

Cetirizine Dihydrochloride 10mg Film-coated Tablets

(cetirizine dihydrochloride)

Read this leaflet carefully before you start taking this medicine.

- This medicine is available without a prescription, however you still need to use Cetirizine Dihydrochloride 10mg Film-coated Tablets carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms change, worsen or do not improve.

In this leaflet:

1. What this medicine is for
2. Before you take the medicine
3. How to take the medicine
4. Possible side effects
5. Storing the medicine
6. Further information

1. What this medicine is for

Cetirizine Dihydrochloride 10mg Film-coated Tablets contain cetirizine dihydrochloride, which belongs to a group of drugs called antihistamines. These medicines help to relieve the symptoms of some allergies.

This medicine is used to relieve:

- symptoms of hayfever and other allergies such as sneezing, runny nose and burning, itchy eyes
- symptoms of skin allergies such as rash, itching or urticaria (hives).

2. Before you take the medicine

This medicine can be taken by adults, and children aged 6 years and over. Some people should not take this medicine or should talk to their pharmacist or doctor first.

Do not take if you:

- Are allergic (hypersensitive) to cetirizine dihydrochloride or any of the other ingredients in the medicine, listed in section 6.
- Have serious kidney problems

Talk to your doctor or pharmacist before taking this medicine if you:

- Have epilepsy or are at risk of convulsions.
- Have problems passing urine (like spinal cord problems, prostate or bladder problems)

Taking this medicine with food and drink

- Avoid alcoholic drink while you are taking this medicine.

Pregnancy and breast-feeding

- **Do not take** if you are pregnant or breast-feeding.

Driving and using machines

- Tests have shown that this medicine does not cause drowsiness in the vast majority of people using it. Therefore it will not normally affect your ability to drive or operate machinery. However there may be very rare exceptions and if you experience dizziness, nausea or drowsiness, do not drive or operate machinery.

Important information about some of the ingredients in your medicine

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

Allergy Testing

- If you are due to have an allergy test, ask your doctor if you should stop taking Cetirizine Dihydrochloride 10mg Film-coated Tablets for several days before testing. This medicine may affect your allergy test results.

Taking other medicines

- Cetirizine Dihydrochloride 10mg Film-coated Tablets are not expected to interact with other medicines you may be taking. However if you are unsure talk to your pharmacist or doctor.

3. How to take the medicine

AGE	DOSE
Adults and children aged 12 years and above	Take 1 tablet once a day
Children aged 6 to 12 years	Take half a tablet twice a day
DO NOT GIVE to children under the age of 6 years	
DO NOT EXCEED THE RECOMMENDED DOSE	

If symptoms worsen or do not improve, talk to your doctor or pharmacist.

If you take too many tablets: Talk to a doctor straight away, or go to your nearest hospital casualty department.

Take the carton and this leaflet with you.

If you forget to take your medicine:

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one, in which case skip the missed dose. Never take two doses together to make up for a missed dose.

4. Possible side effects

Like all medicines, Cetirizine 10mg Film-coated Tablets can sometimes have side effects, although not everybody gets them.

If you experience any of the following, stop taking this medicine and seek immediate medical help:

- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- Bruising or bleeding more easily than normal
- Convulsions (fits)

If you experience any of the following, stop taking this medicine and talk to your doctor:

- Confusion
- Hallucinations
- Abnormal liver function tests
- Rapid heartbeat
- Loss of consciousness

Other effects which may occur include:

Common (affecting 1 in 100 to 1 in 10 people):

- Headache and dizziness
- Drowsiness or tiredness
- Restlessness
- Dry mouth, sore throat
- Upset stomach, diarrhoea, nausea
- Runny nose

Uncommon (affecting 1 in 1000 to 1 in 100 people):

- Agitation
- Weakness
- Malaise
- Pins & needles
- Itching
- Rash
- Abdominal pain

Rarely (affecting 1 in 10,000 to 1 in 1000 people):

- Aggression, depression
- Weight gain
- Swelling
- Movement disorders including muscle spasm
- Insomnia
- Hives

Very Rarely (affecting less than 1 in 10,000 people):

- Taste disorder
- Blurred vision, eye movement disorder
- Difficult, painful or involuntary urination
- Tremors, tics

Some cases of memory loss and/or impairment, suicidal ideation, urinary retention, increased appetite and vertigo have also been reported.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 16762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing the Medicine

Do not use this medicine after the expiry date which is stated on the pack. The expiry date (EXP) refers to the last day of that month. This product does not require any special storage conditions.

Keep out of the sight and reach of children.

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 protect the environment.

6. Further information

What is in this medicine:

The active ingredient is: Cetirizine dihydrochloride. Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

The other ingredients are: Lactose monohydrate, Microcrystalline Cellulose, Maize Starch, Colloidal Anhydrous Silica, Magnesium Stearate, Talc. Film-coat: Hypromellose Lactose monohydrate, Titanium dioxide (E171), Macrogol 4000, Sodium Citrate.

What this medicine looks like and contents of the pack:

Cetirizine Dihydrochloride 10mg Film-coated Tablets are white circular biconvex film-coated tablets, embossed 'A' on one side and a deep score on the other. The tablet can be divided into equal halves. This pack contains 7,14 or 30 Film-coated Tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Chefaro Ireland DAC,
The Sharp Building, Hogan Place,
Dublin 2, Ireland

Manufacturer:

Chanelle Medical, Loughrea, Co. Galway, Ireland.

Text revised: May 2021