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.

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

4.2 Posology and method of administration

Posology

Adults 65 years of age and older:

Consult a doctor.

Adults and adolescents 12 - 64 years of age:

- 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:

- take 1 tablet (5 mg) once daily in the evening
- do not take more than 1 tablet (5 mg) in 24 hours

ALLERWAY 5 is contra-indicated in children below 6 years of age.

Patients with renal impairment:

ALLERWAY 5 is contraindicated in patients with renal impairment.

Patients with hepatic impairment:

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

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.

Duration of use:

The duration of use 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.

4.3 Contraindications

- Hypersensitivity to levocetirizine, to any piperazine derivative or to any of the ingredients of ALLERWAY 5 listed in section 6.1
- Pregnancy and lactation (see section 4.6)
- Renal disease
- Children under the age of 6 years

4.4 Special warnings and precautions for use

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).

Alcohol should be avoided (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.

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.

4.5 Interaction with other medicines and other forms of interaction

The simultaneous administration of ALLERWAY 5 and alcohol or other central nervous system depressants may have depressing effects on the central nervous system. Alcohol should be avoided.

There are no known interactions of ALLERWAY 5 with other medicines through interactions with medicines metabolised by liver enzymes. Studies performed with the racemic cetirizine have shown no evidence of clinically relevant adverse interactions with ketoconazole, erythromycin, azithromycin, cimetidine, glipizide, diazepam and pseudoephedrine.

Ritonavir increases the plasma concentration of racemic cetirizine about 42 %, increases the half-life by 53 % and decreases the clearance 29 %. The disposition of ritonavir is not altered by concomitant cetirizine administration.

A small 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.

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.

4.7 Effects on ability to drive and use machines

Some patients could experience somnolence, fatigue and asthenia during therapy with ALLERWAY 5 and therefore it may interfere with the patient's daytime activities and the ability to drive and use machines.

It is therefore advisable to determine individual response to ALLERWAY 5 before driving or performing complicated tasks.

4.8 Undesirable effects

The risk of adverse reactions to ALLERWAY 5 may be greater in patients with renal impairment.

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 weight and increased appetite

Psychiatric disorders

Less frequent: Aggression, agitation, insomnia, sleep disorders, suicidal ideation

Frequency not known: Hallucination, depression

Nervous system disorders

Frequent: Headache, somnolence, paraesthesia, dizziness, syncope, tremor, dysgeusia

Less frequent: Convulsion

Eye disorders

Less frequent: Visual disturbances

Cardiac disorders

Less frequent: Palpitations

Frequency not known: Tachycardia

Respiratory, thoracic and mediastinal disorders

Frequent: Pharyngitis, nasopharyngitis, dyspnoea

Gastrointestinal disorders

Frequent: Dry mouth

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

Hepato-biliary disorders

Less frequent: Hepatitis, abnormal liver function test

Skin and subcutaneous tissue disorders

Less frequent: Hypersensitivity reactions including skin reactions, rashes, fixed drug eruptions, urticaria, pruritus

Musculoskeletal, connective tissue and bone disorders

Less frequent: Myalgia

Renal and urinary disorders

Frequency not known: Dysuria and urinary retention

General disorders and administration site conditions

Frequent: Fatigue

Less frequent: Asthenia, malaise

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 and initially agitation and restlessness, followed by drowsiness in children. There is no known specific antidote to levocetirizine. Should overdose occur, symptomatic and supportive treatment is recommended.

Levocetirizine is not effectively removed by haemodialysis.

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 absorption is not reduced by food, although the rate is decreased.

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

11/08/2022