Package leaflet: Information for the patient

Well Pharmaceuticals Hayfever and Allergy Relief

10 mg Film-coated Tablets
Cetirizine dihydrochloride

P2823T

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- **Keep this leaflet. You may need to read it again.**
- **Ask your pharmacist if you need more information or advice.**
- **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.**
- **You must talk to a doctor if you do not feel better or if you feel worse after 3 days.**

What is in this leaflet:

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

The full name of this medicine is Well Pharmaceuticals Hayfever & Allergy Relief 10 mg film-coated Tablets but within the leaflet it will be referred to as this medicine. Cetirizine dihydrochloride, the active ingredient of the tablets is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

This medicine is used to treat people who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

Atihistamines like this medicine relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes and skin rashes.

2. What you need to know before you take this medicine

Do not take this medicine if:
- you are allergic to cetirizine dihydrochloride or to any of the other ingredients of this medicine (listed in section 6)
- you are allergic to hydroxyzine or to piperazine derivatives (closely related active ingredients of other medicines)
- you have severe kidney disease requiring dialysis.

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if:
- you have kidney problems with (as you will need to take a lower dose of this medicine as determined by your doctor)
- you have problems passing urine (like spinal cord lesion, prostate or bladder problems) as cetirizine increases the risk of urinary retention
- you suffer from epilepsy or are at risk of convulsions.

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

Allergy Testing
If you are due to have an allergy test, ask your doctor if you should stop taking this medicine for several days before testing. This medicine may affect your allergy test results.

Taking other medicines
This medicine is not known to interact with any other medicines, however, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine with food, drink and alcohol
Avoid alcoholic drink while you are taking this medicine. Although no clinically significant interactions have been observed with alcohol at a blood level of 0.5 grams per litre (corresponding to 1 glass of wine) and cetirizine taken at the recommended dose, there is no data on the safety when higher doses of cetirizine and alcohol are taken together; it is therefore recommended to avoid 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 or pharmacist for advice before taking this medicine.

This medicine should be avoided during pregnancy. Although the use of this medicine should not cause any harmful effects on the foetus, it should only be used if considered necessary after medical advice.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded, therefore you should not take this medicine during breast-feeding unless you have contacted a doctor.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking this medicine at the recommended dose.

You should closely observe your response to the drug after you have taken this medicine if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

This medicine contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content
This medicine contains less than 1mmol of sodium (23 mg) per tablet, that is to say essentially “sodium free”.

3. How to take this medicine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the tablet with a glass of liquid. DO NOT take more than one tablet each day. If you do not feel better within a few days, consult your doctor.

Adults and children aged 12 years and over:
Take one tablet (10 mg) daily. If the tablets make you feel drowsy or dizzy, taking half a tablet twice a day may be better than taking one tablet once a day.

Children aged 6 to 12 years:
The recommended dose is half a tablet (5 mg) twice a day.

This tablet form medicine is not suitable for children under 6 years.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Crescent PHARMA LIMITED

Product:	Well Pharmaceuticals Hayfever and Allergy Relief (Cetirizine)
Item Code:	P2823T
Size:	270 x 210 mm
Min. Point size:	9pt
O. Artwork	01/05/24
Proof No.	1
Amendment Date	

Colours Used	
	Process Black
	Keyline - does not print

Patients with renal impairment
Patients with moderate renal impairment are recommended to take 5 mg (half a tablet) once daily.

Patients suffering with severe kidney disease (adult), please contact your doctor or pharmacist who may decide to adjust the dose accordingly.

If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of this medicine is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints. Please ask your doctor or pharmacist for advice.

If you take more of this medicine than you should
If you accidentally take too many tablets go and see your doctor straight away. After an overdose some of the potential side effects listed below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty emptying the bladder) have been reported.

If you forget to take this medicine
If you forget to take a tablet, you should take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

If you stop taking this medicine
Rarely, pruritis (intense itching) and/or urticaria (hives) may occur/return when you stop taking this medicine.

If you have any further questions on the use of this medicine, ask your pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects are rare or very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice these symptoms:
- Allergic reactions, including severe allergic reactions with symptoms including rash, itchiness and fever, swelling of the throat or face, shortness of breath, wheezing and difficulty breathing.
  These reactions may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported.
Common side effects (may affect up to 1 in 10 people)
- Feeling sleepy
- Headache
- Dry mouth
- Diarrhoea, nausea
- Dizziness
- Pharyngitis (sore throat), rhinitis (stuffy, runny nose) in children
- Fatigue.

Uncommon side effects (may affect up to 1 in 100 people)
- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling unwell).

Rare side effects (may affect up to 1 in 1,000 people)
- Tachycardia (fast heart beat)
- Allergic reactions, some severe (very rare)
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)
- Convulsions
- Increased weight
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness
- Urticaria (hives).

Very rare side effects (may affect up to 1 in 10,000 people)
- Blurred vision, accommodation disorder (difficulty focussing), oculogyric crisis (eyes having uncontrolled circular movements)
- Unusual bleeding or bruising due to thrombocytopenia (low levels of blood platelets)
- Bad taste in the mouth/altered taste
- Tremor, tics
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)
- Fainting
- A recurring rash
- Bed wetting, pain and/or difficulty passing water.

Not known (frequency cannot be estimated from the available data)
- Increased appetite
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to empty the urinary bladder)
- Thoughts about or preoccupation with suicide. If you feel this way, stop taking the tablets and see your doctor.
- Pruritis (intense itching) and/or urticaria (hives) upon discontinuation
- Nightmares
- Memory loss and/or impairment
- Rash with blisters containing pus (acute generalised exanthematous pustulosis)
- Hepatitis (inflammation of the liver)
- Arthralgia (joint pain) and myalgia (muscle pain).

Reporting of side effects
If you get any side effects, talk to 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 this medicine
KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

DO NOT use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

DO NOT throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What this medicine contains
- Each tablet contains 10 mg of the active substance cetirizine dihydrochloride.
- The other ingredients are lactose anhydrous, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, sodium croscarmellose, hydroxypropylmethylcellulose (E464), polydextrose, titanium dioxide (E171), and macrogol/ polyethylene glycol 4000.

What this medicine looks like and contents of the pack
The tablets are white to off-white capsule-shaped film-coated tablets, each with one plain face and with a break line on the other face.

Your medicine is supplied in clear colourless PVC/PVdC-Aluminium blister packs of 7, 14 or 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Crescent Pharma Ltd., Key House,
Sarum Hill, Basingstoke, RG21 8SR, UK.

This leaflet was last revised in 05/2024. P2823T

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