PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF MEDICINE

ALLERGEX® NON DROWSY TABLETS

Strength

Loratadine (micronised) 10 mg

Pharmaceutical form:

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Loratadine (micronised) 10 mg

Contains sugar:

Lactose monohydrate 75 mg

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablets.

White, 8 mm, round, flat tablets, with a breakline.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The relief of symptoms associated with seasonal allergic rhinitis and chronic urticaria.

4.2 Posology and method of administration

Posology

Adults: One tablet to be taken once daily.

ALLERGEX NON DROWSY TABLETS can be taken with or without a meal.

Method of administration

For oral administration.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

The safe use of **ALLERGEX NON DROWSY TABLETS** in the elderly has not been established.

4.4 Special warnings and precautions for use

ALLERGEX NON-DROWSY TABLETS lack significant sedative properties. However, patients should be advised that a small number of individuals may experience sedation. Therefore, the effect of the medicine on a particular patient should be ascertained before they drive or operate machinery. This effect can be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

A lower dose should be administered to patients with hepatic impairment as they may have decreased clearance of loratadine; i.e., an initial dose of 5 mg once daily or 10 mg on alternate days.

Contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **ALLERGEX NON DROWSY TABLETS**.

Contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

H1 receptor antihistamines such as **ALLERGEX NON DROWSY TABLETS** have been shown to cause weight gain.

4.5 Interaction with other medicines and other forms of interaction

The use of **ALLERGEX NON-DROWSY TABLETS** should be stopped several days before skin testing as antihistamines may suppress the positive skin response to allergen extracts.

Medicines known to inhibit the hepatic metabolism of loratadine include cimetidine, erythromycin, ketoconazole, quinidine, fluconazole and fluoxetine.

However, no clinically significant consequences have been observed when these medicines are administered concomitantly.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

No fertility data available.

4.7 Effects on ability to drive and use machines

This medicine lacks significant sedative effects. Patients should be advised that a small number of individuals may experience sedation. (see section 4.4)

4.8 Undesirable effects

Tabulated summary of adverse reactions

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000) and unknown (cannot be estimated from the available data):

System organ class	**Frequency**	**Undesirable effects**
Immune system disorders	Unknown	Hypersensitivity reactions (including angioedema and anaphylaxis)
Metabolism and nutritional disorders	Unknown	Increased appetite
Nervous system disorders	Unknown	Headache, somnolence, sedation, nervousness, dizziness, convulsion
Cardiac disorders	Unknown	Tachycardia**,** palpitations
Gastrointestinal disorders	Unknown	Nausea, dry mouth, vomiting, diarrhoea, gastritis or epigastric pain
Skin and subcutaneous tissue disorders	Unknown	Rash**,** alopecia
General disorders and administrative site conditions	Unknown	Fatigue

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

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

4.9 Overdose

Refer to **"Undesirable effects"**

Cardiac effects such as tachycardia have been reported.

Headache and somnolence have also been reported with overdoses.

In the event of overdosage, treatment should be started immediately.

Treatment is symptomatic and supportive. Haemodialysis is not an effective means of removing loratadine or its metabolite from the body.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 5.7.1 Antihistaminics

Mechanism of action

Loratadine is a long acting piperidine antihistamine. It is a selective H1 receptor antagonist which is a reversible, competitive inhibitor of histamine at H1 receptor sites.

Loratadine is a second generation H1 antagonist.

It does not readily cross the blood brain barrier.

5.2 Pharmacokinetic properties

Peak plasma levels are reached within 1,5 hours and the clinical effect is achieved within 2 hours.

Excretion occurs equally via the faeces and the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline (Avicel pH 102), lactose monohydrate, maize starch, magnesium stearate and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years

6.4 Special precautions for storage

Store at or below 25 ºC. Protect from light.

Do not remove the blister pack from the outer carton until required for use.

6.5 Nature and contents of container

Glass-clear, rigid, glossy, PVC film and aluminium foil blister packs of 7, 10, 14, 21 and 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK 232625

8. REGISTRATION NUMBER

36/ 5.7.1/ 0286

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06 February 2004

10. DATE OF REVISION OF THE TEXT

29 November 2021

Botswana: BOT2103762 S3

Namibia: NS1 05/7.1/0232

adcock ingram