

**PATIENT INFORMATION LEAFLET FOR
ALLECET SYRUP**

SCHEDULING STATUS

S1

ALLECET SYRUP, 1 mg/ 1 mL

Cetirizine dihydrochloride

Contains sugar: sorbitol 2,5 g/ 5 mL

Contains sweetener: monoammonium glycerrhizinate 0,01 g/ 5 mL

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

ALLECET SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ALLECET SYRUP carefully to get the best results from it:

- Keep this leaflet. You may need to read it again.
- Do not share ALLECET SYRUP with any other person.
- Ask your 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 SYRUP is and what it is used for
2. What you need to know before you take ALLECET SYRUP
3. How to take ALLECET SYRUP

4. Possible side effects
5. How to store ALLECET SYRUP
6. Contents of the pack and other information.

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

ALLECET SYRUP is an antihistamine used to treat allergic conditions affecting the:

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

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

Do not take / administer ALLECET SYRUP:

- If you are hypersensitive (allergic) to cetirizine, or any other ingredients of ALLECET SYRUP.
- 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 your baby.
- To children under 2 years of age.

Warnings and precautions

Take special care with ALLECET SYRUP:

ALLECET SYRUP may cause drowsiness in a small number of patients.

Before you take ALLECET SYRUP, 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.

You should avoid taking alcohol while using ALLECET SYRUP.

If you are elderly, you are more likely to experience side effects of ALLECET SYRUP.

You should stop taking ALLECET SYRUP several days before going for any allergy skin tests as this medicine may suppress positive skin test results.

Hypersensitivity reactions, including skin reactions, may occur, when ALLECET SYRUP is stopped.

Other medicines and ALLECET SYRUP

**Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)**

Taking ALLECET SYRUP with other medicines may cause undesirable interactions. Always consult with your healthcare professional before taking ALLECET SYRUP 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 SYRUP 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 SYRUP with food, drink and alcohol

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

Alcohol should be avoided.

Pregnancy, breastfeeding and fertility

Do not take ALLECET SYRUP 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 healthcare professional for advice before taking ALLECET SYRUP.

Driving and using machines

ALLECET SYRUP may cause drowsiness. Do not drive or operate machinery if you feel drowsy/sleepy after taking ALLECET SYRUP.

It is not always possible to predict to what extent ALLECET SYRUP 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 SYRUP affects them.

Important information about some of the ingredients of ALLECET SYRUP

The preservatives methyl parahydroxybenzoate and propyl hydroxybenzoate included in ALLECET SYRUP may cause allergic reactions (possibly delayed).

ALLECET SYRUP contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take ALLECET SYRUP.

3. How to take ALLECET SYRUP

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

Always take ALLECET SYRUP exactly as your doctor, pharmacist or nurse has instructed you. You should check with your doctor, pharmacist or nurse if you are unsure.

If you have problems with your kidneys or liver your doctor may reduce the dose of ALLECET SYRUP.

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

Adults and children 12 years or older:

Take 10 mL (two medicine measures) once a day.

Children 6 to 12 years of age:

Give 10 mL (two medicine measures) once daily as a single dose **OR** 5 mL (one medicine measure) in the morning and 5 mL (one medicine measure) in the evening.

Children 2 to 6 years of age:

Give 5 mL (one medicine measure) once a day as a single dose **OR** 2,5 mL (half a medicine measure) in the morning and 2,5 mL (half a medicine measure) in the evening.

If you have a kidney or liver disorder, you should take half the recommended dose.

If you take more ALLECET SYRUP 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 control centre.**

If you forget to take ALLECET SYRUP

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

4. Possible side effects

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

If any of the following happens, stop taking ALLECET SYRUP 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,
- Severe hives with blister formation or purple/red inflamed spots on your skin,
- Difficulty in swallowing or breathing,
- Wheezing or shortness of breath.

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

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

- Yellowing of the skin and eyes, also called jaundice,
- Convulsions (fits),
- 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 or drowsy
 - Sore throat
 - Headaches
 - Dry mouth
 - Runny and/or itchy nose
 - Nausea
 - Feeling tired
 - Diarrhoea.

- Less frequent side effects include:
 - Feeling weak and or generally unwell
 - Anaemia with symptoms such as fatigue, pale skin, abnormal blood test results
 - Stomach pain
 - 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
 - A wheezing sound when you inhale, thickening of mucous (phlegm)
 - Hair loss, sweating
 - Itchy rash
 - Confusion, depression, insomnia (problems sleeping)
 - Sensitivity to light
 - Distorted sense of taste
 - Problems with eye sight
 - Abnormal liver function
 - Problems (pain or difficulty) urinating
 - Bed-wetting
 - Twitching, muscle spasms, unusual limb movements
 - Weight gain
 - Swelling or fluid retention.

- Side effects with unknown frequency:
 - In-coordination
 - Nervousness
 - Ringing sound in your ears
 - Feeling light-headed
 - Constipation, vomiting, increased appetite.
 - Rash with blisters containing pus
 - Muscle and joint pain
 - Vertigo (feeling unbalanced).

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or to Cipla Medpro (Pty) Ltd. by e-mail: 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 SYRUP.

5. How to store ALLECET SYRUP

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

Do not use after the expiry date stated on the bottle.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What ALLECET SYRUP contains

The active ingredient in ALLECET SYRUP is cetirizine dihydrochloride.

Each 1 mL of ALLECET SYRUP contains 1 mg of cetirizine dihydrochloride.

Preservatives:

Methyl parahydroxybenzoate: 0,2 % m/v

Propyl parahydroxybenzoate: 0,02 % m/v

The inactive ingredients are flavourants (Pineapple Singapore and Sweet Orange No. 1), glycerol, monoammonium glycerrhizinate, propylene glycol, sodium citrate dihydrate, liquid sorbitol and purified water.

ALLECET SYRUP contains sugar (2,5 g sorbitol per 5mL).

What ALLECET SYRUP looks like and contents of the pack

A clear, colourless, pineapple and sweet orange flavoured syrup with a sweet taste.

ALLECET SYRUP is packed in 50 mL or 150 mL amber glass bottles stoppered with a plastic or metal cap fitted with an expanded polyethylene (EPE) or low density polyethylene (LDPE) liner, or in amber PET (plastic) bottles stoppered with a plastic or metal cap fitted with a low density polyethylene (LDPE) or expanded polyethylene (EPE) liner, packed in an outer carton, with a polypropylene measuring cup.

Holder of Certificate of Registration

Cipla Medpro (Pty) Ltd.

Building 9, Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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