

CETIMED®

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

INFORMATION ABOUT CETIMED

Each tablet for oral administration of CETIMED tablet contains 10 mg of cetirizine dihydrochloride with the following excipients: lactose monohydrate, sodium starch glycolate, magnesium stearate, talc.

Each 5 mL of CETIMED syrup contains 5 mg of cetirizine dihydrochloride with the following excipients: sucrose, strawberry flavor, purified water

Cetirizine is a long-acting, non-sedating antihistamine with peripheral H1-receptor histamine antagonist activity; it has also anti-allergic and anti-inflammatory activity.

CETIMED is used for the relief of symptoms associated with:

-Seasonal allergic rhinitis (hay fever). Symptoms treated effectively include sneezing, rhinorrhea, nasal pruritus, ocular pruritus, tearing, and redness of the eyes in patients 2 years of age and older.

-Perennial (Recurrent or persistent) allergic rhinitis. Symptoms treated effectively include sneezing, rhinorrhea, postnasal discharge, nasal pruritus, ocular pruritus, and tearing in patients 6 months of age and older.

-Uncomplicated skin manifestations of chronic idiopathic urticaria. It significantly reduces the occurrence, severity, and duration of hives and significantly reduces pruritus in patients 6 months of age and older.

THE WAY TO TAKE CETIMED

Take CETIMED exactly as prescribed by your doctor.

CETIMED is usually taken once daily preferably in the evening or divided to twice daily dose with or without food.

Age	Dose	Cetimed tablet	Cetimed syrup
Adults and children 6 years of age and older	10 mg once daily or 5 mg twice daily	1 tablet of 10 mg once daily or half tablet twice daily	10 mL once daily or 5 mL twice daily
Children 2 to 5 years of age	5 mg once daily or 2.5 mg twice daily	-	5 mL once daily or 2.5 mL twice daily
Children 12 months to 23 months of age	2.5 mg once daily, increased to a maximum of 2.5 mg twice daily	-	2.5 mL once daily increased to a maximum of 2.5 mL twice daily
Children 6 months to 11 months of age	2.5 mg once daily	-	2.5 mL once daily

Dosage adjustment is recommended for adult patients with moderate to severe renal impairment. No dose adjustment is needed in patients with solely hepatic impairment

DURATION OF TREATMENT

Since seasonal allergic rhinitis may be a chronic, recurrent condition, successful therapy often may require long-term, intermittent use of CETIMED. In the treatment of seasonal allergic rhinitis, antihistamines are more likely to be beneficial when therapy is initiated at the beginning of the hay fever season. The treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance.

In persistent allergic rhinitis, continued treatment may be proposed to the patients during the allergen exposure periods.

IN CASE OF MISSED DOSE

Take the missed dose as soon as you remember, unless the next intake is near. Go on taking the next scheduled dose as directed. You should not take a double dose at once.

IN CASE OF OVERDOSE

In case of the intake of high doses of this medication, inform your doctor at once and seek emergency medical attention.

CONTRAINDICATIONS

Do not use this medication in case of hypersensitivity to it or any of its ingredients or hydroxyzine.

PRECAUTIONS

-This drug should be used with caution in epileptic patients and patients at risk of convulsions.

-Caution should be taken in case of severe renal or hepatic insufficiency.

-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

-Consult your doctor before using this medication in case of pregnancy or lactation. It should be used in pregnancy only if clearly needed. Use in nursing mother is not recommended.

ADVERSE REACTIONS

This drug is generally well tolerated. The most reported adverse effect is somnolence. Drowsiness, headache, sleepiness, fatigue, dry mouth, abdominal pain and rarely hypersensitivity reactions may occur.

Notify your doctor if any of these effects develops or becomes bothersome.

ASSOCIATIONS WITH OTHER MEDICATIONS

Please notify your doctor if other medicines are being taken or have been taken recently.

Special precautions should be taken with drugs that cause drowsiness, sleepiness or relaxation. Avoid excessive alcohol consumption.

STORAGE

Store at controlled room temperature (up to 30°C), protected from sunlight and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

PACK PRESENTATION

CETIMED 10 mg tablets: Pack of 20.

CETIMED 5mg/5 mL syrup: Bottle of 125 mL with dosing cup.

Revision date: 06/2011

CETT1/004