

**PATIENT INFORMATION LEAFLET FOR  
ALLECET**

**SCHEDULING STATUS:** S1

**ALLECET 10mg, tablet**

**Cetirizine dihydrochloride**

**Contains sugar: lactose monohydrate 102 mg**

**Read all of this leaflet carefully because it contains important information for you.**

ALLECET is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ALLECET carefully to get the best results from it:

- Keep this leaflet. You may need to read it again.
- Do not share ALLECET with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve after 5 days.

**What is in this leaflet**

1. What ALLECET is and what it is used for
2. What you need to know before you take ALLECET
3. How to take ALLECET
4. Possible side effects
5. How to store ALLECET

6. Contents of the pack and other information.

## 1. What ALLECET is and what it is used for

ALLECET is an antihistamine used to treat allergic conditions:

- Respiratory system such as allergic rhinitis (sneezing, runny nose, itching of the nasal passages and eyes and tearing of the eyes, runny nose) and hay fever and,
- Allergic skin conditions associated with pruritus (severe itching of the skin) or hives.

ALLECET may be used on its own or with other medicines to treat adults and children over 6 years.

## 2. What you need to know before you take ALLECET

### Do not take ALLECET:

- If you develop hives, itching, fever, swollen lymph glands or swelling of your face, lips or tongue, as these symptoms may be the first signs of a serious allergic reaction, which may be life-threatening. Contact your doctor immediately, as you might be allergic to cetirizine, or any other ingredients of ALLECET (ingredients listed in **section 6**).
- If you are allergic to hydroxyzine (an antihistamine similar to cetirizine).
- If you have severe problems with your kidneys.
- If you are pregnant and/or breastfeeding.
- To children under 2 years of age.
- If you have been told by your doctor that you have an intolerance to some sugars such as lactose.

## **Warnings and precautions**

Take special care with ALLECET:

- ALLECET may cause drowsiness in a small number of patients, especially if taken with alcohol.
- Before you take ALLECET, inform your doctor if you have problems with infrequent urination or you have been diagnosed with an enlarged prostate gland, increased pressure in the eye (glaucoma), obstruction in the gut, epilepsy or heart problems.
- If you are elderly, you are more likely to experience side effects of ALLECET.
- You should avoid taking alcohol while using ALLECET.
- You should stop taking ALLECET several days before going for any skin allergy tests as this medicine may suppress positive skin test results.
- Hypersensitivity reactions, including skin reactions, may occur, when ALLECET is stopped.
- If you are an epileptic patient (have fits), or a patient at risk of convulsions.

## **Children and adolescents**

The use of ALLECET in tablet form is not recommended in children younger than 6 years of age.

## **Other medicines and ALLECET**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of ALLECET with other medicines may cause undesirable interactions. Always consult with your healthcare professional before taking ALLECET with any other medicine.

Please inform your doctor if you are taking medicines for anxiety, medicines used to treat psychosis (such as schizophrenia), opioid analgesics (strong painkillers), sleeping tablets (hypnotics) and barbiturates.

Do not take ALLECET with alcohol as it can lead to impaired concentration and drowsiness.

Please inform your doctor if you are taking antimuscarinic medicines such as atropine, tricyclic antidepressants and monoamine oxidase inhibitors.

Please inform your doctor if you are taking aminoglycoside antibiotics such as tobramycin or gentamycin.

### **ALLECET with food, drink and alcohol**

ALLECET can be taken with or without meals, as food does not affect the extent of absorption.

Do not take ALLECET with alcohol.

### **Pregnancy, breastfeeding and fertility**

Do not take ALLECET if you are pregnant or breastfeeding your child.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ALLECET.

### **Driving and using machines**

Since ALLECET may make you feel dizzy or sleepy, you should use caution before driving a car or operating machinery, until you know if ALLECET affects your ability to perform these tasks.

It is not always possible to predict to what extent ALLECET may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ALLECET affects them.

### **ALLECET contains lactose**

ALLECET 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. If you are lactose intolerant, please speak to your doctor or pharmacist before taking ALLECET, as you may experience unwanted side effects, such as nausea, cramping, bloating, diarrhoea, and flatulence after ingestion of ALLECET.

### **3. How to take ALLECET**

Do not share medicines prescribed for you with any other person.

Always take ALLECET exactly as described in this leaflet or as your doctor, pharmacist or nurse has instructed you.

You should check with your doctor, pharmacist or nurse if you are unsure.

The tablets need to be swallowed with a glass of liquid. The tablet can be divided into 2 equal doses.

If you have problems with your kidneys, your doctor may reduce the dose of ALLECET, or, if you have severe kidney problems, ALLECET should not be taken (see **section 2**).

ALLECET should not be given to children under 2 years of age.

ALLECET tablets should not be given to children under 6 years of age, as it does not allow for the proper adjustment in dosage.

ALLECET must not be used for the treatment of asthma.

Adults and children 12 years or older:

Take 1 tablet once a day.

Children 6 to 12 years of age:

Give one tablet once daily as a single dose **OR** half a tablet (5 mg) in the morning and half a tablet in the evening.

Kidney disease (renal impairment):

Take half the recommended dose. However, in severe renal impairment, ALLECET should not be taken.

Moderate to Severe Liver disease (hepatic impairment):

Take half the recommended dose.

Do not increase your dose of ALLECET or take more frequent doses than those indicated by your doctor.

### **If you take more ALLECET than you should**

In the event of overdose, or if someone else has taken your medicine by mistake, you, or this person may experience any of the side effects listed below.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you forget to take ALLECET**

If you forget to take a dose of ALLECET, take the missed dose as soon as you remember, then wait 24 hours to take the following dose.

Do not take a double dose to make up for forgotten individual doses.

## **4. Possible side effects**

ALLECET can have side effects. Not all side effects reported for ALLECET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

If any of the following happens, stop taking ALLECET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, which may include swelling of eyelids, face or lips and tongue,
- Severe hives with blister formation or purple/red inflamed spots on your skin,
- Difficulty in swallowing or breathing,
- Wheezing or shortness of breath,
- Yellowing of the skin or eyes (jaundice),
- Convulsions (fits).

These are all very serious side effects. If you have them, you may have had a serious reaction to ALLECET. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fast pounding or uneven heartbeat,
- Tremors (uncontrolled shaking),
- Thoughts of killing yourself (suicidal ideation),
- Memory impairment (loss) or,
- Loss of consciousness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- *Frequent side effects include:*
  - Feeling dizzy,
  - Feeling drowsy or sleepy,
  - Sore throat,
  - Headaches,
  - Dry mouth,
  - Runny and/or itchy nose,
  - Nausea,
  - Feeling tired,
  - Diarrhoea.
  
- *Less frequent side effects include:*

- Stomach pain,
  - A wheezing sound when you inhale, thickening of mucous (phlegm),
  - Feeling light-headed,
  - Ringing sound in your ears,
  - Vertigo (feeling unbalanced),
  - Constipation,
  - Sensitivity to light,
  - Hair loss, sweating,
  - Anaemia with symptoms such as fatigue, pale skin, abnormal blood test results.
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- *Side effects with unknown frequency:*
    - Feeling weak and/or generally unwell,
    - Hallucinations (seeing and/or hearing things that are not real) and nightmares,
    - Tingling or pricking feeling in your extremities (pins and needles) e.g. fingers and feet,
    - Feeling agitated,
    - Bleeding and bruising easily,
    - Confusion, depression, insomnia (problems sleeping),
    - Distorted sense of taste,
    - Problems with eyesight,
    - Abnormal liver function,
    - Problems (pain or difficulty) urinating,
    - Bed-wetting,

- Twitching, muscle spasms, unusual limb movements,
- Weight gain,
- Swelling or fluid retention,
- Nervousness,
- Increased appetite,
- Rash with blisters containing pus,
- Muscle and joint pain,
- Itchy rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “Adverse drug reaction and quality problem reporting form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/> or to Cipla Medpro (Pty) Ltd. by e-mail: [drugsafetysa@cipla.com](mailto:drugsafetysa@cipla.com) or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ALLECET.

### **5. How to store ALLECET**

Store at or below 25 ° C in a dry place.

Store all medicines out of reach of children.

Store in the original container.

Do not use after the expiry date stated on the carton or blister foil.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What ALLECET contains**

The active ingredient in ALLECET is cetirizine dihydrochloride. Cetirizine dihydrochloride is an antihistamine used to treat allergic conditions such as allergic rhinitis, hay fever and itching.

Each ALLECET tablet contains 10 mg of cetirizine dihydrochloride.

The inactive ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, purified talc and Opadry white (film-coating) [containing hypromellose, lactose monohydrate, macrogol/PEG 4000, sodium citrate dihydrate, titanium dioxide].

### **What ALLECET looks like and contents of the pack**

White, circular, biconvex, film-coated tablets with "A" debossed on one side and a deep score on the other.

ALLECET is packed in aluminium foil and colourless, transparent PVC film strips of 10 tablets, packed in 10's or 30's in an outer carton.

### **Holder of certificate of registration**

**CIPLA MEDPRO (PTY) LTD.**

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