

Cetirizine Tablets BP

10mg

Composition:

Each film-coated tablet contains:
Cetirizine hydrochloride BP.....10 mg
Excipients.....q.s.
Color: Approved color used.

Therapeutic indications:

Cetirizine 10 mg film-coated tablets are indicated in adults and pediatric patients aged 6 years and older:
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of symptoms of chronic idiopathic urticaria.

Posology and method of administration:

Posology

10 mg once daily (1 tablet).

Special populations

Elderly: Data do not suggest that the dose needs to be reduced in elderly individuals, provided renal function is normal.

Hepatic impairment: No dose adjustment is required in patients with hepatic impairment alone. In patients with both hepatic and renal impairment, dose adjustment is recommended (see Patients with moderate to severe renal impairment above).

Pediatric population

The tablet formulation should not be used in children under 6 years of age, as it does not allow for the necessary dose adjustments.

Children aged 6 to 12 years: 5 mg twice daily (half a tablet twice daily).

Adolescents over 12 years of age: 10 mg once daily (1 tablet).

In pediatric patients with renal impairment, the dose must be adjusted individually taking into account the patient's renal clearance, age, and body weight.

Method of administration:

The tablets should be swallowed with a glass of liquid.

Contraindications:

Hypersensitivity to the active substance, to hydroxyzine, or to any piperazine derivative.

Patients with severe renal impairment with a creatinine clearance of less than 10 ml/min.

Special warnings and precautions for use:

At therapeutic doses, no clinically significant interaction with alcohol (at a blood alcohol level of 0.5 g/L) has been demonstrated. However, caution is recommended if alcohol is consumed concomitantly.

Caution should be exercised in patients with predisposing factors for urinary retention (e.g., spinal cord injury, prostatic hyperplasia), as cetirizine may increase the risk of urinary retention.

Caution is recommended in patients with epilepsy and patients at risk of convulsions. Allergy skin test responses are inhibited by antihistamines, and a wash-out period (of 3 days) is required before performing them.

Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take cetirizine film-coated tablets.

Pruritus and/or urticaria may occur when cetirizine is discontinued, even if these symptoms were not present prior to the start of treatment. In some cases, the symptoms may be intense and require the resumption of treatment. The symptoms should resolve when treatment is restarted.

Pediatric population

Use of the film-coated tablet formulation is not recommended in children under 6 years of age, as this formulation does not allow for appropriate dose adjustment. Use of a pediatric cetirizine formulation is recommended.

Fertility, pregnancy, and lactation:

Pregnancy

For cetirizine, prospectively collected data on pregnancy outcomes do not suggest a potential for maternal or fetal/embryonic toxicity above background rates.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/fetal development, parturition, or postnatal development. Caution should be exercised when prescribing to pregnant women.

Breastfeeding

Cetirizine passes into breast milk. The risk of side effects in nursing infants cannot be ruled out. Cetirizine is excreted in human milk at concentrations representing 25% to 90% of those measured in plasma, depending on the time of sampling after administration. Therefore, caution should be exercised when prescribing cetirizine to breastfeeding women.

Fertility

Limited data on human fertility are available, but no safety concerns have been identified.

Animal data show no safety concerns regarding human reproduction.

Storage:

Store below 30°C in a dry place. Protect from light.

Keep the medicine out of the reach of children.

Presentation: A pack of 10 x 10 tablets.

Manufactured by :

