

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

S1

### 1 NAME OF THE MEDICINE

ALLERWAY MELTAWAY 5, 5 mg, Orodispersible tablets.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orodispersible tablet contains levocetirizine dihydrochloride 5 mg.

#### Excipient(s) with known effect

Contains sugar (104,00 mg lactose monohydrate per tablet, 67,15 mg mannitol per tablet and 3,95 mg sorbitol per tablet).

Contains 5,00 mg aspartame per tablet.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Orodispersible tablet.

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

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

ALLERWAY MELTAWAY 5 is indicated for the relief of symptoms associated with the following allergic conditions:

- seasonal allergic rhinitis
- perennial allergic rhinitis
- chronic idiopathic urticaria

#### 4.2 Posology and method of administration

## Posology

*Adults and adolescents 12 years of age and older:*

The daily recommended dose is one 5 mg tablet.

*Children aged 6 – 12 years:*

The daily recommended dose is one 5 mg tablet.

*Children 2 – 6 years:*

ALLERWAY MELTAWAY 5 orodispersible tablets should not be used in children aged 2 – 6 years, as no adjusted dosage is possible with the orodispersible tablet formulation (see sections 4.3 and 4.4).

*Children aged less than 2 years:*

ALLERWAY MELTAWAY 5 orodispersible tablets is contraindicated in children aged less than 2 years (see sections 4.3 and 4.4).

## Special populations

*Elderly:*

Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment (see *Adults with renal impairment* below).

*Adults with renal impairment:*

The dosing interval must be individualised according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL<sub>Cr</sub>) in mL/min is needed.

The CL<sub>Cr</sub> (mL/min) may be estimated from serum creatinine (µmol/l) determination using the following formula:

$$\text{CL}_{\text{Cr}} = \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{\text{serum creatinine (}\mu\text{mol/l)}} \quad (\times 0,85 \text{ for women})$$

**Dosing adjustments for patients with impaired renal function:**

<b>Group</b>	<b>Creatinine clearance (mL/min)</b>	<b>Dosage and frequency</b>
Normal	≥ 80	5 mg once daily
Mild	50 - 79	5 mg once daily
Moderate	30 - 49	5 mg once every 2 days
Severe	< 30	5 mg once every 3 days
End-stage renal disease – Patients undergoing dialysis	< 10	Contraindicated

*In paediatric patients suffering from renal impairment:*

The dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient and his/her body weight. There are no specific data for children with renal impairment.

*Patients with hepatic impairment:*

No dose adjustment is needed in patients with solely hepatic impairment.

In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended (see *Adults with renal impairment* above).

Method of administration

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.

*Duration of use:*

Intermittent allergic rhinitis (symptoms < 4 days/week or for less than 4 weeks a year)

has to be treated according to the disease and its history; it can be stopped once the symptoms have disappeared and can be restarted again when symptoms reappear. In case of persistent allergic rhinitis (symptoms > 4 days/week or for more than 4 weeks a year), continuous therapy can be proposed to the patient during the period of exposure to allergens.

*Missed dose:*

Patients who forget to take ALLERWAY MELTAWAY 5 should be advised to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

### **4.3 Contraindications**

ALLERWAY MELTAWAY 5 is contraindicated:

- in hypersensitivity to levocetirizine, to cetirizine, to hydroxyzine, to any piperazine derivative or to any of the excipients of ALLERWAY MELTAWAY 5 listed in section 6.1
- in pregnancy and lactation (see section 4.6)
- in patients with end-stage renal disease (creatinine clearance < 10 mL/min) and patients undergoing dialysis
- in infants and children under 2 years as safety and efficacy have not been demonstrated (see sections 4.2 and 4.4)
- in children from ages 2 – 6 years as no dosage adjustment is possible with the orodispersible tablet formulation (see sections 4.2 and 4.4).

### **4.4 Special warnings and precautions for use**

*Alcohol:*

Precaution is recommended with concurrent intake of alcohol (see section 4.5).

ALLERWAY MELTAWAY 5 lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system

depressants (see section 4.5).

*Risk of urinary retention:*

Caution should be taken in patients with predisposing factors of urinary retention (e.g., spinal cord lesion, prostatic hyperplasia) as ALLERWAY MELTAWAY 5 may increase the risk of urinary retention.

*Epilepsy:*

Caution should be taken in patients with epilepsy and patients at risk of convulsion as ALLERWAY MELTAWAY 5 may cause seizure aggravation.

*Allergy skin tests:*

Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.

*Withdrawal syndrome:*

Pruritus may occur when ALLERWAY MELTAWAY 5 is stopped even if those symptoms were not present before treatment initiation (see section 4.8). 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.

*Lactose:*

ALLERWAY MELTAWAY 5 contains lactose. Patients with the rare hereditary conditions of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take ALLERWAY MELTAWAY 5.

Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

*Sorbitol:*

ALLERWAY MELTAWAY 5 contains sorbitol. Patients with hereditary fructose intolerance (HFI) should not take ALLERWAY MELTAWAY 5.

*Aspartame:*

This medicine contains 5 mg aspartame in each orodispersible tablet, which is equivalent to 5 mg weight.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Paediatric population:

*Children aged less than 6 years:*

ALLERWAY MELTAWAY 5 orodispersible tablets are not indicated in patients under 6 years of age as this formulation does not allow for appropriate dose adaptation (see sections 4.2 and 4.3).

**4.5 Interaction with other medicines and other forms of interaction**

No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers). Studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with antipyrine, azithromycin, cimetidine, diazepam, erythromycin, glipizide, ketoconazole and pseudoephedrine).

*Theophylline:*

A decrease in the clearance of cetirizine (16 %) was observed in a multiple dose study with theophylline (400 mg once a day); while the disposition of theophylline was not altered by concomitant cetirizine administration.

*Ritonavir:*

In a multiple dose study of ritonavir (600 mg twice daily) and cetirizine (10 mg daily), the extent of exposure to cetirizine was increased by about 40 % while the disposition of ritonavir was slightly altered (-11 %) further to concomitant cetirizine administration.

*Food:*

The extent of absorption of levocetirizine is not reduced with food, although the rate of absorption is decreased.

*Alcohol:*

In sensitive patients, the simultaneous administration of ALLERWAY MELTAWAY 5 and alcohol or other central nervous system (CNS) depressants may cause additional

reductions in alertness and impairment of performance.

It is advisable to avoid excessive alcohol consumption.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

ALLERWAY MELTAWAY 5 is contraindicated in pregnancy, as safety has not been demonstrated.

##### Lactation

ALLERWAY MELTAWAY 5 is contraindicated in women who are breastfeeding their babies, since levocetirizine dihydrochloride is excreted in breast milk.

##### Fertility

No clinical data are available.

#### **4.7 Effects on ability to drive and use machines**

Some patients could experience somnolence, fatigue and asthenia during therapy with ALLERWAY MELTAWAY 5. Patients experiencing these should avoid driving, engaging in potentially hazardous activities or use of machines.

#### **4.8 Undesirable effects**

The following side effects have been reported:

##### Immune system disorders

*Frequency not known:* Hypersensitivity including anaphylaxis, angioedema

##### Metabolism and nutrition disorders

*Frequency not known:* Increased appetite

##### Psychiatric disorders

*Frequent:* Sleep disorders

*Frequency not known:* Aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmares

##### Nervous system disorders

*Frequent:* Headache, somnolence

*Frequency not known:* Convulsions, paraesthesia, dizziness, syncope, tremor, dysgeusia

#### Eye disorders

*Frequency not known:* Visual disturbances, blurred vision, oculogyration.

#### Ear and labyrinth disorders

*Frequency not known:* Vertigo

#### Cardiac disorders

*Frequency not known:* Palpitations, tachycardia

#### Respiratory, thoracic and mediastinal disorders

*Frequency not known:* Dyspnoea

#### Gastrointestinal disorders

*Frequent:* Dry mouth, diarrhoea, constipation

*Less frequent:* Nausea and gastro-intestinal discomfort, abdominal pain, vomiting

#### Hepato-biliary disorders

*Frequency not known:* Hepatitis

#### Skin and subcutaneous tissue disorders

*Frequency not known:* In some individuals, hypersensitivity reactions including skin reactions, urticaria and pruritus may develop.

Angioedema, fixed drug eruption, rash

#### Musculoskeletal, connective tissue and bone disorders

*Frequency not known:* Myalgia, arthralgia

#### Renal and urinary disorders

*Frequency not known:* Dysuria, urinary retention

#### General disorders and administration site conditions

*Frequent:* Fatigue

*Less frequent:* Asthenia, malaise

*Frequency not known:* Oedema

#### Investigations

*Frequency not known:* Increased weight, abnormal liver function tests

#### Description of selected adverse reactions

After ALLERWAY MELTAWAY 5 discontinuation, pruritus has been reported (see section 4.4).

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

### **4.9 Overdose**

Symptoms of overdose may include drowsiness in adults.

In children, agitation and restlessness may occur, followed by drowsiness.

There is no known specific antidote to levocetirizine. Should overdose occur, symptomatic and supportive treatment is recommended. Levocetirizine is not effectively removed by haemodialysis.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

#### Pharmacological classification

##### A 5.7.1 Antihistaminics

Levocetirizine, the (R) enantiomer of cetirizine, is a histamine H<sub>1</sub> receptor antagonist.

### **5.2 Pharmacokinetic properties**

Levocetirizine is absorbed after oral administration with peak blood levels reached 0,9 hours after oral administration. Plasma levels are linearly related between 2,5 mg and 20 mg.

The extent of metabolism is less than 14 % of the dose.

The plasma half-life is approximately 8 hours in adults. The main route of excretion is via urine, accounting for approximately 85 % of the dose. Approximately 13 % is excreted in the faeces. Levocetirizine is 90 % bound to human plasma proteins.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

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

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store at or below 30 °C.

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

### **6.5 Nature and contents of container**

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.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 HOLDER OF CERTIFICATE OF REGISTRATION**

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road

Morningside

Sandton

2057

## **8 REGISTRATION NUMBER(S)**

55/5.7.1/0712

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

23 May 2023

## **10 DATE OF REVISION OF TEXT**

01 February 2024