PACKAGE LEAFLET INFORMATION FOR THE USER **Pollenase** Allergy & Hayfever Relief 10mg Tablets

Read all 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 has 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 a few days.

What is in this leaflet:



- What Allergy & Hayfever Relief Tablets are and what they are used for
- What you need to know before you take Allergy & Hayfever Relief Tablets
- How to take Allergy & Hayfever Relief Tablets
- Possible side effects
- How to store Allergy & Hayfever Relief Tablets
- Contents of the pack and other information

1. What Allergy & Hayfever Relief Tablets are and what they are

The active ingredient (which makes this medicine work) is called cetirizine hydrochloride, which belongs to a family of medicines called antihistamines. Allergy & Hayfever Relief Tablets are used to treat people who have hayfever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

Antihistamines like Allergy & Hayfever Relief Tablets 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.

What you need to know before you take Allergy & Hayfever Relief Tablets

Do not take Allergy & Hayfever Relief Tablets if you:

- are allergic to cetirizine hydrochloride or to any of the ingredients listed in section 6, to hydroxyzine or to any piperazine derivatives (closely related active substances of other medicines)
- suffer from severe kidney failure (creatinine clearance less than 10ml/min).

Warnings and precautions

Talk to your doctor or pharmacist before taking Allergy & Hayfever Relief Tablets.

- If you-are a patient-with-**renal insufficiency**, please-ask your doctor-for-advice; if- - necessary you will take a lower dose. The new dose will be determined by your doctor.
- If you have problems passing urine (eg: spinal cord problems or prostate or bladder problems) as cetirizine increases the risk of urinary retention.
- If you suffer from epilepsy or are at risk of convulsions, you should ask your pharmacist for advice.

Children and Allergy & Hayfever Relief Tablets

The use of this medicine is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation.

Other medicines and Allergy & Hayfever Relief Tablets

Tell your doctor or a pharmacist if you are taking, have recently taken or might take any

Allergy & Hayfever Relief Tablets with food and drink and alcohol

Food does not affect absorption of this medicine. Avoid alcohol while you are 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.

Allergy & Hayfever Relief 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

Cetirizine passes into breast milk. Therefore you should not take Allergy & Hayfever Relief Tablets during breast-feeding unless you have consulted a doctor.

Allergy Testing

If you are due to have an allergy test, ask your doctor if you should stop taking Allergy & Hayfever Relief Tablets for several days before testing. 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 Allergy & Hayfever Relief Tablets at the recommended dose. You should closely observe your response to the drug after you have taken Allergy & Hayfever Relief Tablets if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Allergy & Hayfever Relief Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take Allergy & Hayfever Relief Tablets

Always take this medicine exactly as described in this leaflet or as you doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the tablet with a glass of water. Do not take more than one tablet each day. If you do not feel better within a few days, consult your doctor.

Children aged 6 to 12 years: Half a tablet twice a day.

Adults and children aged 12 years and over: The recommended dose is 10 mg once daily as one tablet daily. If the tablets make you feel drowsy or dizzy, taking half a tablet twice a day may be better than taking one table once a day.

Allergy & Hayfever Relief Tablets are not suitable for children under 6.

Patients with renal impairment: Patients with moderate renal impairment are recommended to take 5 mg once daily. If you have kidney problems (or liver and kidney problems together) please contact your doctor or pharmacist who may adjust

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

Duration of treatment

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

If you take more than you should

If you accidentally take too much medicine, contact your doctor or nearest casualty

After an overdose, the side effects described below may occur with increased intensity, Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate. tremors and urinary retention have been reported.

Artwork Brand: Strength Form: Component: Pack Size: Country: Version:

Dr Reddy's Dr.Reddy Histease Allergy Product Name: Relief 10 mg **Tablets** Leaflet N/A Date Created: 24/01/2018 00/00/2018 Date Modified: 1.0

Technical Information



Printer: Chesapeke Dimensions: 135 x 390 mm

Colours





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If you forget to take Allergy & Hayfever Relief Tablets

Do not take a double dose to make up for a forgotten tablet. 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

If you stop taking Allergy & Hayfever Relief Tablets

Rarely pruritus (intense itching) and/or urticaria may return if you stop taking Allergy & Hayfever Relief Tablets.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects are very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice these symptoms:

A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine or it might start later.

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

- Somnolence (sleepiness)
 Headache
 Dizziness
 Diarrhoea
- Dry mouth
 - Nausea
- Fatigue
- Uncommon side effects (may affect up to 1 in 100 patients)

 Agitation

 Asthenia (extreme fatigue), malaise

 Abdominal pain

 Paraesthesia (abnormal feelings of the skin).

(children only).

Pharyngitis, cold like symptoms of the nose

- Pruritus (itchy skin), rash
- Rare side effects (may affect up to 1 in 1000 patients)

- Allergic reactions, some severe (very rare)
- Depression, agression, confusion, hallucination-(hearing or-seeing things), insomnia-Convulsions
- Fast heart beat
- Abnormal liver function test results (your doctor will know what to do)
- Urticaria (hives)
- Oedema (generalised swelling due to water retention)

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

- Thrombocytopenia (low levels of blood platelets)
- Blurred vision, difficulty focussing, oculogyration (eyes having uncontrolled circular movements)
- Tics (habit spasms)
- Syncope, involuntary movements and/or jerking of the limbs (dyskinesia), tremor
- Muscle spasms in the neck and shoulders
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- Bed wetting, pain and/or difficulty passing water.

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

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmares
 Vertigo sensation of rotation or movement)
 Urinary retention (inability to completely empty the bladder)
- Memory loss and/or impairment Pruritus (intense itching) and/or urticaria upon discontinuation
- Joint pain Rash with blisters containing pus.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Allergy & Hayfever Relief Tablets

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 blister and carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater 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 Allergy & Hayfever Relief Tablets contain

-Each tablet contains-10mg of cetirizine hydrochloride (the active ingredient). They alsocontain: lactose, microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, titanium dioxide (E171), macrogol 4000 and sodium citrate.

What Allergy & Hayfever Relief Tablets look like

The tablets are white circular bi-convex, film-coated tablets marked C on one side and a breakline on the other.

Available in cartons containing 7, 14 and 30 tablets.

Revision date January 2018 Marketing authorisation Dr. Reddy's Histease Allergy Relief holder and manufacturer 10mg Tablets PL 08553/0194 Dr. Reddy's Laboratories(UK) Ltd. © Dr. Reddy's Laboratories (UK)Ltd 6 Riverview Road, Beverley, East Yorkshire. HU17 0LD