

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

ALLERGEX® NON DROWSY TABLETS 10 mg

Active substance is:

Loratadine (micronised) 10 mg

Contains sugar: Lactose monohydrate 75 mg

Read all of this leaflet carefully before you start taking ALLERGEX NON DROWSY TABLETS 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.

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.

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ALLERGEX NON DROWSY TABLETS is 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 severe 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:

- 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 **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 penicillin's) or cimetidine (a medicine used to treat stomach ulcers, acid reflux, or to prevent and treat symptoms of heartburn associated with

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acid, indigestion and sour stomach), 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) can enhance the plasma concentrations of loratadine.

ALLERGEX NON DROWSY TABLETS with food, drinks and alcohol

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 nor is there fertility data available.

Driving and using machines

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 monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take ALLERGEX NON DROWSY TABLETS

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.

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The usual dose is:

Adults: Take one tablet once daily.

For oral use

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 take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

ALLERGEX NON DROWSY TABLETS can have 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 healthcare provider for advice.

If any of the following happens, stop taking ALLERGEX NON DROWSY TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching.

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These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ALLERGEX NON DROWSY TABLETS**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Hypersensitivity reactions including angioedema (rapid swelling under the deeper skin layer) and anaphylaxis (serious life-threatening allergic reaction) including swelling.
- Increased appetite.
- Headache, sleepiness, drowsiness, nervousness, dizziness, difficulty sleeping
- 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).
- Gastrointestinal side effects including nausea (feeling sick), dry mouth, vomiting, upset stomach, gastritis (Inflammation (swelling and redness) of the stomach lining).
- Red, itchy or irritated skin
- Hair loss
- Fatigue

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org), found under SAHPRA website.

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 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN

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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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Botswana: S3 BOT2103762
