

## Package leaflet: Information for the patient

# Oradus Beta Oral Solution

Desloratadine 1 mg/ml and Betamethasone 0.05 mg/ml

## 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.

### What is in this leaflet

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

### 1. What Oradus Beta Oral Solution is and what it is used for

Oradus Beta Oral Solution 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 children over the age of 2 years.

### 2. What you need to know before you take Oradus Beta Oral Solution

#### Do not take Oradus Beta Oral Solution:

- 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 an infection and have not yet started taking medicine (e.g. antibiotics) to treat it.
- 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 Oral Solution, especially if you have or have had any of the following conditions:

- Glaucoma (raised eye pressure) or any family history
- Severe mental illness
- Severe depression or manic depression (bipolar disorder). This includes having had depression before or while taking steroid medicines or family history for these illnesses

- Any infection including tuberculosis (TB)

- Recently had contact with someone who has chickenpox, shingles or measles, or recently had chickenpox, shingles or measles yourself. This product may make chickenpox, shingles or measles much worse
- Stomach or duodenal ulcers
- Liver, heart or kidney disease
- High blood pressure (hypertension)
- Osteoporosis (thinning of the bones).

Post-menopausal women are particularly at risk of this;

- A disease of the muscles called myasthenia gravis (which causes muscle weakness)

- Epilepsy (fits)
- Recently had a heart attack
- Diabetes or family history of diabetes
- Underactive thyroid gland
- History of muscle wasting due to corticosteroid
- Pregnant or breast feeding (see “Pregnancy and breast-feeding” section below).

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 Oral Solution

- Mental problems while taking betamethasone: Mental health problems can happen while taking steroids like betamethasone (see also side effects section). These illnesses can be serious

- Usually they start within a few days or weeks of starting the medicine
- They are more likely to happen at high doses
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone who is taking this medicine) show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

- Chickenpox, shingles or measles

You should avoid contact with anyone who has either chickenpox, shingles or measles as it could be extremely serious if you caught it from them. Ask your doctor immediately if you suspect you may have come into contact with a person who has chickenpox, shingles or measles.

However, do not stop taking your medicine, unless your doctor tells you to.

#### Children and adolescents:

This medicine should not be used in children under 2 years old. The use of steroids can slow down normal growth of children and adolescents.

#### Other medicines and Oradus Beta Oral Solution:

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 rifampicin and rifabutin
- Medicines used to treat nasal congestion such as ephedrine
- Oral contraceptive (the pill), mifepristone (anti-progesterone) and somatotropin (growth hormone)
- Water pills (diuretics)
- Amphotericin B (anti-fungal)
- Medicines used to treat heart failure such as cardiac glycosides
- Medicines for thinning the blood such as warfarin
- Non-steroidal anti-inflammatory drugs such as ibuprofen

- Salicylates (e.g. aspirin)
- Insulin or oral antidiabetic drugs
- Medicines for high blood pressure
- Medicines for myasthenia gravis called anticholinesterases
- Acetazolamide (used to treat glaucoma)
- Carbenoxolone (an ulcer healing drug)
- Theophylline (used to treat asthma and other breathing difficulties)
- Ritonavir (anti-viral for infections)
- Vecuronium and other muscle relaxants
- Fluoroquinolones (used for some infections)
- Quetiapine (improves symptoms of some mental illnesses)
- Tretinoin (used for skin problems such as bad acne)

Talk to your doctor before performing any laboratory test.

#### Oradus Beta Oral Solution with food and drink:

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

Use with caution when taking Oradus Beta Oral Solution with alcohol.

#### Pregnancy and breast-feeding:

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.

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

Taking steroids often or for a long time during pregnancy can slow the baby's growth in the womb or may temporarily affect the baby's heart and body movements. Sometimes the baby may get digestive juices going up into the tube that carries food from the mouth to the stomach. The baby may also make less of its own steroid after birth, but this rarely causes any problems. If you become pregnant whilst taking this medicine, please tell your doctor but DO NOT stop taking the tablets unless told to do so (see section “If you stop taking Oradus Beta Oral Solution” below).

If you are breast-feeding, the steroid may enter the baby and lower their hormone levels if you are taking high doses for a long time.

#### Driving and using machines:

This medicine may cause mood changes, visual disturbances or somnolence. If you notice this, caution should be exercised in driving and operating machinery.

#### Oradus Beta Oral Solution contains sorbitol:

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

#### Oradus Beta Oral Solution contains Propylene glycol

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

#### 3. How to take Oradus Beta Oral Solution

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

#### Children:

2 through 5 years of age:  
The recommended dose is 1.25 ml (¼ of a 5 ml spoonful) of Oral Solution once a day.

6 through 11 years of age:  
The recommended dose is 2.5 ml (½ of a 5 ml spoonful) of Oral Solution once a day.

#### Adults and adolescents 12 years of age and older:

The recommended dose is 5 ml (one 5 ml spoonful) of Oral Solution once a day.

- This medicine is for oral use. Swallow the dose of oral solution and then drink some water.

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

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

#### If you take more Oradus Beta Oral Solution 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 Oral Solution

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

#### If you stop taking Oradus Beta Oral Solution

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 your medicine too suddenly, you may suffer from some of the following: fever, joint and muscle pain, itching eyes, nose or skin, mood changes, loss of weight, low hormone levels and low blood pressure, symptoms of which may include dizziness, headaches or fainting. In extreme cases, this can be fatal.

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 Oral Solution as well.

Desloratadine:

In most children and adults, side effects were about the same as with a dummy solution (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.

The following side effects were reported very rarely in adults:

Severe allergic reactions, rash, pounding or irregular heartbeat, fast heartbeat, stomach ache, feeling sick

(nausea), vomiting, upset stomach, diarrhea, dizziness, drowsiness, inability to sleep, muscle pain, hallucinations, seizures, restlessness with increased body movement, liver inflammation, and abnormal liver function tests.

Other side effects were reported in adults but the frequency is not known:

- unusual weakness
- change in the way the heart beats
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- yellowing of the skin and/or eyes

Side effects with unknown frequency were reported in children:

- slow heartbeat
- change in the way the heart beats

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.

Serious effects: tell a doctor straight away.

Steroids including betamethasone can cause serious mental health problems. These are common in both adults and children.

They can affect about 5 in every 100 people taking medicines like betamethasone.

- Feeling depressed, including thinking about suicide
- Feeling high (mania) or moods that go up and down
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
- Feeling, seeing or hearing things which do not exist.
- Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems talk to a doctor straight away.

Most people find that using this medicine for a short time causes no problems. High doses taken for a long time, or repeated short courses, can lead to side effects such as:

- Low levels of hormones which can cause irregular menstrual periods in women, suppression of growth in adolescents and children, changes in blood sugar, salt or protein levels, extra hair growth and/or weight gain, increased sweating or increases in appetite
- Increased levels of cholesterol in your blood
- Increased susceptibility to infection, including worsening of tuberculosis (TB) if this is already present

- Wasting of muscles, thinning of the bones (osteoporosis) or fractures, breaking of tendons and breakdown of the bone due to lack of blood supply

- Water retention (which may cause a bloated feeling), or higher blood pressure (symptoms may include headaches), or changes in blood chemistry due to loss of potassium

- If you have recently had a heart attack, betamethasone can sometimes cause a serious complication of the heart, whereby the tissues can become affected by tears or breaks

- Mood changes, depression, sleep problems, or worsening of epilepsy or schizophrenia if you already have either of these problems

- Children may experience swelling and fluid build-up near the eyes and brain (this may result in a throbbing headache which may be worse upon waking up, coughing, or sudden movement, and patchy vision with blind spots and possible lack of colour vision)

- Increased pressure in the eye (glaucoma), cataract, worsening of viral or fungal diseases, thinning of the cornea or sclera (the outer membrane of the eye) or other eye problems (which may cause headaches or blurred vision)

- Heartburn or indigestion, hiccups, nausea, bloating of the abdomen, stomach ulcers which may bleed, oesophageal ulcer, thrush in the mouth or throat, or pancreas disorders

- Bruising, poor wound healing, abscesses, acne, rashes, thinning of the skin, prominent veins, changes in skin colour, or blistering of the skin, mouth, eyes and genitals

- Blood clots, or allergic reactions (which can include rashes, breathing difficulties or shock), blood disorders, or heart failure.

Additional care should be taken if this medicine is given to elderly patients, as side effects may be more serious.

#### 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 Oral Solution

- 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 label and the outer packaging.

The expiry date refers to the last day of that month.

- Do not store above 30°C.

- Do not refrigerate or freeze. Store in the original package.

- Do not use this medicine if you notice any change in the appearance of the Oral Solution.

- 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 Oral Solution contains

- The active substances are desloratadine 1 mg/ml and betamethasone 0.05 mg/ml.

- The other ingredients are sorbitol, propylene glycol, sucralose, hypromellose, sodium citrate dihydrate, natural and artificial flavour (tutti frutti), citric acid, disodium edetate and purified water.

##### What Oradus Beta Oral Solution looks like and contents of the pack

Oradus Beta Oral Solution is available in a bottle of 60 ml as a clear colorless solution. A measuring spoon is available, marked for doses of 1.25 ml, 2.5 ml and 5 ml.

##### Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon  
P.O. Box 90201 Jdeidet-El-Metn, Lebanon  
Contact us: pharmaline@maliagroup.com  
Website: www.pharmaline.com.lb

Reg. N°. for Oradus Beta Oral Solution: 45817/1

#### 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

The leaflet was last revised in September 2022.