



Zyrtec®

Cetirizine hydrochloride

Forms and strengths

Box containing 10 and 20 film-coated tablets at 10mg of cetirizine dihydrochloride.
Bottle containing 10 and 20 ml drops at 10mg/ml of cetirizine dihydrochloride.
Bottle containing 75 ml and 200 ml solution at 1mg/ml of cetirizine dihydrochloride.

Route of Administration

Oral use

Formula

- **10 mg "film-coated" tablet** : Cetirizine dihydrochloride 10 mg - Microcrystalline cellulose - Lactose monohydrate - Colloidal anhydrous silica - Magnesium stearate q.s. for one tablet - Opadry Y-1-7000 (=Hydroxypropylmethylcellulose - Titanium dioxide - Macrogol 400) for coating.
- **10 mg/ml oral drops** : Cetirizine dihydrochloride 10 mg - Acetic acid - Glycerol - Methylparahydroxybenzoate - Propylparahydroxybenzoate - Sodium acetate - Sodium saccharinate - Propyleneglycol - Purified water q.s. for one ml (=20 drops).
- **1 mg/ml oral solution** : Cetirizine dihydrochloride 1 mg - Acetic acid - Glycerol - Methylparahydroxybenzoate - Propylparahydroxybenzoate - Sodium acetate - Sodium saccharinate - Propyleneglycol - Sorbitol 70 per cent (non-crystallizing) - Synth. banana flavour (derog. 42/1076) - Purified water q.s. for one ml.

Pharmacotherapeutic group

Antiallergic

Marketing Authorization Holder

UCB S.A.
60, Allée de la Recherche
1070 Bruxelles Belgium

Manufacturer

Tablets:
UCB FARCHIM S.A.
Z.I. de Planchy - Ch. De Croix Blanche
1630 BULLE - SWITZERLAND

Drops and solution:

UCB PHARMA S.p.A.
Via Praglia, 15
10044 PIANEZZA (TO) - ITALY

Indications

Adults and children of 2 years or above:
Symptomatic treatment of seasonal rhinitis and conjunctivitis as well as perennial rhinitis.

Adults: treatment of pruritus and urticaria of allergic origin.

Contra-indications

Hypersensitivity to any of the drug.

Interaction

To date, there are no known interactions with other drugs.
Nevertheless, caution is recommended if sedatives are also being taken.

Special Warnings

Cetirizine at therapeutic doses has not shown a potential of the effects of alcohol (for an alcohol blood level of 0,8g/l). Nevertheless, precaution is recommended.

Pregnancy and breastfeeding

Teratology studies in animals have not demonstrated any special adverse effects. As a precaution, however, cetirizine should not be administered to pregnant women during the first three months of pregnancy, nor should women who are breastfeeding take the drug.

Driving a car and operating machine

Studies in healthy volunteers on 20 or 25 mg/day have not revealed effects on alertness or reaction time.

Patient should be advised, however, to take care not to exceed the recommended dose.

Instructions for use

Adults and children of 6 years or above:

In most cases, the recommended dose is 10 mg daily as a single dose.

It is advisable to take the drug with a little liquid during the evening meal since the symptoms for which the product is given usually appear during the night.

In patients affected by side effects, the dose may be taken as 5 mg in the morning and 5 mg in the evening.

Children between 2 and 6 years:

The recommended dose is 5 mg daily as a single intake or 2.5 mg in the morning and the evening.

Tablets: 1 tablet=10 mg / 1/2 tablet=5 mg

Drops: 20 drops (=1 ml) = 10 mg / 10 drops (=0,5 ml) = 5 mg/5 drops (=0,25 ml) = 2,5 mg

Overdosage

Drowsiness can be a symptom of overdosage, occurring from administration of 50 mg as a single dose.

To date, there is no specific antidote. In the case of massive overdosage, gastric lavage should be performed as soon as possible. Apart from the usual supportive measures, all vital parameters have to be monitored regularly.

Undesirable effects

There have been occasional reports of mild and transient subjective side-effects, such as headache, dizziness, drowsiness, agitation, dry mouth and gastro-intestinal discomfort.

In objective tests of psychomotor function, the incidence of sedation with cetirizine was similar to that of placebo.

Very occasionally symptoms of hypersensitivity have been reported.

Expiry date

The expiry date should be checked. This is indicated on the packing after the word "Exp".

Storage

Store at room temperature (15 to 25°C).

Date of last revision

October 2004

In case of complaint, mention the batch number indicated on the packaging.