PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

ALLERGEX® NON DROWSY TABLETS

Active substance is:

Loratadine (micronised) 10 mg

Contains sugar: Lactose monohydrate 75 mg

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ALLERGEX NON DROWSY TABLETS 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 10 days.

What is in this leaflet

1. What ALLERGEX NON DROWSY TABLETS is and what it is used for
2. What you need to know before you take ALLERGEX NON DROWSY TABLETS
3. How to take ALLERGEX NON DROWSY TABLETS
4. Possible side effects
5. How to store ALLERGEX NON DROWSY TABLETS
6. Contents of the pack and other information

1. WHAT ALLERGEX NON DROWSY TABLETS IS AND WHAT IT IS USED FOR

ALLERGEX NON DROWSY TABLETS belongs to a group of medicines called antihistamines.

ALLERGEX NON DROWSY TABLETS is an anti-allergy medicine. It helps control your allergic reaction and its symptoms.

ALLERGEX NON DROWSY TABLETS are used to relieve:

- Allergy symptoms such as runny and blocked nose, sneezing, watery eyes (e.g. in hayfever)
- A skin condition with pale or red irregular raised patches and sever itching (urticaria)

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

Do not take ALLERGEX NON DROWSY TABLETS

- If you are hypersensitive (allergic) to the active substances or any of the other ingredients of ALLERGEX NON DROWSY TABLETS (listed in section 6).
- The safe use of ALLERGEX NON DROWSY TABLETS in the elderly has not been established.

Warnings and precautions

Take special care with ALLERGEX NON DROWSY TABLETS:

- Safe use of ALLERGEX NON DROWSY TABLETS in the elderly has not been established.
- At the recommended dose, ALLERGEX NON DROWSY TABLETS is not expected to cause you to be drowsy or less alert. However, you should not drive or use machines, until you are certain that you are unaffected in this way.
- You can suffer sedation if you take alcohol or other central nervous system depressant at the same time as taking ALLERGEX NON DROWSY TABLETS.
- You may experience sedation if you take alcohol or other central nervous system depressants (drugs that slow down brain activity) at the same time as taking ALLERGEX NON DROWSY TABLETS.
- If you have liver disease, talk to your doctor before taking ALLERGEX NON DROWSY TABLETS.
- Weight gain has been reported with the use of loratadine.
- Contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ALLERGEX NON DROWSY TABLETS.

Other medicines and ALLERGEX NON DROWSY TABLETS:

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 (an antifungal medicine 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.) or cimetidine (a medicine used treat stomach ulcers, acid reflux, or to prevent and treat symptoms of heartburn associated with acid, indigestion and sour stomach) can enhance the plasma concentrations of loratadine, quinidine (used to treat certain types of irregular heartbeats), fluconazole (antifungal medication used for a number of fungal and yeast infections) and fluoxetine (is used to treat depression).

ALLERGEX NON DROWSY TABLETS with food and drink:
ALLERGEX NON DROWSY TABLETS can be taken with or without a meal.

Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.
The safety of ALLERGEX NON DROWSY TABLETS during pregnancy and breastfeeding has not been established. No fertility data available.

Driving and using machinery
At the recommended dose, ALLERGEX NON DROWSY TABLETS 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.
You can experience sedation if you take alcohol or other central nervous system depressants at the same time as taking ALLERGEX NON DROWSY TABLETS.

ALLERGEX NON DROWSY TABLETS contains lactose
ALLERGEX NON DROWSY TABLETS contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ALLERGEX NON DROWSY TABLETS.

ALLERGEX NON DROWSY TABLETS contains lactose which have an effect on the control of your blood sugar if you have diabetes mellitus.

3. HOW TO TAKE ALLERGEX NON DROWSY TABLETS

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:

Adults: Take one tablet once daily.

For oral use

Do not share this medicine with any other person.

If you take more ALLERGEX NON DROWSY TABLETS than you should

If you take more ALLERGEX NON DROWSY TABLETS than you were told to, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

You may experience symptoms of sleepiness, irregular or rapid heartbeat and headache if you take more ALLERGEX NON DROWSY TABLETS than you should. In the event of this happening, treatment should be started immediately.

Treatment: 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 TABLETS

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

4. POSSIBLE SIDE EFFECTS

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

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

System organ class	Frequency	Undesirable effects
Immune system disorders	Unknown	Hypersensitivity (allergic) reactions (including painless swelling under the skin triggered by an allergy and severe, potentially life-threatening allergic reaction)
Metabolism and nutritional disorders	Unknown	Increased appetite
Nervous system disorders	Unknown	Headache, strong desire for sleep and feeling of drowsiness., sedation, nervousness, dizziness, convulsion
Cardiac disorders	Unknown	Rapid heartbeat that may be regular or irregular, rapid strong or irregular heartbeat
Gastrointestinal disorders	Unknown	Nausea, dry mouth, vomiting, diarrhoea, stomach inflammation or pain in the upper, middle region of your stomach
Skin and subcutaneous tissue disorders	Unknown	Rash**,** hair loss
General disorders and administrative site conditions	Unknown	Feeling of constant tiredness or weakness

Reporting of side effects

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug**

Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **ALLERGEX NON DROWSY TABLETS.**

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

5. HOW TO STORE ALLERGEX NON DROWSY TABLETS

Store at or below 25 ºC. Protect from light.

KEEP OUT OF REACH OF CHILDREN

Store in the original container

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

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 medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ALLERGEX NON DROWSY TABLETS contains:

Each tablets contains*:*

The active substances are: Loratadine

The other ingredient are: Cellulose microcrystalline (Avicel pH 102), lactose monohydrate, maize starch, magnesium stearate and purified water.

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

ALLERGEX NON DROWSY TABLETS are white, 8 mm, round, flat tablets, with a breakline. It is packaged in glass-clear, rigid, glossy, PVC film and aluminium foil blister packs of 7, 10, 14, 21 and 30 tablets.

Holder of Certificate of Registration

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Access to the corresponding professional information

It is contained in the packaging of the medicine

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