

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 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).

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

Do not take ALLERWAY 5

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine (see “What ALLERWAY 5 contains”)
- Children under the age of 6 years
- If you are pregnant or breastfeeding (see “Pregnancy and breastfeeding”)
- if you have kidney disease

Warnings and precautions

Ask a doctor before use if you have:

- ever had trouble urinating or emptying your bladder

When using this product:

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if:

- you have trouble urinating or emptying your bladder
- an allergic reaction to this product occurs. Seek medical help right away.

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 infection)
- Theophylline (a medicine used to treat lung diseases).

Taking ALLERWAY 5 with food and drink

- Avoid alcoholic drinks (see “Warnings and precautions”).

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.

- You should not take ALLERWAY 5 if you are breastfeeding your baby, since the active ingredient (levocetirizine dihydrochloride) passes into breast milk.
- You should 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

- You may experience sleepiness/drowsiness, tiredness and weakness when treated with ALLERWAY 5. If you are intending to drive, engage in potentially hazardous activities or use machines, you are advised to first wait until you know how ALLERWAY 5 affects you.

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.

Directions

Adults 65 years of age and older	Ask a doctor
Adults and adolescents 12 - 64 years of age	<ul style="list-style-type: none"> • take 1 tablet (5 mg) once daily in the evening • do not take more than 1 tablet (5 mg) in 24 hours
Children 6 - 11 years	<ul style="list-style-type: none"> • take 1 tablet (5 mg) once daily in the evening • do not take more than 1 tablet (5 mg) in 24 hours
Duration of use	The duration of treatment depends on the type, duration and course of the complaints. However, patients must talk to a doctor if they do not feel better or feel worse after 14 – 21 days.
Children below 6 years of age	Do not use
Consumers with kidney disease	Do not use

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

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

If you forget to take ALLERWAY 5

- Do not take a double dose to make up for a forgotten dose.
- Skip the missed dose and take the next tablet at the usual time.

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:

- Swelling of the mouth, tongue, face and/or throat
- Difficulty breathing or swallowing
- Hives (red and lumpy skin rash)
- Sudden fall in blood pressure leading to collapse or shock.

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:

- Seizure (fits)
- Abnormal heartbeats

- Hallucinations (false perceptions), recurring thoughts of or preoccupation with suicide, depression, aggressive or agitated behaviour.

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.

Less frequently reported side effects include:

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

Side effects with unknown frequencies include:

- Increased heart rate
- Weight gain
- Increased appetite
- Painful or difficult urination, inability to completely empty 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, 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 debossed with 'R 5' on one side and plain on other side.

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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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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