■ **SHELF LIFE** : 2 Years

■ **PACKING** : 10 Tablets /Box

※ This drug is manufactured in accordance with Korea Good Manufacturing Practice (KGMP) as recommended by WHO.

Manufactured by

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