

PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

ALLESOOTHE 10 mg Film coated tablets

Cetirizine dihydrochloride

ALLESOOTHE contains sugar (lactose monohydrate, 63,70 mg per film coated tablet)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ALLESOOTHE 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.

What is in this leaflet

1. What ALLESOOTHE is and what it is used for
2. What you need to know before you take ALLESOOTHE
3. How to take ALLESOOTHE
4. Possible side effects
5. How to store ALLESOOTHE
6. Contents of the pack and other information

1. What ALLESOOTHE is and what it is used for

PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

ALLESOOTHE is a film coated tablet that contains 10 mg cetirizine dihydrochloride as the active ingredient.

ALLESOOTHE is used for the management of allergies, including:

- Hay fever,
- Allergic rhinitis and
- Allergic skin conditions that are associate with itching.

2. What you need to know before you take ALLESOOTHE

Do not take ALLESOOTHE

- If you are hypersensitive (allergic) to cetirizine, hydroxyzine, and any piperazine derivatives or any of the other ingredients of ALLESOOTHE (listed in section 6)
- If you have severe kidney disease and your creatinine clearance is less than 30 mL/min
- If you suffer from asthma and have previously experienced side effects to antihistamines
- If you are pregnant, as safety of ALLESOOTHE during pregnancy has not been established (see Pregnancy, breastfeeding and fertility)
- If you are breastfeeding, as ALLESOOTHE is excreted into breast milk (see Pregnancy, breastfeeding and fertility).

Warnings and Precautions

Take special care with ALLESOOTHE:

- If you have any condition that results in urinary retention (difficulty in emptying your bladder)
- ALLESOOTHE a non-sedating medicine, however some patients may become drowsy after taking the tablet (see Driving and using machinery)
- If your kidney(s) or liver is not functioning normally your daily dosage should be reduced (see 3. How to take ALLESOOTHE)
- An alternative dosage form is to be used if your kidney(s) or liver is not



PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

functioning normally because ALLESOOTHE is a film coated tablet that cannot be halved.

- If your child's kidneys are not functioning normally, consult your doctor, as the dosage may have to be reduced.
- If you are an epileptic or at risk of convulsions.
- If you are scheduled for an allergy skin test, because ALLESOOTHE can interfere with the test results. It is recommended to stop taking ALLESOOTHE 3 days prior to your scheduled allergy skin test.
- When taking ALLESOOTHE, alcohol should not be consumed (see Taking ALLESOOTHE with food and drink)
- If you are elderly, you are more likely to experience side effects of ALLESOOTHE.

Other medicines and ALLESOOTHE

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

- Tell your doctor or pharmacist if you are currently taking anticoagulant medicine (used to thin your blood and prevent blood clots from forming).
- As with other antihistamines it is advisable to avoid excessive alcohol consumption.

ALLESOOTHE with food, drink and alcohol

ALLESOOTHE can be taken with or without food.

Do not consume alcohol while taking ALLESOOTHE, as this may make you feel sleepier.

Pregnancy and breastfeeding

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 provider for

PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

advice before taking this medicine.

Do not take ALLESOOTHE if you are pregnant or breastfeeding your baby (see Do not take ALLESOOTHE).

Driving and using machines

ALLESOOTHE does not produce significant sedative effects. However, a small number of individuals may experience sedation that results in drowsiness.

- Therefore, it is recommended to determine your individual response to ALLESOOTHE before driving a vehicle or using machines.
- Do not exceed the recommended dose if driving a vehicle or operating machinery, even though ALLESOOTHE has no or negligible influence on these parameters.
- This sedative effect may be increased by the simultaneous intake of alcohol.

ALLESOOTHE contains sugar (lactose monohydrate)

ALLESOOTHE contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ALLESOOTHE

Do not share your medicines with any other person.

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

The usual dose of ALLESOOTHE is:

- Adults and children 12 years of age or older: Take 1 (one) tablet daily.
- Children 6 to 12 years of age: Take 1 (one) tablet daily.
- If your kidney(s) or liver is not functioning normally, speak to your doctor before taking ALLESOOTHE because the daily dosage must be reduced. An alternative dosage form is to be used because ALLESOOTHE is a film



PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

coated tablet that cannot be halved.

- No dose adjustment is necessary in healthy elderly patients with normal kidney function.

Do not exceed the recommended daily dosage.

If you have the impression that the effect of ALLESOOTHE is too strong or too weak, tell your doctor or pharmacist.

If you take more ALLESOOTHE than you should

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

The following may be signs and symptoms of overdosage:

- Drowsiness, confusion, diarrhoea, dizziness, headache, general unwell feeling, dilated pupils, restlessness, stunned state in which it is difficult to get a response, feeling sleepy or tired, agitated, skin rash, passing less urine than is normal for you, uncontrolled trembling or shaking, and rapid heart rate. (see Possible side effects)

If you forget to take a dose of ALLESOOTHE

Always take ALLESOOTHE as indicated (see 3. How to take ALLESOOTHE). If you have missed a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose of ALLESOOTHE to make up for forgotten individual doses.

If you stop taking ALLESOOTHE

When stopping treatment with ALLESOOTHE, you may experience severe itching or raised bumps on the skin. If this occurs, restart treatment with ALLESOOTHE,

PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

and the side effects should stop.

4. Possible side effects

ALLESOOTHE can cause side effects.

Not all side effects reported for ALLESOOTHE are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking ALLESOOTHE, please consult your healthcare professional for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ALLESOOTHE. 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:

- Pharyngitis (inflammation of the throat), rhinitis (inflammation and swelling in the nose).
- Signs of recurrent infections, such as fever and a sore throat.
- Bleeding or bruising more easily than normal.
- Fast or irregular heartbeat.
- Liver disorders including increase in liver enzymes and bilirubin (dark urine, light-coloured, bloody or black stools, loss of appetite).
- Yellowing of the skin and eyes, also called jaundice.
- Urinary tract disorders including painful urination (discomfort or burning sensation when passing urine) and inability to control urination.



PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

- Recurring thoughts of harming or killing yourself
- Inflammation of the liver (hepatitis).

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

Tell your doctor if you notice any of the following:

Frequent

- Drowsiness
- Dizziness, headache
- Abdominal pain, dry mouth, nausea (feeling sick).
- Fatigue (tiredness).

Less frequent

- Agitation, aggression, confusion, depression, hallucinations, insomnia and repetitive spasm-like movements.
- Convulsions (fits/seizures), distortion of sense of taste, fainting, movement disorders, pins and needles sensation, uncontrollable twitching and tremor, drowsiness.
- Unusual muscle tone causing distortion of the body (dystonia).
- Eye accommodation disorder, blurred vision, abnormal movement of the eye.
- Ringing sounds in the ear (tinnitus), sensation of spinning (vertigo)
- Low blood pressure (characterised by dizziness and light-headedness).
- Thickening of mucous,
- Diarrhoea (may be frequent in children aged 6 to 12 years), gastrointestinal discomfort, constipation.
- Hair loss (temporary), sweating.
- Aching muscles
- Painful or a burning sensation when urinating, accidental urinating
- Malaise (generally feeling unwell), physical weakness, swelling and weight



PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

gain.

Side effects of unknown frequency:

- Increased appetite.
- Nightmare
- Loss of memory or memory impairment, anxiety and nervousness
- Acute generalised exanthematous pustulosis (AGEP), a reaction to medicine characterised by sudden skin eruptions.
- Joint pain
- Difficulty in emptying the 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. 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 ALLESOOTHE.

5. How to store ALLESOOTHE

- Store at or below 30 °C.
- Protect from light and moisture.
- Do not remove blister strips from the outer carton until required for use.
- Do not take ALLESOOTHE after the expiry date stated on the package.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**



PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

6. Contents of the pack and other information

What ALLESOOTHE contains

The active substance in 10 mg cetirizine dihydrochloride.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, magnesium stearate and microcrystalline cellulose.

Coating materials include hypromellose, polyethylene glycol, purified talc and titanium dioxide.

What ALLESOOTHE looks like and contents of the pack

White, slightly biconvex, round, film coated tablet, plain on both sides.

ALLESOOTHE is supplied in PVC-Alu blister strips of 10 tablets in pack sizes of 10, 30 and 100 tablets.

The blister strips will be placed in an outer carton.

Holder of the certificate of registration

Forrester Pharma (Pty) Ltd.

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

This leaflet was revised in

27 February 2025

Registration number

Cetirizine dihydrochloride Film coated tablets 10 mg
Forrester Pharma (Pty) Ltd.

PROPOSED PATIENT INFORMATION LEAFLET FOR ALLESOOTHE

48/5.7.1/1197