

CETRIZET D TABLET

Cetirizine hydrochloride/Pseudoephedrine hydrochloride (5mg/120mg)

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What *Cetirizet D* is used for

Cetirizet D should be administered when both the antiallergic properties of cetirizine HCl and the nasal decongestant activity of pseudoephedrine HCl are desired.

Cetirizet D is used in the treatment of symptoms associated with seasonal allergy or hay fever, perennial (throughout the year) allergic rhinitis (inflammation of the mucous membrane inside the nose) and common cold e.g., nasal congestion, sneezing, rhinorrhea (runny nose), nasal and ocular pruritus (itchy eyes).

How *Cetirizet D* works

Cetirizine is an antihistamine that helps to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body during an allergic reaction.

Pseudoephedrine is a decongestant that works by reducing swelling of the blood vessels inside your nose. This helps to open up your nasal airway, making breathing easier.

Before you use *Cetirizet D*

When you must not use it

Do not use *Cetirizet D* if you have any of the following:

- A history of hypersensitivity to any of the constituents, to ephedrine or to any piperazines.
- Previous intolerance to pseudoephedrine.
- Breast Feeding

- Have severe high blood pressure or severe coronary artery disease (heart disease).
- Taking or have taken monoamine oxidase inhibitors (for depression) within the preceding two weeks. The concomitant use of pseudoephedrine and this type of product may occasionally cause a rise in blood pressure.
- Kidney insufficiency, uncontrolled hyperthyroidism (overactive thyroid), severe arrhythmia (abnormal heart rhythm), increased intraocular pressure (fluid pressure inside the eye) or urinary retention (inability to completely empty the bladder).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking *Cetirizet D*.

Pregnancy and lactation

There is no specific data on the use of cetirizine or pseudoephedrine during pregnancy.

Therefore, *Cetirizet-D* should be given only if the potential benefit justifies the potential risks to the fetus/newborn. Cetirizine and pseudoephedrine are found in breast milk in small amounts but the effect of this on breast-fed infants is not known.

Before you start to use it

Cetirizet D should be used with caution if you have:

- diabetes
- overactive thyroid gland
- high blood pressure
- abnormal rapid heart rate
- irregular heartbeat
- kidney or liver insufficiency
- enlargement of prostate
- urethral dysfunction

Use in Children: Although cetirizine and pseudoephedrine have both proven to be efficacious in children > 2 years, *Cetirizet-D* has not been tested in children < 12 years.

Use in the elderly: Caution is required if you are >50 years.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription.

Caution should be taken when taking concurrently with:

- Alcohol
- Diazepam
- Antihistamine
- Antacids
- Kaolin
- Sympathomimetics agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants or with monoamine oxidase inhibitors,
- Antihypertensive agent (e.g., bretylium, bethanidine, guanethidine, reserpine, debrisoquine, methyl dopa, alpha and beta-adrenergic blocking agents).

How to use *Cetirizet D*

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

How much to use

Adult and children 12 years and above:

The recommended dosage is 1 tablet, twice daily. Do not take more often than one tablet every twelve hours.

When to use it

Use as directed by your doctor or pharmacist.

The tablet should preferably be swallowed with some liquid and should not be chewed.

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How long to use it

Continue taking *Cetriset D* for as long as your doctor recommends.

Treatment should normally not exceed the symptomatic period. When adequate relief from nasal symptoms is obtained, treatment with an antihistaminic medicine should be continued, if appropriate.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

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 if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause:

Cetirizine hydrochloride

- Drowsiness

Pseudoephedrine hydrochloride

- Irritability
- Restless
- Tremor
- Convulsions
- Difficulty in urination
- Palpitations (feeling pounding of heartbeat)
- High blood pressure
- Tachycardia (an abnormally rapid heart rate)
- Arrhythmia (irregular heart rhythm)
- signs of central nervous system depression (sedation, temporary cessation of breathing, unconsciousness, skin become bluish) or stimulation (sleeping difficulty)

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors and pharmacists that are treating you that you are taking *Cetriset D*.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Tell your doctor immediately if you become pregnant while taking this medication.

Do not take any new medicines without consulting your doctor.

Do not give *Cetriset D* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

Caution should be exercised when driving a car or operating potentially dangerous machinery after taking *Cetriset D*. Concurrent use of *Cetriset D* with alcohol or sedatives should be avoided as this may impair performance.

Allergy skin test may be affected by antihistamines. Tell your doctor if you are taking *Cetriset D* before performing the test.

Side Effects

Like all medicines, *Cetriset D* can sometimes have side effects, although not everybody gets them.

Cetirizine Hydrochloride

There have been occasional reports of mild and transient side effects such as headache, dizziness, drowsiness, agitation, dry mouth, insomnia, somnolence (sleepiness), asthenia (weakness), tachycardia (abnormally rapid heart rate), nervousness, spinning sensation, nausea and gastrointestinal discomfort.

Pseudoephedrine Hydrochloride

Serious adverse effects associated with the use of pseudoephedrine are rare. Symptoms of central nervous system excitation may occur, including sleep disturbances and rarely hallucinations have been reported. Skin rashes, with or without irritation, have occasionally been reported. Urinary retention has been reported occasionally in men receiving pseudoephedrine; prostatic enlargement could have been an important predisposing factor. Other reactions include fear, anxiety, tenseness, restlessness, tremor, weakness, pallor (unhealthy pale appearance), breathing difficulty, dysuria (painful or difficult urination), seizures, CNS depression, arrhythmias (abnormal heart rhythm) and cardiovascular collapse (a sudden loss of effective blood flow) with low blood pressure.

Talk to your doctor or pharmacist if any of the side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of *Cetriset D*

Storage

Store in a cool dry place below 25°C. Protect from light.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

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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.

Date of revision

28/03/2017

Serial Number:

BPFK(R4/1)070317/00020

Product Description

What it looks like

A yellow coloured, circular, film coated tablet with break line marked on one side and plain on the other side.

Ingredients

Active ingredient(s):

Cetirizine Hydrochloride
Pseudoephedrine Hydrochloride

Inactive ingredients:

Lactose
Starch
Hydroxypropyl Methyl Cellulose
Ethyl Cellulose M50
Talc
Microcrystalline Cellulose
Magnesium Stearate
Colloidal Silicon Dioxide
Sodium Lauryl Sulphate
Polyvinyl Pyrrolidone K30
Sodium Starch Glycolate
Eudragit E 100
Dibutyl Phthalate
Titanium Dioxide
Polyethylene Glycol 6000
Quinoline Yellow Lake
Isopropyl Alcohol
Acetone
Purified Water

MAL number: MAL05072018AZ

Manufacturer

Sun Pharmaceutical Industries Ltd.
Survey No 214, Plot No. 20,
Govt. Industrial Area, Phase II,
Piparia, Silvassa-396230
U.T. Of Dadra & Nagar Haveli, India

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
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Jalan Meru, 41050 Klang, Selangor
Malaysia