

ANNOTATED PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ALLERMINE TABLETS 10 mg

Cetirizine dihydrochloride

Contains sugar: Lactose monohydrate 74,30 mg

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

ALLERMINE is available without a doctor's prescription. Nevertheless, you still need to use ALLERMINE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALLERMINE 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 ALLERMINE is and what it is used for
2. What you need to know before you take ALLERMINE
3. How to take ALLERMINE
4. Possible side effects
5. How to store ALLERMINE
6. Contents of the pack and other information

1. What ALLERMINE is and what it is used for

Allermine contains cetirizine dihydrochloride. It is an antihistamine to treat the following allergic conditions:

- Respiratory conditions such as allergic rhinitis (symptoms such as sneezing, stuffy or runny nose, itchy eyes and coughing caused by allergens in the air) and hay fever (your body has an allergic reaction to things like pollen from trees, grass or flowers which causes sneezing, a stuffy or runny nose, itchy eyes, and a sore throat);
- Allergic conditions of the skin which cause severe itching e.g. hives (raised, red, itchy bumps or welts on your skin).

2. What you need to know before you take ALLERMINE

Do not take ALLERMINE:

- If you are hypersensitive (allergic) to cetirizine dihydrochloride or any of the other ingredients of ALLERMINE (listed in section 5);
- If you are allergic to hydroxyzine or to piperazine derivatives (closely related active ingredients of other medicines);
- If you are breastfeeding because cetirizine dihydrochloride is excreted into the breast milk;
- If you are pregnant;
- For children under the age of 2 years;
- If you have a severe kidney disease requiring dialysis.

Warnings and precautions

Take special care with ALLERMINE:

- ALLERMINE can cause drowsiness, therefore take special care when taking it together with alcohol;

- If you have porphyria;
- Before you take ALLERMINE, inform your doctor if you have problems with passing urine (like spinal cord problems or prostate or bladder problems) or if you have an enlarged prostate;
- Before you take ALLERMINE, inform your doctor if you have increased pressure in the eye or a blockage in the stomach;
- If you are an epileptic patient or a patient at risk of convulsions (you have fits), you should ask your doctor for advice;
- You should stop taking ALLERMINE at least 3 days before taking a skin allergy test because it can prevent positive skin test results;
- If you stop taking ALLERMINE, you might develop itching of the skin and hives, even if you did not have these symptoms before. Please consult your doctor;
- ALLERMINE contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

Children

ALLERMINE should not be given to children younger than 6 years as the necessary dosage adjustment cannot be done with the tablet formulation.

Other medicines and ALLERMINE

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

Avoid taking ALLERMINE with alcohol or other medicines that cause sedation. Examples of these medicines are anti-anxiety medicines, sleeping medicines, anti-

psychotic medicines and pain killers. They can increase drowsiness and can affect your concentration.

The antimuscarinic side effects of ALLERMINE such as dry mouth, sore throat, urinary retention, blurred vision etc., may be increased by other medicines with the same side effects. Examples of these medicines are atropine, tricyclic antidepressants and monoamine oxidase inhibitors.

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

ALLERMINE with food, drink and alcohol

Food does not affect the extent of absorption of ALLERMINE.

Do not take ALLERMINE with alcohol.

Pregnancy, breastfeeding and fertility

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 this medicine.

Do not take ALLERMINE if you are pregnant.

ALLERMINE passes into breastmilk. Therefore, do not take ALLERMINE if you are breastfeeding.

Driving and using machines

ALLERMINE tablets usually don't cause drowsiness, but a few people may feel sleepy after taking them. To be safe, see how the medicine affects you before driving or doing anything that requires focus. Drinking alcohol or taking certain medications that affect the brain, like sedatives, can increase this drowsy effect.

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

ALLERMINE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to take ALLERMINE

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

Always take ALLERMINE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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

The usual dose is:

Adults or children 12 years of age or older:

One 10 mg tablet once a day.

Children 6 to 12 years old:

One 10 mg tablet once a day or 5 mg (half a tablet) twice a day.

No dose adjustment is necessary in healthy elderly patients with normal renal (kidney) function.

Patients with kidney disease:

Patients with moderate kidney disease are recommended to take 5 mg daily.

If you suffer from severe kidney disease, please contact your doctor who may adjust the dose accordingly.

If your child suffers from kidney disease, please contact your doctor who may adjust the dose according to your child's needs.

Patients with liver disease:

Patients with moderate to severe liver disease are recommended to take 5 mg daily.

Paediatric population

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

If you feel that the effect of ALLERMINE is too weak or too strong, please consult your doctor.

The duration of treatment depends on the type, duration and course of your complaints. Please ask your doctor or pharmacist for advice.

If you take more ALLERMINE than you should

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in completely emptying the bladder) have been reported.

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

If you forget to take ALLERMINE

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

If you stop taking using ALLERMINE

Rarely, pruritus (intense itching) and/or urticaria (hives) may return if you stop taking ALLERMINE. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

ALLERMINE can have side effects.

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

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

- Allergic reactions which may include swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- 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 ALLERMINE. 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

- Somnolence (sleepiness);
- Dizziness, headache;
- Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children);
- Dry mouth, nausea, gastrointestinal discomfort, diarrhoea, constipation;

- Fatigue (tiredness);

Less frequent

- Leucopenia (low levels of white blood cells), Haemolytic anaemia (excessive breakdown of red blood cells causing tiredness and pale skin), agranulocytosis (very low level of a type of white blood cell, which are important for fighting off infection);
- Thrombocytopenia (low levels of blood platelets which can lead to bleeding and bruising);
- Agitation, aggression, confusion, depression, hallucination (seeing, hearing or feeling things that are not there), insomnia, tics (habit spasm);
- Paraesthesia (abnormal feelings of the skin), dysgeusia (altered taste), syncope (fainting), tremor, dystonia (abnormal prolonged muscular contractions), dyskinesia (involuntary movements);
- Blurred vision, accommodation disorder (difficulty focusing), oculogyric crisis (eyes having uncontrolled circular movements);
- Ringing in the ears;
- Hypotension (low blood pressure);
- Thickening of mucous, bronchospasm (breathing difficulty);
- Abdominal pain;
- Liver function abnormal;
- Pruritus (itchy skin), rash, urticaria (hives), angioneurotic oedema (rapid swelling beneath the skin), fixed drug eruption (drug allergy), photosensitivity (sensitivity to light), hair loss, sweating;
- Painful urination, bed wetting
- Asthenia (extreme fatigue), malaise (feeling unwell), oedema (swelling)
- Weight increased.

Frequency unknown

- Increased appetite;
- Nightmare;
- Anxiety, nervousness
- Vertigo (sensation of rotation or movement);
- Hepatitis (inflammation of the liver);
- Acute generalized exanthematous pustulosis (rash with blisters containing pus);
- Arthralgia (joint pain), myalgia (muscular pain);
- Urinary retention (inability to completely empty the urinary bladder);

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ALLERMINE.

5. How to store ALLERMINE

- Store below 25 °C in well-closed containers, protected from light.
- Do not remove the blister from the carton until required for use.
- Store all medicines out of reach of children.
- Store in the original package.

- There are no special storage instructions for ALLERMINE.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the carton.
- 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 ALLERMINE contains

The active substance is cetirizine dihydrochloride.

Tablet core: Lactose monohydrate, Magnesium Stearate, Povidone K 29/32, Pregelatinised Maize Starch.

Coating: Opadry White Y-1-7000 (Hydroxypropylmethylcellulose 5 cP (E464), Polyethylene Glycol 400, Talc, Titanium Dioxide (E171)).

What ALLERMINE looks like and contents of the pack

White film-coated, capsule-shaped tablet with a break line on one side.

ALLERMINE tablets are supplied in:

PVC/Aluminium foil blister strips of 10 tablets, packed in unit cartons of 10 or 30 tablets, or

White, opaque polypropylene securitainers containing 30 tablets, or

Amber glass containers containing 30 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.trinitypharma.co.za