

Package leaflet: Information for the patient

Oradus Beta Film-Coated Tablets

Desloratadine 5 mg and Betamethasone 0.6 mg

Read all of this 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, ask your doctor or pharmacist.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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1. What Oradus Beta is and what it is used for

Oradus Beta contains the active substances desloratadine and betamethasone. Desloratadine is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Betamethasone belongs to a group of medicines called corticosteroids. Corticosteroids are hormones that are found naturally in your body. Taking extra corticosteroids, such as betamethasone, is used to treat various illnesses involving inflammation in your body.

This medicine is used for the treatment of severe allergic conditions which require co-administration of an antiallergy medication and a corticosteroid. These conditions include:

Atopic dermatitis, angioedema, urticaria, intermittent and persistent allergic rhinitis, allergic reactions due to food and medicines, allergic contact dermatitis and allergic processes involving the eye, such as allergic conjunctivitis.

This medicine is indicated for adults and adolescents (12 years of age and older).

2. What you need to know before you take Oradus Beta

Do not take Oradus Beta:

- If you are allergic (hypersensitive) to desloratadine, loratadine, betamethasone or other corticosteroids or to any of the ingredients of this medicine (listed in section 6).

- If you have a general infection caused by a fungus.

- If you have active tuberculosis (TB).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Oradus Beta, especially if you have or have had any of the following conditions:

- Eye diseases (glaucoma or injury of the cornea)

- Mental illness

- Medical or familial history of seizures

- Abscess or other infection including hepatitis B, tuberculosis, polio, chickenpox, roundworms

- Inflammation of your digestive tract, ulcers or connection of two bowel parts after surgery

- Kidney disease (renal insufficiency)

- High blood pressure (hypertension)

- Brittle bones (osteoporosis)

- A disease of the muscles called myasthenia gravis

Also tell your doctor if you have recently had (within the last 2 weeks) or plan to have (within the next 8 weeks) a vaccination.

Other things you should know about Oradus Beta

These tablets can affect your immune system that protects your body against diseases. Thus vaccination with an inactivated vaccine (e.g. flu or cholera vaccines) may not be as effective, certain viral diseases (chickenpox and measles) may be more severe especially if you have not been vaccinated against them and you may be at a greater risk of other severe infections.

If you are developing an infection, it may be more difficult to be detected while you are taking these tablets.

You may need a smaller dose of these tablets if you have:

Hypothyroidism (underactive thyroid gland) or liver cirrhosis (a disease caused by alcoholism or hepatitis).

You may need a higher dose of these tablets during stressful events such as a surgical procedure or a recent infection.

In some patients, corticosteroids may alter sperm motility and count.

Children and adolescents:

This medicine should not be used in children under 12 years old. The use of steroids can slow down normal growth of children and adolescents.

Other medicines and Oradus Beta:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. **Desloratadine:** There are no known interactions of desloratadine with other medicines.

Betamethasone: Other medicines can affect the way betamethasone works or betamethasone can affect the way they work.

In particular:

- Medicines used to treat epilepsy such as phenobarbital, phenytoin, primidone and carbamazepine

- Medicines used to treat tuberculosis such as rifampicine and rifabutine

- Medicines used to treat nasal congestion such as ephedrine

- Hormones such as estrogens and somatotropin

- Potassium-depleting derivatives such as certain water pills (diuretics) and amphotericin B

- Medicines used to treat heart failure such as cardiac glycosides

- Certain anticoagulants used to prevent blood clots such as coumarines

- Medicines which can cause stomach ulcers (e.g. painkillers like aspirin, ibuprofen)

- Salicylates (e.g. aspirin)

- Antidiabetic medicines used to control blood sugar levels

Talk to your doctor before performing any laboratory test.

Oradus Beta with food and drinks:

This medicine can be taken with or without food. Your doctor may tell you to reduce dietary salt and you prescribe potassium supplementation while taking this medicine.

Use with caution when taking Oradus Beta with alcohol.

Pregnancy and breast-feeding:

If you are pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or nursing a baby, taking this medicine is not recommended.

Driving and using machines:

At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicine.

3. How to take Oradus Beta

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

Adults and adolescents (12 years of age and older):

- Take one tablet once a day.

- Swallow the tablet whole with water.

- Your doctor may adjust the dose according to your condition. Treatment must be continued until a proper therapeutic response is observed.

- If you have a liver or kidney disease, your doctor may initiate your treatment with half of the recommended dose until the degree of therapeutic response is established.

- Once your allergic symptoms suppressed, your doctor will gradually discontinue your treatment.

If necessary your doctor will subsequently prescribe an antiallergy medicine as a single drug.

If you take more Oradus Beta than you should

Take this medicine only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more of this medicine than you were told to, contact your doctor or pharmacist or go to the nearest hospital. You may experience somnolence and an increase in your heart rate.

If you forget to take Oradus Beta

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Oradus Beta

It can be dangerous to stop taking this medicine suddenly. If you need to stop this treatment, follow your doctor's advice. Your doctor may tell you to lower the amount of medicine you are taking gradually until you stop taking it altogether. If you stop taking this medicine too quickly, your condition may get worse.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects can be serious and need immediate medical attention.

If you experience the following, stop taking this medicine and tell your doctor immediately or go to your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect. You may need urgent medical attention or hospitalization

Adverse drug reactions previously reported with one of the individual components (desloratadine and betamethasone) may be potential undesirable effects with Oradus Beta as well.

Desloratadine:

In adults, side effects were about the same as with a dummy tablet (placebo). However, fatigue, dry mouth and headache were reported more often than with a placebo.

In adolescents, headache was the most commonly reported side effect.

Very rare side effects have been reported:

Severe allergic reaction, rash, pounding or irregular heartbeat, fast heartbeat, stomach ache, nausea (feeling sick), vomiting, upset stomach, diarrhoea, dizziness, drowsiness, inability to sleep, muscle pain, hallucinations, seizures, restlessness with increased body movement, liver inflammation and abnormal liver function tests.

Betamethasone:

Side effects reported for betamethasone are similar to those reported for other corticosteroids and were related to dosage and treatment duration. Betamethasone is usually well tolerated by patients.

On short-term treatment the side effects include: Gastrointestinal complaints, such as an upset stomach or inflammation of the pancreas, ulcer of the stomach, ulcer of the duodendum, or bleeding ulcer.

On long-term treatment the side effects include:

Filling or rounding of the face, neck and body; dehydration, weakness; hormone deficiency; irregular periods or complete absence of periods; abnormal hair growth, weight gain or weight loss, increased or decreased appetite; in diabetics: the need for more insulin or antidiabetic tablets;

recurring infections or mild infections getting worse e.g. chickenpox; being less protected after inoculation; having a decreased response to skin test; recurrence of dormant tuberculosis (TB); brittle bones (osteoporosis) or bone disease (osteonecrosis); muscle weakness; fluid retention in the tissues, usually marked by swelling of ankles or feet; sodium retention, usually marked by an increase in blood pressure; calcium deficiency; high blood pressure; potassium loss; changes of mood (nervousness, depression, euphoria, psychological dependence and schizophrenia); sleeplessness; aggravation of epilepsy; certain eye diseases (increased pressure in the eye, glaucoma, papilloedema (optic nerve swelling), cataracts (clouding of vision), thinning of the cornea or outer wall (sclera) and worsening of a viral or fungal eye disease); abdominal or stomach pain; nausea and vomiting; candidiasis (thrush); slower healing of wounds; easy bruising; skin problems; fracture (spinal fracture); tendon rupture; telangiectasia (spider veins); in children: delayed or stunted growth and increased intracranial pressure (pseudo tumor cerebri); increase in the amount of white blood cells in your blood; blood clot in your vessels; in elderly: symptoms of diabetes (unusual thirst, frequent urination); loss of bone tissue with symptoms such as low back pain, loss of stature and fractures.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oradus Beta

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.

- Do not store above 30°C. Keep away from humidity. - Do not use this medicine if you notice visible signs of deterioration.

- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oradus Beta contains

The active substances are desloratadine and betamethasone.

Each film-coated tablet contains 5 mg of desloratadine and 0.6 mg of betamethasone. The other ingredients are microcrystalline cellulose, maize starch, calcium hydrogen phosphate dihydrate, colloidal anhydrous silica, talc, red iron oxide (E172), yellow iron oxide (E172), polyvinyl alcohol, titanium dioxide, lecithin, and xanthan gum.

What Oradus Beta looks like and contents of the pack

Oradus Beta are pink, round, film-coated tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. N°. for Oarus Beta film-coated tablets in Lebanon: 186536/13

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

This leaflet was last revised in December 2021