

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALERINIT 5 mg film coated tablet

Oral use.

- **Active ingredient:** Each film coated tablet contains 5 mg levocetirizine dihydrochloride
- **Excipients:** Microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide, macrogol 400, polysorbate 80.

Read all of these leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- During the use of this medicine, tell your doctor that you're taking this medicine when you refer to a doctor or hospital.
- Follow the instructions in this leaflet exactly. Do not take a dose **higher or lower** than recommended.

In this leaflet:

1. *What ALERINIT is and what is it used for?*
2. *Before you take ALERINIT*
3. *How to take ALERINIT?*
4. *What are the possible side effects?*
5. *How to store ALERINIT*

will be addressed.

1. What ALERINIT is and what is it used for?

- ALERINIT contains the active substance, levocetirizine. Levocetirizine belongs to a group of antiallergic medicines called antihistamines.
- ALERINIT is indicated for the treatment of symptoms such as sneezing, runny nose and watery eyes associated with; allergic rhinitis (including persistent allergic rhinitis) and to relieve the rashes and itching of chronic urticaria.
- ALERINIT is presented in blister of 10 tablets each. A box contains a leaflet and 20 tablets. Alerinit is a white, one side scored, oval shaped, standard concave film coated tablet. The tablet should be swallowed whole with 1 glass of water. The score-line is non-functional and only for visual purposes. Do not break the tablet.

2. Before you take ALERINIT

Please do not take ALERINIT:

If:

- You are using other antiallergic medicines,
- You are allergic (hypersensitive) to levocetirizine, cetirizine, hydroxyzine, any piperazine derivatives (closely related active substances of other medicines) or any of

the other ingredients of ALERINIT,

- You have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 ml/min).

Take special care with ALERINIT:

Talk to your doctor or pharmacist before taking ALERINIT.

If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of ALERINIT may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking ALERINIT for several days before testing. This medicine may affect your allergy test results.

Children

The use of ALERINIT is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

Taking ALERINIT with food and drink

You may take ALERINIT together with food.

Avoid alcohol while you are taking ALERINIT.

Caution is advised if you take ALERINIT at the same time as alcohol. In sensitive patients, the concurrent administration of ALERINIT and alcohol may cause additional reductions in alertness and impairment of performance.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Some of the patients who use ALERINIT felt drowsy, tired or weak. Use caution when driving or operating machinery until you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy subjects after taking ALERINIT in the recommended dosage.

Some important information about the excipients in ALERINIT

ALERINIT contains lactose. If your doctor had informed you that you could not tolerate some glucose, please contact your doctor prior to administering this drug.

Use with other drugs

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

3. How to take ALERINIT?

- **Instructions for appropriate use and dose / administration frequency:**

- Do not take ALERINIT for longer than 7 days, without advice of your doctor or pharmacist.
- Contact your doctor if your symptoms worsen or do not improve after 3 days.
- Please always take ALERINIT exactly as your doctor has told you. If you are not sure, you should contact your doctor or pharmacist.

In children between 6-12 years old: Once a day 5 mg (1 film coated tablet)

In adults and children aged 12 years and over: Once a day 5 mg (1 film coated tablet)

- **Administration route and method:**

- ALERINIT is administrated orally.
- Film tablet should be swallowed as a whole with a glass of water. Daily dose is recommended to be administrated in one single dose.
- ALERINIT may be administrated with the following foods or alone.

Elderly:

In elderly patients with normal renal functions, the usual dose for adults may be taken.

- **Specific use:**

Renal/Hepatic insufficiency:

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Patients who have severe impairment of kidney function must not take Alerinit.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

If you take more ALERINIT than you should:

If you take more than the recommended dose of ALERINIT, tell your doctor or pharmacist.
Symptoms of overdose in adults may include drowsiness. Children may initially show agitation and restlessness, followed by drowsiness.

If you forget to take ALERINIT

If you forget to take ALERINIT, take the next dose at the usual time.
Do not take a double dose to make up for a forgotten dose.

Possible effects after stopping ALERINIT

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking ALERINIT, even if those symptoms were not present before

treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon: may affect up to 1 in 100 people

Exhaustion and abdominal pain

Not known: frequency cannot be estimated from the available data

Other side effects such as palpitations, increased heart rate, fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful or difficult urination, inability to completely empty the bladder, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported. Pruritus (intense itching) upon discontinuation.

At the first signs of a hypersensitivity reaction, stop taking ALERINIT and tell your doctor. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal.

5. How to store ALERINIT

Keep ALERINIT out of the reach and sight of children and in its packaging.

Store below 30°C.

Use in accordance with expiry date.

Keep it in its original package.

After the expiration date on the label please do not use ALERINIT.

If you notice any damage to the medicine or its package, do not use ALERINIT.

Product Registrant: Goldplus Universal Pte. Ltd., Singapore

Manufacturer:

İlko İlaç Sanayi ve Ticaret A.Ş.

3. Organize Sanayi Bölgesi Kuddusi Cad.

23. Sok. No:1 Selçuklu/Konya-Turkey