

# CETYREC-AP FILM-COATED TABLET 5MG

Levocetirizine dihydrochloride (5 mg)

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## What Cetyrec-AP is used for

Cetyrec-AP is indicated for the symptomatic treatment of allergic rhinitis (including persistent allergic rhinitis) and chronic idiopathic urticaria.

## How Cetyrec-AP works

Cetyrec-AP contains the active ingredient Levocetirizine dihydrochloride. Levocetirizine is the active *R*-enantiomer of cetirizine, a second generation antihistamine. The drug is selective antagonism of histamine H<sub>1</sub>-receptors.

## Before you use Cetyrec-AP

### When you must not use it

- If you are allergic to Levocetirizine or any ingredient in the formulation or to cetirizine.
- If you have a severe kidney impairment with creatinine clearance below 10 ml/min or undergoing hemodialysis.

### Pregnancy and breastfeeding

Pregnancy Category B. Safety for use during pregnancy has not been established.

Levocetirizine is expected to be distributed into milk (since cetirizine is distributed into milk). The use of levocetirizine in breast-feeding mother is not recommended.

### Before you start to use it

- Talk to your doctor or pharmacist before taking Cetyrec-AP.
- If you are likely to be unable to empty your bladder (due to conditions such as a spinal cord injury or enlarged prostate), ask your doctor for advice.
- If you have an intolerance to some sugars, inform your doctor before using Cetyrec-AP.

### Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Other medicines may be affected by levocetirizine. They, in turn, may affect how well Cetyrec-AP works.

## How to use Cetyrec-AP

### How much to use

Always take Cetyrec-AP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose

- Adults and adolescents 12 years of age and above: The daily recommended dose is 5 mg (1 film-coated tablet).
- Children aged 6 - 12 years: The daily recommended dose is 5 mg (1 film-coated tablet).
- Elderly: Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment.
- Renal impairment: The dosing intervals must be individualized according to renal function

- Hepatic impairment: No dosage adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended.

## Recommended Dose

### Dosage and Administration

Levocetirizine dihydrochloride, 5 mg, film-coated tablet

The film-coated tablet must be taken orally, swallowed whole with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake.

### Duration of use

Intermittent allergic rhinitis (symptoms <4 days/week or for less than 4 weeks a year) has to be treated according to the disease and its history; it can be stopped once the symptoms have disappeared and can be restarted again when symptoms reappear.

In case of persistent allergic rhinitis (symptoms >4 days/week or for more than 4 weeks a year), continuous therapy can be proposed to the patient during the period of exposure to allergens. There is clinical experience with the use of levocetirizine for treatment periods of at least 6 months. In chronic urticaria and chronic allergic rhinitis, there is clinical experience of use of cetirizine (racemate) for up to one year.

### Route of Administration

For oral use.

### When to use it

Use as directed by your doctor or pharmacist.

Cetyrec-AP should be taken orally once daily without regard to meals.

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## How long to use it

Continue taking Cetyrec-AP for as long as your doctor recommend.

## If you forget to use it

Do not take a double dose to make up for the missed dose. 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.

## 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 attention.

Symptoms of overdose may include drowsiness in adults. In children agitation and restlessness may initially occur, followed by drowsiness.

## **While you are using Cetyrec-AP**

### Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Cetyrec-AP.

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

### Things you must not do

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

Do not take any new medicines without consulting your doctor.

Do not give Cetyrec-AP to others. It may harm them, even if their symptoms are the same as yours.

## Things to be careful of

You should be cautious if you take Cetyrec-AP at the same time as alcohol. In sensitive people, may cause additional reductions in alertness and impairment of performance.

Do not exceed the recommended dose and you have to take into account of how this medicine will affect you if you intend to drive, engage in potentially hazardous activities or operate machinery.

## **Side effects**

Like all medicines, Cetyrec-AP can cause side effects, although not everybody gets them. Adverse events observed in association with the use of Cetyrec-AP are listed below.

Gastrointestinal: Constipation, Diarrhea, Painful teething

Neurologic: Asthenia, Somnolence

Respiratory: Nasopharyngitis, Pharyngitis, Xerostomia

Other: Fatigue, Fever

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my)[Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## **Storage and Disposal of Cetyrec-AP**

### Storage

Keep out of the reach and sight of children.

Do not use Cetyrec-AP after the expiry date which is stated on the carton box and blister.

Store at a temperature below 30°C

### Disposal

Do not throw away any medicine via wastewater or household waste. Ask your

pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **Product Description**

### What it looks like

Biconvex, oval, white film coated tablet. One side has score and letter “L” and “C” on each side. Another side has figure “5”.

Dosage form: Film-coated tablet

Packaging: 10 tablets in Aluminium-Aluminium blister, which packed in carton box of 5 blisters.

### Ingredients

- Active ingredient

Each film-coated tablet contains Levocetirizine dihydrochloride 5 mg

- Inactive ingredients

Colloidal silicon dioxide, Granulated lactose, Microcrystalline cellulose PH 102, PVP-CL, Magnesium stearate, HPMC E15, HPMC E50, Talcum, Titanium dioxide, Propylene glycol

### MAL number:

MAL23056024AZ

## **Manufacturer**

COMMUNITY PHARMACY PUBLIC COMPANY LIMITED

1 Soi Khubon 11, Ramintra, Kannayao, Bangkok 10230, Thailand

## **Product Registration Holder**

STADPHARM

E-9-01, Oasis Square, Ara Damansara, No.2 Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia

## **Date of revision**

03/01/2025

## **Serial Number**

NPRA (R2)22/042