PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S1**

ALLERGEX NON DROWSY SYRUP

Active substance per 5 ml is Loratadine (micronised) 5 mg

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

Propylene Glycol 300,00 mg in 5 ml (equivalent to 6 % *w/v*)

Sodium Hydroxide Pellets (this medicine contains less than 1 mmol sodium (0,273 mg) per 5 ml, that is to say essentially 'sodium-free'.)

Contains sugar: Sucrose 1 000 mg

Read all of this leaflet carefully because it contains important information for you.

ALLERGEX NON DROWSY SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **ALLERGEX NON DROWSY SYRUP** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ALLERGEX NON DROWSY SYRUP** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What **ALLERGEX NON DROWSY SYRUP** is and what it is used for
2. What you need to know before you take **ALLERGEX NON DROWSY SYRUP**
3. How to take **ALLERGEX NON DROWSY SYRUP**
4. Possible side effects
5. How to store **ALLERGEX NON DROWSY SYRUP**

6. Contents of the pack and other information.

1. What ALLERGEX NON DROWSY SYRUP IS AND WHAT IT IS USED FOR

ALLERGEX NON DROWSY SYRUP belongs to a group of medicines called antihistamines. **ALLERGEX NON DROWSY SYRUP** is an anti-allergy medicine. It helps control your allergic reaction and its symptoms.

ALLERGEX NON DROWSY SYRUP is used to relieve:

- Allergy symptoms such as runny and blocked nose, sneezing, watery eyes (e.g.in hay fever).
- A skin condition with pale or red irregular raised patches and severe itching (urticaria) and other allergic skin disorders**.**

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALLERGEX NON DROWSY SYRUP

Do not take ALLERGEX NON DROWSY SYRUP

- If you are hypersensitive (allergic) to loratadine or any of the other ingredients of **ALLERGEX NON DROWSY SYRUP** (listed in section 6).
- In children under 2 years of age and in the elderly.

Warnings and precautions

Take special care with **ALLERGEX NON DROWSY SYRUP**:

- Weight gain has been reported with the use of loratadine.
- **ALLERGEX NON DROWSY SYRUP** lacks significant sedative effects; however, a small number of individuals may experience sedation.

- If you have a medical or family history of seizures (epilepsy), this medicine may cause convulsions in the epileptic population.

Special populations

Liver disease

If you have liver disease, a reduced dose should be given; an initial dose of 5 ml once daily or 10 ml on alternate days is recommended.

Children

Safety of **ALLERGEX NON DROWSY SYRUP** in children younger than 2 years of age and the elderly has not been established.

Other medicines and ALLERGEX NON DROWSY SYRUP

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines)

- If you are about to have skin tests. Stop taking this medicine at least 48 hours before Skin testing, because this medicine may affect test results
- Ketoconazole, fluconazole (antifungal medicines used to treat certain kinds of fungal or yeast infections)**,** erythromycin (an antibiotic medicine used to treat certain kinds of bacterial infections and often used for people who have an allergy to penicillins), Cimetidine (a medicine used to treat stomach ulcers, acid reflux or to prevent and treat symptoms of heartburn associated with acid, indigestion and sour stomach), Quinidine (a medicine used to treat certain types of irregular heartbeats) and fluoxetine (medicine used to treat depression) can enhance the plasma concentrations of loratadine.

ALLERGEX NON DROWSY SYRUP with food and drink:

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The safety of **ALLERGEX NON DROWSY SYRUP** during fertility, pregnancy and breastfeeding is not recommended.

Driving and using machines

At the recommended dose, **ALLERGEX NON DROWSY SYRUP** is not expected to cause you to be drowsy or less alert. However, you should not drive or carry out skilled tasks, such as using machinery, until you are certain that you are unaffected in this way. Patients should be advised that a small number of individuals may experience sedation.

It is not always possible to predict to what extent **ALLERGEX NON DROWSY SYRUP** may interfere with the daily activities until they are aware of the measure to which **ALLERGEX NON DROWSY SYRUP** affects them.

ALLERGEX NON DROWSY SYRUP contains sugar

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ALLERGEX NON DROWSY SYRUP.**

ALLERGEX NON DROWSY SYRUP contains sucrose which may have an effect on the control of your blood sugar if you have 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.*

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

ALLERGEX NON DROWSY SYRUP contains sodium hydroxide

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that 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* %.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. HOW TO TAKE ALLERGEX NON DROWSY SYRUP

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

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.

Do not take **ALLERGEX NON DROWSY SYRUP** for longer than 14 days.

For oral use

If you take more ALLERGEX NON DROWSY SYRUP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital poison control centre. You may experience symptoms of sleepiness, irregular or rapid heartbeat and headache if you take more **ALLERGEX NON DROWSY SYRUP** than you should. If this happens, treatment should be started immediately.

Treatment is symptomatic and supportive.

After emergency treatment, you should continue to be medically monitored.

If you forget to take / missed a dose of ALLERGEX NON DROWSY SYRUP

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

ALLERGEX NON DROWSY SYRUP can have side effects.

Not all side effects reported for **ALLERGEX NON DROWSY SYRUP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this **ALLERGEX NON DROWSY SYRUP**, please consult your healthcare provider for advice.

The following side effects may be experienced while taking **ALLERGEX NON DROWSY SYRUP:**

Side effects with unknown frequency:

- Blood disorders including agranulocytosis (low number of granulocytes, a type of white blood cell), leucopaenia (reduced white blood cells), haemolytic anaemia

(low number of red blood cells) and thrombocytopaenia (decreased number of blood platelets)

- Oversensitivity of skin to light may occur
- Increased appetite and weight gain
- Headache, sleepiness, drowsiness, sleep disturbances, sedation, depression, dizziness, extrapyramidal effects, tremor, sweating, abnormal sensation
- ringing in the ear
- low blood pressure
- vomiting, upset, stomach, diarrhoea (loose watery stools), epigastric pain (upper abdominal pain).
- Myalgia (muscle pain)

Less frequent side effects:

- Hypersensitivity reactions including angioedema (rapid swelling under the deeper skin layer) and anaphylaxis (serious life threatening allergic reaction).
- Nervousness and uncontrollable shaking
- Tachycardia (period of a very rapid and regular heartbeats that begin and ends suddenly).
- Palpitations (unpleasant sensation of irregular and/or forceful beating of the heart)
- Nausea (feeling sick) and dry mouth
- Abnormal liver function
- Rash, alopecia (hair loss)
- Fatigue (tiredness)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **ALLERGEX NON DROWSY SYRUP.**

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

Adcock.AEReports@adcock.com

5. HOW TO STORE ALLERGEX NON DROWSY SYRUP

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

KEEP OUT OF REACH OF CHILDREN.

Store in the original container.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems(e.g., toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ALLERGEX NON DROWSY SYRUP contains:

Each 5 ml contains:

The active substance is: Loratadine 5 mg

The other ingredients are: Glycerin, hydrochloric acid 32%, peach flavour LR 999. Propylene glycol (E1520), purified water, sodium benzoate (E211) sodium hydroxide pellets, sucrose, xanthan gum.

What ALLERGEX NON DROWSY SYRUP looks like and contents of the pack:

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

It is packaged in amber glass bottles of 100 ml and 150 ml syrup and 28 mm white lined screw-cap generic closure.

Not all pack sizes are marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer care: 0860 ADCOCK / 232625

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