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Cetirizine Dihydrochloride 10 mg Film-Coated Tablets

(GSL)

Leaflet Size : 350 x 150 mm

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150 mm Front

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Package Leaflet: Information for the user
**CETIRIZINE DIHYDROCHLORIDE 10 mg
FILM-COATED TABLETS**

(cetirizine dihydrochloride)

PHARMA
CODE

XXXX

Pharmacode Reading Direction

The name of this medicine is Cetirizine Dihydrochloride 10 mg Film-Coated Tablets, which will be referred to as Cetirizine Tablets throughout this leaflet.

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 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 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.

What is in this leaflet

1. What Cetirizine Tablets are and what they are used for
2. What you need to know before you take Cetirizine Tablets
3. How to take Cetirizine Tablets
4. Possible side effects
5. How to store Cetirizine Tablets
6. Contents of the pack and other information

1. WHAT CETIRIZINE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in your tablets is cetirizine hydrochloride, which belongs to a group of medicines called antihistamines. These block the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions. Cetirizine is used to relieve the symptoms of seasonal allergic rhinitis (e.g. hay fever), perennial allergic rhinitis (e.g. year round allergies often due to house dust mites or animal allergies) and urticaria (itchy, red, swollen skin). These symptoms include itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE TABLETS

Do not take Cetirizine Tablets:

- If you are allergic to cetirizine hydrochloride, hydroxyzine, piperazine derivatives or any of the other ingredients of this medicine (listed in section 6)
- If you have a severe kidney disease (severe renal failure with creatine clearance below 10ml/min)

Warnings and precautions

Talk to your doctor or pharmacist:

If you are a patient with liver problems or 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 spinal cord lesion or enlargement of the prostate or any predisposing factors for urinary retention.

If you are an epileptic patient or a patient at risk of convulsions (fits)

Other medicines and Cetirizine Tablets

Please tell your doctor if you are taking or have recently taken any of the following medicines, as they may decrease or increase the effect of Cetirizine Tablets and vice versa.

- medication for anxiety or stress (CNS depressants)

It may still be alright for you to take Cetirizine Tablets and your doctor will be able to decide what is suitable for you. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Allergy Testing

Cetirizine Tablets can affect the results of allergy skin tests. If you require an allergy test, you should stop taking Cetirizine Tablets 3 days before you have the tests.

Cetirizine Tablets with food, drink and alcohol

Cetirizine Tablets can be taken with or without food. **Be careful when drinking alcohol** while using Cetirizine. It can increase the effects of alcohol. No interactions susceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per ml corresponding to one glass of wine) and cetirizine used at the normal doses. However, as is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. As with other drugs, the use of Cetirizine Tablets should be avoided in pregnant women. You should not take Cetirizine Tablets during breast-feeding because cetirizine passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetirizine Solution at the recommended dose.

If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug. This medicine does not normally make you feel sleepy. However, everyone reacts differently.

If you do feel sleepy do not drive or use tools or machines. Do not drink alcohol.

Cetirizine Tablets contain Lactose

Cetirizine 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 these tablets.

3. HOW TO TAKE CETIRIZINE TABLETS

Remember. 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. Always take Cetirizine Tablets exactly as your doctor or pharmacist has told you to do so. You should check with your doctor or pharmacist if you are not sure

Dosage

The usual dosage is:

Children aged 6 - 12 years:

Take one tablet (10 mg) daily or half a tablet (5 mg) twice daily (morning and evening).

Adults and children over 12 years and over:

Take one tablet (10 mg) once 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. Cetirizine tablets are not suitable for children under 6.

Patients with kidney problems:

Patients with moderate kidney problems are recommended to take 5 mg once daily. In pediatric patients with renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance, age and weight.

If you take more Cetirizine Tablets than you should

If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you.

The most common signs and symptoms of overdose may include feeling unwell, confused, restless, shaky, dizzy, tired or very sleepy. You may also notice a rapid heartbeat, having dilated

pupils or blurred vision, and experience headache, itching, diarrhoea, or difficulty urinating.

If you forget to take Cetirizine Tablets

If you have forgotten to take your tablet, take it as soon as you remember, but wait at least 24 hours before taking your next dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetirizine Tablets can cause side effects, although not everybody gets them. If you get any of the following symptoms after taking these tablets you **should contact your doctor or pharmacist immediately**:

- a severe allergic reaction including rash, itchiness and fever, swelling of the eyelids, face, lips or throat. This reaction may start soon after you first take the medicine, or it might start later.
- any sudden wheeziness or difficulty in breathing
- In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor.

The following side effects have also been reported:

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

- drowsiness, fatigue
- dry mouth,
- nausea, abdominal pain
- diarrhoea (children only)
- dizziness,
- headache
- sore or inflamed throat, swelling and irritation of the lining of the nose

Uncommon side effects (may affect up to 1 in 100 people):

- agitation
- paraesthesia (feeling of pins and needles)
- rash, itching
- feelings of weakness and/or extreme tiredness, feeling unwell.
- diarrhoea

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

- allergic/ hypersensitivity reactions, some severe (very rare)
- feelings of aggression, confusion and depression
- convulsions, movement disorders
- abnormal involuntary eye movements
- rapid heart beat
- oedema (swelling of the feet or ankles)
- hives (urticaria)
- unusual weight gain
- changes in liver function tests, indicating the possibility of damage to the liver.
- hallucinations, difficulty in sleeping

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

- anaphylactic shock
- tics, shaking
- distorted sense of taste
- fainting
- blurred vision, difficulty in focusing the eyes, having uncontrolled circular movements of the eye (oculogyration)
- swelling of the face, lips or throat
- severe blistering skin rash
- difficult and/or painful urination or loss of urinary control
- an increased tendency to bruise or bleed easily (thrombocytopenia)
- involuntary movements &/or jerking of the limbs (dyskinesia)
- muscle spasms in the neck and shoulders
- a recurring rash

Not known: frequency cannot be estimated from the available data

- forgetfulness, memory impairment
- increased appetite
- vertigo (sensation of spinning)
- urinary retention (inability to urinate)
- Some cases of memory loss and/or impairment have been reported.
- Nightmares
- Joint pain
- Suicidal ideation
- Hepatitis
- Pustular rash
- Pruritus and/or urticaria upon discontinuation

Long term treatment with Cetirizine Tablets can lead to a dry mouth, it is therefore important that adequate oral hygiene is maintained

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 by searching 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 TABLETS

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date on the carton. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. Return any medicine you no longer need to your pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cetirizine Tablets contain:

The active ingredient is cetirizine dihydrochloride. Each tablet contains 10 mg cetirizine dihydrochloride.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, maize starch, talc, magnesium stearate, titanium dioxide (E171), hypromellose, macrogol, sodium citrate

What Cetirizine Tablets look like and the contents of the pack:

Cetirizine Tablets are white coloured, circular, biconvex film coated tablets. They are marked with "A" on one side, and a break-line on the other.

Your medicine is available in packs containing 7, 14 and 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House,
11-15 Peterborough Road,
Harrow, Middlesex,
HA1 2AX, United Kingdom.

Manufacturer:
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