SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

ALLERGEX NON DROWSY SYRUP 5 mg/ 5 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of **ALLERGEX NON DROWSY SYRUP** contains:

Loratadine (micronised) 5 mg

Excipients with known effect

Preservative: Sodium benzoate 5 mg (equivalent to 0,1 % *m/v*)

Propylene Glycol 300 mg in 5 ml (equivalent to 6 % *w/v)*

Contains sugar:

Sucrose 1 000 mg

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

ALLERGEX NON DROWSY SYRUP is a clear, colourless syrupy solution with a peach odour. It is free from particulate matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhoea, and itching of nose and throat.

ALLERGEX NON DROWSY SYRUP is also indicated for the relief of chronic idiopathic urticaria and other allergic dermatoses.

4.2 Posology and method of administration

Children 2 to 5 years of age: 5 ml (1 medicine measure) once daily.

Children 6 to 12 years of age: 10 ml (2 medicine measures) once daily.

Adults and Children 12 years of age and over: 10 ml (2 medicine measures) once daily.

The use of **ALLERGEX NON DROWSY SYRUP** should be limited to 14 days.

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

Method of administration

For oral administration.

Shake the bottle before use.

Special Populations

Hepatic Impairment

Patients with hepatic impairment should be administered a reduced dose as they may have decreased clearance of loratadine; an initial dose of 5 ml once daily or 10 ml on alternate days is recommended.

Children

Efficacy of **ALLERGEX NON DROWSY SYRUP** has not been established in children younger than 2 years of age (see section 4.3).

4.3 Contraindications

- Hypersensitivity to loratadine or to any of the excipients listed in section 6.1.
- The safe use of **ALLERGEX NON DROWSY SYRUP** in children under 2 years of age and in the elderly has not been established.

4.4 Special warnings and precautions for use

- **ALLERGEX NON DROWSY SYRUP** lacks significant sedative properties. However, patients should be advised that a small number of individuals may experience sedation (see section 4.7).
- Use with caution in patients with epilepsy due to less frequent reports of convulsions. Cross sensitivity to related drugs may occur.
- H1 receptor antihistamines such as **ALLERGEX NON DROWSY SYRUP** may cause weight gain.

ALLERGEX NON DROWSY SYRUP contains sucrose

Patients with rare hereditary conditions of fructose intolerance e.g., glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **ALLERGEX NON DROWSY SYRUP**.

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

ALLERGEX NON DROWSY SYRUP contains sodium benzoate

This medicine contains 5 mg of sodium benzoate in each 5 ml which is equivalent to 0,1 % *m/v.*

Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

ALLERGEX NON DROWSY SYRUP contains sodium hydroxide

This medicine contains less than 1 mmol sodium (0,273 mg) per 5 ml, that it is to say essentially "sodium-free".

ALLERGEX NON DROWSY SYRUP contains propylene glycol

This medicine contains 300 mg propylene glycol in each 5 ml dosage unit which is equivalent to 6 % *w/v*.

Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates.

4.5 Interaction with other medicines and other forms of interaction

The use of **ALLERGEX NON-DROWSY SYRUP** should be stopped approximately 48 hours 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.

These medicines should therefore not be administered concomitantly with loratadine as they may raise the plasma concentrations of loratadine.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established. The use of **ALLERGEX NON DROWSY SYRUP** during pregnancy is therefore not recommended.

Lactation

Loratadine and its metabolites are distributed into breastmilk, therefore its administration during lactation is not advised.

Fertility

No data has been reported on male and female fertility.

4.7 Effects on ability to drive and use machines

Patient's should be advised that a small number of individuals may experience sedation (see section 4.4). Therefore, the effect of the medicine on a particular patient should be ascertained before they drive or generate machinery.

4.8 Undesirable Effects

Tabulated list of adverse effects reactions presented in system organ class

System organ class	Frequency	Undesirable effects
Blood and lymphatic system disorders	Unknown	Agranulocytosis, leucopaenia, haemolytic anaemia and thrombocytopaenia
Immune system disorders	Less frequent	Hypersensitivity reactions (including angioedema and anaphylaxis)
	Unknown	Photosensitivity may occur
Metabolism and nutritional disorders	Unknown	Increased appetite and weight gain
Nervous system disorders	Unknown	Headache, somnolence, sleep disturbances, sedation, Depression, nervousness, Extrapyramidal effects, tremor, Sweating, paraesthesia
	Less frequent	Dizziness, convulsions
Ear and labyrinth disorders	Unknown	Tinnitus
Cardiac disorders	Less frequent	Tachycardia, palpitations
Vascular disorders	Unknown	Hypotension
	Less frequent	Nausea, dry mouth

Gastrointestinal disorders	Unknown	Vomiting, diarrhoea, epigastric pain
Hepato-biliary disorders	Less frequent	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Less frequent	Rash, alopecia
Musculoskeletal and connective tissue disorders	Unknown	Myalgia
General disorders and administrative site conditions	Less frequent	Fatigue

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 Medsafety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org found on SAHPRA website.

You may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

4.9 Overdose

See section 4.8.

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

Pharmacotherapeutic group: antihistamines – H1 antagonist

ATC Code: R06AX13

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

Following oral administration, peak plasma concentrations are achieved in 2 to 3 hours. Loratadine is metabolised in the liver to active metabolites by the hepatic microsomal P450 enzymes.

The pharmacokinetic profile of loratadine in infants 1 to 2 years after the administration of a single 2,5 mg dose of **ALLERGEX NON DROWSY SYRUP** is similar to that in older children and adults.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin, hydrochloric acid 32 %, peach flavour LR 999, Propylene glycol (E1520), purified water, sodium benzoate (E 211), sodium hydroxide pellets, sucrose, xanthan gum.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years

6.4 Special precautions for storage

Store in a well-closed container below 25 ºC. Protect from light.

6.5 Nature and contents of container

Amber glass bottles of 100 ml and 150 ml with a 28 mm white lined screw-cap generic closure.

Not all packs and pack sizes are marketed.

6.6 Special precautions for disposal

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

36/5.7.1/0008

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24 January 2003

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