

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

ALLERWAY 5, 5 mg, film-coated tablets

Levocetirizine dihydrochloride

Contains sugar (lactose monohydrate)

Each film-coated tablet contains 88,00 mg lactose monohydrate.

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

ALLERWAY 5 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ALLERWAY 5 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALLERWAY 5 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You or your child must see a doctor if your symptoms worsen or do not improve after 14 to 21 days.

What is in this leaflet

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

1. What ALLERWAY 5 is and what it is used for

ALLERWAY 5 is an antiallergic medication.

ALLERWAY 5 is used to treat symptoms associated with allergic conditions, such as:

- Seasonal and year-round allergic rhinitis (nose and eye itching, watery eyes, stuffy or runny nose, sneezing)
- Long-term hives/nettle rash with no known cause (chronic idiopathic urticaria).

2. What you need to know before you take ALLERWAY 5

Do not take ALLERWAY 5

- if you or your child are hypersensitive (allergic) to levocetirizine dihydrochloride, to cetirizine, to hydroxyzine or any other substances with a similar chemical structure or to one of the other ingredients of ALLERWAY 5 (see “What ALLERWAY 5 contains”)
- if you are pregnant or breastfeeding your baby (see “Pregnancy and breastfeeding”)
- if you or your child have a severe impairment of kidney function (severe kidney failure with creatinine clearance below 10 ml/min)
- if you or your child are on dialysis

- if your child is under the age of 6 years.

Warnings and precautions

- Some patients being treated with ALLERWAY 5 may experience sedative effects such as drowsiness or sleepiness. The simultaneous use of alcohol or medicines affecting the central nervous system may add to these effects caused by ALLERWAY 5. This may have an effect on alertness and ability to drive and use machines (see “Driving and using machines”).
- Take special care if you have predisposing factors of urinary retention (inability to completely empty your bladder) (eg., spinal cord lesions, prostatic hyperplasia (enlarged prostate)) as ALLERWAY 5 may increase the risk of urinary retention.
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of ALLERWAY 5 may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking ALLERWAY 5 for several days before testing. This medicine may affect your allergy test results.
- ALLERWAY 5 is not suitable for children under the age of 6 (see Do not take ALLERWAY 5).

Other medicines and ALLERWAY 5

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Some medicines may interact with ALLERWAY 5.

Before taking ALLERWAY 5, tell your doctor if you are using any of the following medicines

- Central nervous system depressants (medicines used to slow down brain activity) and that may make you sleepy (such as other cold or allergy medicine, sleeping pills, muscle relaxers, and medicines for seizures, depression, or anxiety)
- Ritonavir (a medicine used to treat HIV/AIDS infection)

- Theophylline (a medicine used to treat respiratory diseases such as asthma).

ALLERWAY 5 with food and alcohol

You may take ALLERWAY 5 with or without food. ALLERWAY 5 should be taken with liquid.

Caution is advised if ALLERWAY 5 is taken at the same time as alcohol or other medicines acting on the brain. In sensitive patients, the simultaneous use of ALLERWAY 5 and alcohol or medicines acting on the brain may have effects on alertness, impairment of performance and ability to drive and use machines.

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 health care provider for advice before taking ALLERWAY 5.

- Do not take ALLERWAY 5 if you are breastfeeding your baby, since the active ingredient (levocetirizine dihydrochloride) passes into breast milk.
- Do not take ALLERWAY 5 if you are pregnant or planning to become pregnant, as safety during pregnancy has not been established.

Driving and using machines

Some patients being treated with ALLERWAY 5 may experience somnolence/drowsiness, tiredness and exhaustion. If you experience these, you should avoid driving, engaging in potentially hazardous activities or operating machinery.

ALLERWAY 5 contains lactose

ALLERWAY 5 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars such as galactose or lactose (milk sugar), you should not take ALLERWAY 5.

3. How to take ALLERWAY 5

Always take ALLERWAY 5 exactly as described in this leaflet or as your doctor or pharmacist have told you. You should check with your doctor or pharmacist if you are not sure.

- You should swallow the tablet with water.
- ALLERWAY 5 may be taken with or without food.

The usual dose is:

- Adults or adolescents aged 12 years and older:
The daily recommended dose is one tablet.
- Children aged 6 to 12 years:
The daily recommended dose is one tablet.

ALLERWAY 5 must not be used in children under 6 years of age.

Kidney and liver impairment

Adults with impaired kidney function may be given a lower dose according to the severity of their kidney disease, the dose will be determined by your doctor.

In children with impaired kidney function, the dose will be chosen on the basis of body weight.

Patients who have severe impairment of kidney function (creatinine clearance below 10 ml/min) must not take ALLERWAY 5.

No adaptation of the dose is necessary in elderly patients, provided their kidney function is normal.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of their kidney disease; the dose will be determined by your doctor.

If you have the impression that the effect of ALLERWAY 5 is too strong or too weak, tell your doctor or pharmacist.

How long should you take ALLERWAY 5?

The duration of use depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more ALLERWAY 5 than you should

- An overdose may cause drowsiness in adults.
- Children may initially show agitation and restlessness followed by drowsiness.

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

If you forget to take ALLERWAY 5

If you forget to take ALLERWAY 5, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day.

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

If you stop taking ALLERWAY 5

Pruritus (intense itching) may occur if you stop taking ALLERWAY 5, even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

4. Possible side effects

ALLERWAY 5 can have side effects.

Not all side effects reported for ALLERWAY 5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALLERWAY 5, please consult your health care provider for advice.

If any of the following happens, stop taking ALLERWAY 5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

Side effects with unknown frequencies:

- Swelling of the mouth, tongue, face and/or throat
- Difficulty breathing (chest tightness or wheezing) or swallowing
- Rash or itching
- Sudden fall in blood pressure leading to collapse or shock, which may be fatal.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ALLERWAY 5. 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:

Less frequent side effects:

- Seizure (fits)
- Abnormal heartbeats
- Recurring thoughts of or preoccupation with suicide, aggressive or agitated behaviour.

Side effects – frequency unknown:

- Hallucinations (false perceptions), depression.

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

Tell your doctor if you notice any of the following:

Frequently reported side effects include:

- Shortness of breath
- Headache
- Somnolence/drowsiness
- Pins and needles
- Dizziness
- Fainting
- Tremor (shaking)
- Distortion of the sense of taste

- Tiredness
- Sore throat, runny or stuffy nose
- Dry mouth, constipation
- Problems with sleeping.

Less frequently reported side effects include:

- Hepatitis (inflammation of the liver), abnormal liver function tests
- Problems with vision
- Nausea (feeling sick), vomiting, abdominal pain, diarrhoea and gastrointestinal (affecting the stomach and intestines) discomfort
- Skin reactions, rashes, skin eruption, urticaria (swelling, redness and itchiness of the skin), itchiness
- Muscular pain
- Feeling of weakness, feeling unwell
- Insomnia (inability to sleep).

Side effects with unknown frequencies include:

- Weight gain
- Increased appetite
- Nightmares
- Blurred vision, oculogyration (eyes having uncontrolled circular movements)
- Sensation of rotation or movement
- Increased heart rate
- Joint pain
- Painful or difficult urination, inability to completely empty the bladder
- Swelling caused by fluid
- Swelling caused by excess fluid trapped in your body's tissues
- Pruritus (intense itching) upon discontinuation.

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>.

By reporting side effects, you can help provide more information on the safety of ALLERWAY 5.

5. How to store ALLERWAY 5

Store all medicines out of reach of children.

Store at or below 25 °C.

The HDPE containers must be tightly closed.

The blisters must be kept in the carton until required for use.

Do not store in bathrooms.

Do not use after the expiry date stated on the container. 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 ALLERWAY 5 contains

- The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains levocetirizine dihydrochloride 5 mg.
- The other ingredients are: Lactose monohydrate, magnesium stearate, microcrystalline cellulose and silica colloidal anhydrous. The Opadry™ white film-coating material contains: Hypromellose, macrogol and titanium dioxide (C. I. No: 77891).

What ALLERWAY 5 looks like and contents of the pack

ALLERWAY 5

White to off white, oval, film-coated biconvex tablets and plain on both sides.

The tablets are packed in:

White HDPE containers in a pack size of 30 tablets or in a silver-coloured Alu/Alu (foil) blister strip containing 10 tablets, packed in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

17 July 2024

Registration number

43/5.7.1/0815

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories

(Pty) Ltd. website: <http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the

Holder of Certificate of Registration:

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