PROFESSIONAL INFORMATION

SCHEDULING STATUS **S1**

1 NAME OF THE MEDICINE

ALLERWAY 5, 5 mg, Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains levocetirizine dihydrochloride 5 mg.

Excipient with known effect:

Contains 88,00 mg lactose monohydrate per tablet.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

ALLERWAY 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 5 film-coated tablets should not be used in children aged 2 – 6 years, as no adjusted dosage is possible with the film-coated tablet formulation (see section 4.4).

Children aged less than 2 years:

ALLERWAY 5 film-coated 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 intervals must be individualised according to renal function. Use the table below to adjust the dosage intervals as indicated.

The patient's creatinine clearance (CLcr) can be estimated from the serum creatinine determination using the modified formula of Cockroft and Gault:

$$\text{CLcr (ml/min)} = \frac{(140 - \text{age in years}) \times \text{weight in kg}}{\text{serum creatinine (µmol/l)}} \quad (\times 0{,}85 \text{ for women})$$

Dosage in patients with renal impairment:

Renal status	**Creatinine clearance (CLcr)**	**Dose**
Normal	≥ 80 ml/min	5 mg once daily
Mild impairment	50 - 79 ml/min	5 mg once daily
Moderate impairment	30 - 49 ml/min	5 mg once every second day
Severe impairment	< 30 ml/min	5 mg once every third day
End-stage renal disease/ receiving dialysis	< 10 ml/min	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).

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 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.

Method of administration

ALLERWAY 5 must be taken orally, swallowed with liquid. It may be taken with or without food. It is recommended to take the daily dose in one single intake.

4.3 Contraindications

ALLERWAY 5 is contraindicated:

- in hypersensitivity to levocetirizine, to cetirizine, to hydroxyzine, to any piperazine derivative or to any of the excipients of ALLERWAY 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 in 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).

4.4 Special warnings and precautions for use

Alcohol:

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

ALLERWAY 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 5 may increase the risk of urinary retention.

Risk of seizure aggravation:

Caution should be taken in patients with epilepsy and patients at risk of convulsion as ALLERWAY 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 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 intolerance:

ALLERWAY 5 tablets contain lactose. Patients who are lactose intolerant or have rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take ALLERWAY 5.

Paediatric population:

Children aged less than 6 years:

ALLERWAY 5 film-coated 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 ALLERWAY 5 (including no studies with CYP3A4 inducers).

Studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with ketoconazole, erythromycin, azithromycin, cimetidine, antipyrine, pseudoephedrine, glipizide and diazepam).

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 decreased (-11 %).

Food:

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

Alcohol:

In sensitive patients, the concurrent administration of ALLERWAY 5 and alcohol or other central nervous system (CNS) depressants may cause additional reductions in alertness and impairment of performance.

4.6 Fertility, pregnancy and lactation

Pregnancy

ALLERWAY 5 is contra-indicated in pregnancy, as safety has not been demonstrated.

Breast-feeding

ALLERWAY 5 is contra-indicated in lactating women 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 5.

Patients experiencing these should avoid driving, engaging in potentially hazardous activities or use of machines.

4.8 Undesirable effects

a) Tabulated summary of adverse reactions

System Organ Class	**Frequency**	**Side effects**
Immune system disorders	Frequency not known	Hypersensitivity including anaphylaxis, angioedema
Metabolism and nutrition disorders	Frequency not known	Increased weight, increased appetite
Psychiatric disorders	Frequent	Sleep disorders
	Less frequent	Aggression, agitation, insomnia, suicidal ideation
	Frequency not known	Hallucination, depression, nightmares
Nervous system disorders	Frequent	Headache, somnolence, paraesthesia, dizziness, syncope, tremor, dysgeusia

	Less frequent	Convulsions
Eye disorders	Less frequent	Visual disturbances
	Frequency not known	Blurred vision, oculogyration
Ear and labyrinth disorders:	Frequency not known	Vertigo
Cardiac disorders	Less frequent	Palpitations
	Frequency not known	Tachycardia
Respiratory, thoracic and mediastinal disorders	Frequent	Pharyngitis, nasopharyngitis, dyspnoea
Gastrointestinal disorders	Frequent	Dry mouth, constipation
	Less frequent	Nausea, vomiting, abdominal pain, diarrhoea and gastro-intestinal discomfort
Hepato-biliary disorders	Less frequent	Hepatitis, abnormal liver function tests
Skin and subcutaneous tissue disorders	Less frequent	Hypersensitivity reactions including skin reactions, rashes, fixed drug eruptions, urticaria, pruritus
	Frequency	Angioedema

	not known	
Musculoskeletal and connective tissue disorders	Less frequent	Myalgia
	Frequency not known	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

b. Description of selected adverse reactions

Skin reactions occuring after discontinuation of ALLERWAY 5:

After discontinuation of ALLERWAY 5, 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_1 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

Core Tablet

Magnesium stearate

Microcrystalline cellulose

Lactose monohydrate

Silica colloidal anhydrous.

White film-coating

(Opadry™) consisting of:

Hypromellose

Macrogol

Titanium dioxide (C.I. No. 77891).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

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.

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

The tablets are packed in white HDPE containers in a pack size of 30 tablets.

The tablets are packed in silver-coloured Alu/Alu blister strips containing 10 tablets, which are packed in an outer carton tablet box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance

with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Dr. Reddy's Laboratories (Pty) Ltd

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8 REGISTRATION NUMBER(S)

43/5.7.1/0815

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/07/2012

10 DATE OF REVISION OF TEXT

17/07/2024