Cetirizine Hayfever and Allergy Relief 10 mg Tablets
(Cetirizine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This medicine is available without prescription. However, you still need to use Cetirizine Hayfever and Allergy Relief 10 mg Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Cetirizine Hayfever and Allergy Relief 10 mg Tablets are and what they are used for
2. What you need to know before you take Cetirizine Hayfever and Allergy Relief 10 mg Tablets
3. How to take Cetirizine Hayfever and Allergy Relief 10 mg Tablets
4. Possible side effects
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1. WHAT CETIRIZINE HAYFEVER AND ALLERGY RELIEF 10 MG TABLETS ARE AND WHAT THEY ARE USED FOR

Cetirizine hydrochloride is the active ingredient of Cetirizine Hayfever and Allergy Relief 10 mg Tablets. Cetirizine Hayfever and Allergy Relief 10 mg Tablets is an antihistaminic medication.

In adults and children aged 6 years and above, Cetirizine Hayfever and Allergy Relief 10 mg Tablets are indicated
- for the relief of symptoms of hay fever (seasonal allergic rhinitis) and allergies such as dust or pet allergies (perennial allergic rhinitis), such as sneezing, itchy, runny and blocked nose, itchy, red and watery eyes.
- for the relief of swelling, redness and itchiness of the skin (symptoms of chronic idiopathic urticaria, which is also known as chronic nettle rash).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE HAYFEVER AND ALLERGY RELIEF 10 MG TABLETS

Do not take Cetirizine Hayfever and Allergy Relief 10 mg Tablets
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).
- if you are known to be allergic (hypersensitive) to the active substance of Cetirizine Hayfever and Allergy Relief 10 mg Tablets or any of the other ingredients of these tablets (these are listed below, in section 6 “Further information”).
- if you are known to be allergic (hypersensitive) to hydroxyzine (a closely related active substance of other medicines).
- if you are known to be allergic (hypersensitive) to drugs from the piperazine family, for example buclizine, cyclizine, medazoline, levocetirizine.

Warnings and precautions
Talk to your or pharmacist doctor before taking Cetirizine Hayfever and Allergy Relief 10 mg Tablets:
If you have kidney problems, please ask your doctor for advice; if necessary, you may have to take a lower dose. The new dose will be determined by your doctor. If you have predisposition factors of urinary retention (eg: spinal cord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention, please ask your doctor for advice.
If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

Children
Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow the necessary dose adjustments.

Other medicines and Cetirizine Hayfever and Allergy Relief 10 mg Tablets
Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.
Due to the profile of cetirizine, no interactions with other drugs are expected.
Taking Cetirizine Hayfever and Allergy Relief 10 mg Tablets with food and drink
Food does not noticeably affect the absorption of cetirizine.

No interactions having a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses. However, as it is the case with all antihistamines, it is recommended to avoid consumption of alcohol while taking this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Cetirizine Hayfever and Allergy Relief 10 mg Tablets should be avoided in pregnant women.
Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the medicine should only be administered if necessary and after medical advice.
Cetirizine passes into breast milk. Therefore, you should not take Cetirizine Hayfever and Allergy Relief 10 mg Tablets during breast-feeding unless you have contacted a doctor.

Allergy skin test
If you are going to have an allergy skin test stop taking Cetirizine Hayfever and Allergy Relief 10 mg Tablets for three days before the test. This medicine may affect your allergy test results.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetirizine Hayfever and Allergy Relief 10 mg Tablets at the recommended dose. You should closely observe your response to the drug after you have taken Cetirizine Hayfever and Allergy Relief 10 mg Tablets for three days. If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Cetirizine Hayfever and Allergy Relief 10 mg Tablets contains lactose.
Cetirizine Hayfever and Allergy Relief 10 mg Tablets contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. HOW TO TAKE CETIRIZINE HAYFEVER AND ALLERGY RELIEF 10 MG TABLETS
Always take Cetirizine Hayfever and Allergy Relief 10 mg Tablets exactly as your doctor has told you. Check with your doctor if you are not sure.
Tablets need to be swallowed with a glass of liquid. Children aged 6 to 12 years
The recommended dose is 5 mg twice daily as half a tablet twice a day.
Oedema (generalised swelling due to water retention)

Rare side effects (may affect up to 1 in 1,000 patients)

- Paraesthesia (abnormal feelings of the skin), tingling in the
- Asthenia (feeling of weakness), malaise (feeling of being
- Agitation
- Abdominal pain
- Dizziness, headache,
- Fatigue, somnolence (sleepiness)

Common side effects (may affect up to 1 in 10 patients)

The following side effects have also been reported.

- The other ingredients are: pregelatinized starch, lactose,
- The active substance of Cetirizine Hayfever and Allergy
- Convolusions
- Weight increased
- Aggression, confusion, depression, hallucination (hearing or seeing things), insomnia (difficulty sleeping)
- Urticaria (swelling, redness and itchiness of the skin)

Very rare side effects (may affect up to 1 in 10,000 patients)

- Thrombocytopenia (low level of blood platelets), which increases risk of bleeding or bruising
- Accommodation disorder (impaired ability of the eye to focus), blurred vision, oscillogyration (eyes moving in an uncontrolled circular manner)
- Syncope (fainting), dyskinesia (involuntary movements),
- Dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Tic (sudden abnormal repetitive muscle movement)
- Swelling of the skin particularly around the face, fixed drug eruption (may look like round or oval patches of redness and swelling of the skin)
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

Not known frequency of side effects (frequency cannot be estimated from the available data)

- Increased appetite
- Nightmare
- Amnesia (loss of memory), memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria may return if you stop taking Cetirizine Hayfever and Allergy Relief 10 mg Tablets.

Reporting of suspected adverse reactions

If you think you have any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CETIRIZINE HAYFEVER AND ALLERGY RELIEF 10 MG TABLETS

Keep out of the sight and reach of children.

Do not use Cetirizine Hayfever and Allergy Relief 10 mg Tablets after the expiry date which is stated on the box and blister.

This medicine does not require any special storage conditions.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Cetirizine Hayfever and Allergy Relief 10 mg Tablets contain:

- The active substance of Cetirizine Hayfever and Allergy Relief 10 mg Tablets is cetirizine hydrochloride. One film-coated tablet contains 10 mg cetirizine hydrochloride.
- The other ingredients are: pregelatinized starch, lactose, maize starch, povidone, magnesium stearate, macrogol 6000, basic polymethacrylate, titanium dioxide (E171), talc.

What Cetirizine Hayfever and Allergy Relief 10 mg Tablets look like and contents of the pack

White, capsule shaped film-coated tablets with a score on one side.

There are 7 or 14 tablets in a pack.

Not all pack sizes may be marketed.

Marketing Authorization Holder / Manufacturer:

Daiichi-Sankyo Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

This leaflet was last revised in August 2018.

V-1490