

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S1**

### **ALLERWAY MELTAWAY 5**

**5 mg, Orodispersible tablets**

**Levocetirizine dihydrochloride**

**Contains sugar (lactose monohydrate, mannitol, sorbitol)**

**Contains aspartame**

Each orodispersible tablet contains 104,00 mg of lactose monohydrate, 67,15 mg of mannitol and 3,95 mg of sorbitol per tablet.

Contains 5,00 mg aspartame per tablet.

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

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

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

### **1. What ALLERWAY MELTAWAY 5 is and what it is used for**

ALLERWAY MELTAWAY 5 is an antiallergic medication.

ALLERWAY MELTAWAY 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 MELTAWAY 5**

#### **Do not take ALLERWAY MELTAWAY 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 MELTAWAY 5 (see “What ALLERWAY MELTAWAY 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 MELTAWAY 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 MELTAWAY 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 MELTAWAY 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 MELTAWAY 5 may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking ALLERWAY MELTAWAY 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 MELTAWAY 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 MELTAWAY 5.

Before taking ALLERWAY MELTAWAY 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)
- Theophylline (a medicine used to treat respiratory diseases such as asthma).

#### **ALLERWAY MELTAWAY 5 with food, drink and alcohol**

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

You may take ALLERWAY MELTAWAY 5 with or without food.

#### **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 MELTAWAY 5.

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

### **Driving and using machines**

Some patients being treated with ALLERWAY MELTAWAY 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 MELTAWAY 5 contains lactose, sorbitol, and aspartame**

ALLERWAY MELTAWAY 5 contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ALLERWAY MELTAWAY 5.

Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

ALLERWAY MELTAWAY 5 contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take ALLERWAY MELTAWAY 5.

ALLERWAY MELTAWAY 5 contains aspartame. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine. Tell your doctor if you have any intolerance to phenylalanine.

### **3. How to take ALLERWAY MELTAWAY 5**

Always take ALLERWAY MELTAWAY 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.

ALLERWAY MELTAWAY 5 tablet should be placed on the tongue and should be sucked, not chewed, until complete disintegration. The resulting suspension has to be swallowed with saliva.

ALLERWAY MELTAWAY 5 can be taken with or without water and 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 MELTAWAY 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 MELTAWAY 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 MELTAWAY 5 is too strong

or too weak, tell your doctor or pharmacist.

### **How long should you take ALLERWAY MELTAWAY 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 MELTAWAY 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 MELTAWAY 5**

If you forget to take ALLERWAY MELTAWAY 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 MELTAWAY 5**

Pruritus (intense itching) may occur if you stop taking ALLERWAY MELTAWAY 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 MELTAWAY 5 can have side effects.

Not all side effects reported for ALLERWAY MELTAWAY 5 are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ALLERWAY MELTAWAY 5, please consult your health care provider for advice.

**If any of the following happens, stop taking ALLERWAY MELTAWAY 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
- breathing or swallowing difficulties (chest tightness or wheezing)
- hives (red and lumpy skin rash)
- 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 very serious allergic reaction to ALLERWAY MELTAWAY 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:**

- seizures (fits)
- palpitations (irregular heartbeat)
- 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:**

Frequent side effects:

- sleep disorders
- headache
- somnolence/drowsiness
- dry mouth, diarrhoea, constipation
- exhaustion

Less frequent side effects:

- nausea, gastro-intestinal (affecting the stomach and intestines) discomfort,

abdominal pain, vomiting

- feeling of weakness, feeling unwell

Side effects with unknown frequencies:

- allergic reactions
- convulsions
- pins and needles
- dizziness, fainting, sensation of rotation or movement
- tremor (shaking)
- distortion of the sense of taste
- visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements)
- palpitations (irregular heartbeat), increased heart rate
- shortness of breath
- liver inflammation
- skin reactions, urticaria (swelling, redness and itchiness of the skin), rashes, pruritis (itchiness), skin eruption
- muscular pain, joint pain
- painful or difficult urination, inability to completely empty the bladder
- oedema (swelling)
- Swelling caused by excess fluid trapped in your body's tissues
- increased appetite, weight increase
- hallucinations (false perceptions), recurring thoughts of or preoccupation with suicide, depression, aggressive or agitated behaviour
- insomnia (inability to sleep), nightmares
- abnormal liver function
- 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 MELTAWAY 5.

### **5. How to store ALLERWAY MELTAWAY 5**

Store all medicines out of reach of children.

Store at or below 30 °C.

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 MELTAWAY 5 contains**

- The active substance is levocetirizine dihydrochloride. Each orodispersible tablet contains levocetirizine dihydrochloride 5 mg.
- The other ingredients are: Aspartame, flavour – blackcurrant (flavouring substances, flavouring preparations, natural flavouring substances, maize maltodextrin, glyceryl triacetate, triethyl citrate, sulphite ammonia caramel, moisture), lactose monohydrate, magnesium stearate, Pharmaburst B2 (mannitol 85 %, polyplasdone 10 %, sorbitol 5 %, syloid less than 1 %),

polacrillin potassium, silica colloidal anhydrous.

### **What ALLERWAY MELTAWAY 5 looks like and contents of the pack**

#### ALLERWAY MELTAWAY 5

Round, white to off-white, flat, bevelled edged tablets with "LV' engraved on one side and plain on other side.

The tablets are packed in Alu-Alu blisters and are available in pack sizes of 10's, 20's and 30's. Blister strips are packed into cartons.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

Dr. Reddy's Laboratories (Pty) Ltd

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2057

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### **Registration number**

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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:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100