

# RINCIT™ Film-Coated Tablet

## [Levocetirizine dihydrochloride 5mg/tablet]

### COMPOSITION:

Each tablet contains:

- Active ingredient: Levocetirizine dihydrochloride .....5mg
- Excipients: HPMC (Pharmacoat), Avicel PH 102, Croscarmellose Sodium, Lactose, Magnesium Stearate, Titanium Dioxide, P.E.G. 6000, Brilliant Blue Lake Color.

### INDICATIONS:

RINCIT (Levocetirizine) is indicated in adults and children over 6 years of age for the treatment of symptoms associated with allergic conditions such as:

- Seasonal allergic rhinitis (including ocular symptoms)
- Perennial allergic rhinitis
- Chronic idiopathic urticaria.

### DOSAGE AND ADMINISTRATION:

RINCIT (Levocetirizine) Tablets may be taken with or without food. It is recommended to take the daily dose in one single intake.

- *Adults and Children over 6 years of age:*

The recommended dose is RINCIT tablet (5mg Levocetirizine dihydrochloride) daily.

- *Patient with renal impairment:*

The recommended dose in patients with moderate renal impairment is one RINCIT (Levocetirizine) tablet every two days. In those with severe renal impairment, the dose interval should be increased to every three days. Patients with end stage renal disease should not be given Levocetirizine.

### CONTRAINDICATIONS:

RINCIT is contraindicated in patients with:

- Hypersensitivity to drug or any component of this medication.
- Severe renal impairment at less than 10ml/min creatinine clearance.
- Not recommended for use in children less than 6 years of age.

### UNDESIRABLE EFFECTS:

Generally levocetirizine is well tolerated. However, a few side effects like headache, migraine, sleepiness, asthenia, rhinitis, abdominal pain, dry mouth, fatigue, and pharyngitis have been reported.

### PRECAUTIONS:

General

- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medication.
- Should not take alcohol during therapy.

### EFFECTS ON ABILITY TO DRIVE AND OPERATE MACHINE:

Comparative clinical trials have revealed no evidence that levocetirizine at the recommended dose impairs mental alertness, reactivity or the ability to drive. Nevertheless, some patients could experience somnolence, fatigue and asthenia under therapy with RINCIT. Therefore, patients intending to drive, engage in potentially hazardous activities or operate machinery should take their response to the medicinal product into account.

### DRUG INTERACTIONS:

In sensitive patients, the simultaneous administration of levocetirizine and alcohol or other CNS depressants may have effects on the central nervous system.

### USE IN PREGNANCY AND LACTATION

*Pregnancy*

There are no adequate and well-controlled studies of Levocetirizine in pregnant women. Levocetirizine should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

*Nursing Mothers*

Levocetirizine is excreted into human breast milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**STORAGE CONDITIONS:** Store at temperature below 30°C. Protect from sunlight and moisture.

**SHELF-LIFE:** 24 months from the manufacturing date.

**HOW SUPPLIED:** 1 Blister x 10 Tablets/Box & 10 Blisters x 10 Tablets/Box.

**SPECIFICATION:** Manufacturer.

### WARNING:

- Read carefully the leaflet before use.
- For further information, please contact your doctor.
- This drug is dispensed on prescription only.
- Keep out of reach of children.



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