PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ZEALARGY 10 mg tablets

Rupatadine

Contains sugar (lactose monohydrate 60 mg/tablet)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ZEALARGY with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What ZEALARGY is and what it is used for

ZEALARGY is an antihistamine.

ZEALARGY is used to relieve symptoms in adults and adolescents (over 12 years of age) of:

- Allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose.

- Urticaria (an allergic skin rash) such as itching and hives (localised skin redness and swelling).

2. What you need to know before you take ZEALARGY

Do not take ZEALARGY:

- If you are hypersensitive (allergic) to rupatadine or any of the other ingredients of ZEALARGY (listed in section 6).
- If the patient is younger than 12 years of age.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with ZEALARGY:

- If you have, or have had liver or kidney disease, ask your doctor for advice. The use of ZEALARGY is not recommended in patients with impaired kidney or liver functions
- If you have heart conditions or low potassium blood levels, talk you your doctor or pharmacist, as ZEALARGY can worsen these conditions
- If you are over the age of 65 years, as you can be more sensitive and can experience side effects.

Children

ZEALARGY is not recommended for use in children under 12 years as safety is not established.

Other medicines and ZEALARGY

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

Tell your doctor or pharmacist if you are taking any of the following:

- Ketoconazole or erythromycin (medicines used to treat infections) as these medicines can increase the effect of ZEALARGY
- Alcohol.
- CNS depressants (medicines used to treat anxiety, panic attacks and acute stress reactions and sleep disorders)
- Statins (medicines to help lower cholesterol levels in the blood)
- Medicines used to treat infections, e.g. itraconazole, ketoconazole, voriconazole, posaconazole, erythromycin, fluconazole, clarithromycin
- Medicines used to treat HIV, e.g. saquinavir, indinavir, ritonavir, nelfinavir, amprenavir, fosamprenavir,
- Nefazodone (medicines used to treat depression)
- Diltiazem (medicine used to treat certain heart conditions).

ZEALARGY with food and drink

- Do not take ZEALARGY with grapefruit juice.
- ZEALARGY can be taken with or without meals.

Pregnancy and breastfeeding

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 health care provider for advice before taking this medicine.

Do not take ZEALARGY when you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent ZEALARGY may interfere with your daily

activities. At recommended doses, ZEALARGY is not expected to influence your ability to drive or use machinery. However, when you first start taking ZEALARGY you should take care to see how the treatment affects you before driving or using machinery.

ZEALARGY contains lactose

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

3. How to take ZEALARGY

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

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

ZEALARGY is for adolescents (from 12 years and older) and adults.

The usual dose is one tablet per day.

Take the tablet at the same time of day, with a glass of water.

If you take more ZEALARGY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZEALARGY

Do not take a double dose to make up for forgotten individual doses. If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

ZEALARGY can have side effects.

Not all side effects reported for ZEALARGY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZEALARGY, please consult your health care provider for advice.

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

- Allergic (itching, hives and swelling of the face, lips, tongue or throat).

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- Sleepiness, headache, dizziness
- Dry mouth
- Sensation of weakness and fatigue.

Less frequent

- Sore throat, running nose
- Increased appetite
- Irritability
- Difficulty concentrating
- Rapid or regular heartbeat
- Nosebleed, nasal dryness, sore throat,

- Cough, dry throat, pain in tonsils area
- Nausea, stomach pain, diarrhea, indigestion, vomiting, constipation
- Rash
- Back pain, joint pain, muscle pain
- Thirst, general discomfort, fever
- Changes in some laboratory blood tests.

Frequency unknown

- Disorientation
- Tremor
- Increased sweating
- Unable to walk in the normal way
- Redness of the eye and eyelid, blisters on the eyelid
- Redness of the skin or mucus membranes
- Redness of the genitals

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 “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 ZEALARGY.

5. How to store ZEALARGY

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package/ container.
- Keep blister in original container to protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the blister or 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 ZEALARGY contains

- The active substance is rupatadine.
- The other ingredients are lactose monohydrate (see section 2), microcrystalline cellulose, pregelatinised maize starch, colour iron oxide red, colour iron oxide yellow, magnesium stearate.

What ZEALARGY looks like and contents of the pack

ZEALARGY tablets are salmon coloured, round, biconvex, uncoated tablets, plain on both sides. It is packed in PVC/PVDC and aluminium foil. Each blister contains 10 tablets. Blisters of 10 tablets are packed in a carton in pack sizes of 10, 20 or 30 tablets.

Holder of Certificate of Registration

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