

URTIRIZINE TABLET

Cetirizine dihydrochloride (10mg)

What is in this leaflet:

1. What Urtirizine Tablet is used for
2. How Urtirizine Tablet works
3. Before you use Urtirizine Tablet
4. How to use Urtirizine Tablet
5. While you are using it
6. Side Effects
7. Storage and Disposal of Urtirizine Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Urtirizine Tablet is used for

Urtirizine Tablet is indicated for the symptomatic treatment of seasonal rhinitis (inflammation of the inside of the nose), persistent allergic rhinitis (allergic rhinitis for prolonged period) and urticaria (raised, itchy rash that appears on the skin) of allergic origin.

How Urtirizine Tablet works

Cetirizine dihydrochloride is the active ingredient of Urtirizine Tablet. It is a type of anti-histamine. Histamine is a chemical released into the body during an allergic reaction. It causes itching and inflammation.

Urtirizine Tablet works by blocking the effects of the naturally occurring chemical histamine in your body. Urtirizine Tablet markedly reduces respiratory hyperactivity to histamine in the asthmatic person. It also reduces the allergic reaction induced by specific allergens.

Before you use Urtirizine Tablet

-When you must not use it:

- If you are allergic (hypersensitive) to cetirizine dihydrochloride or to an antihistamine or any of the other ingredients of Urtirizine Tablet.
- If you are breast feeding as it is found in breast milk.
- If you have porphyria (a rare hereditary disease in which the blood pigment hemoglobin is abnormally metabolized).

- If you are in the first three months of pregnancy.

-Before you start to use it:

You must tell your doctor if:

- you have allergies to any medicine which you have taken previously to treat your current condition.
- you are pregnant, trying to become pregnant or breast-feeding.

-Taking other medicines:

There is no known interaction with other medicines. It should be used with caution if sedatives are also being taken.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

How to use Urtirizine Tablet

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

-How much to use:

Children (2 to 6 years): 2.5mg twice daily.

Adults and children over 6 years old: 10mg once daily. A 5mg starting dose may be proposed if this leads to satisfactory control of the symptoms.

Patient with liver and renal impairment

Dosage should be adjusted.

-When to use it:

Use as directed by your doctor or pharmacist. Take this medicine only by mouth.

-How long to use it:

Continue using Urtirizine Tablet for as long as your doctor recommends.

-If you forget to use it:

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

-If you use too much (overdose):

Symptoms: sedation, drowsiness and antimuscarinic effects (urinary retention, dry mouth, blurred vision)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

-Things you must do:

Contact your doctor if your symptoms worsen or they do not improve.

If you do become pregnant whilst taking Urtirizine Tablet, tell your doctor.

Excess alcohol should be avoided.

-Things you must not do:

Do not give Urtirizine Tablet to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Urtirizine Tablet for you and your condition.

This medication should not be given to premature infants or neonates.

-Things to be careful of:

Be cautious when driving a car or operating potentially dangerous machinery as occurrence of somnolence (drowsy) has been reported.

Used with caution in epilepsy (fits), enlarged prostate gland or pyloroduodenal obstruction (obstruction of the stomach outlet), urinary retention, glaucoma (damage to the optic nerve), liver disease and severe heart and blood vessel disorders.

Side effects

Incidence of sedation is relatively low. Other occasional mild and transient side effects include headache, dizziness, drowsiness, agitation, dry mouth and gastrointestinal discomfort.

Other less common side effects includes symptoms of hypersensitivity reactions.

Elderly is more susceptible to many adverse effects of antihistamines, including antimuscarinic effects, sedation and low blood pressure.

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

Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Urtirizine Tablet

Storage:

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Store below 30°C in well-closed containers. Protect from light, heat and moisture.

Keep out of the reach and sight of children.

-Disposal:

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

Product Description

What it looks like:

A white, scored, oblong tablet of size 10 x 4mm.

They are supplied in 50x10's blisterpack.

-Ingredients:

- Active ingredient(s)
Each tablet contains 10mg of the active substance, cetirizine dihydrochloride.
- Inactive ingredients
The other ingredients are lactose, corn starch, croscarmellose sodium, magnesium stearate and colloidal silicone dioxide.

-MAL number:

MAL20040211AZ

Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd.
Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Penang, Malaysia.

Date of Revision

11/03/2019

Serial Number:

BPFK (R4/1) 170317/00036