

Oradus P

12 Hour Extended Release Tablets

(Desloratadine and Pseudoephedrine sulfate)

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

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

Oradus P 12 Hour Extended Release Tablets contain a combination of two active ingredients, desloratadine which is an antihistamine and pseudoephedrine sulfate which is a decongestant.

Antihistamines help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced by the body. Decongestants help to clear nasal congestion (blocked/stuffy nose).

Oradus P 12 Hour Extended Release Tablets relieve symptoms associated with seasonal allergic rhinitis (hay fever), such as sneezing, runny or itchy nose and itchy eyes, when accompanied by nasal congestion in adults and adolescents 12 years of age and older.

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

Do not take Oradus P tablets:

- If you are allergic to desloratadine, loratadine, pseudoephedrine sulfate, adrenergic medicines, or any of the ingredients of this medicine (listed in section 6).
- If you have high blood pressure, heart or blood vessel disease or a history of stroke.
- If you have glaucoma, difficulty in urinating, urinary tract blockage, or an overactive thyroid.
- If you are taking monoamine oxidase (MAO) inhibitor (a class of antidepressant medicines) therapy or have stopped taking these types of medicines within the last 14 days.

Talk to your doctor before taking this medicine if you have any of these conditions.

Warnings and precautions

Certain conditions may make you unusually sensitive to the decongestant pseudoephedrine sulfate contained in this medicine. Talk to your doctor or pharmacist before taking Oradus P tablets:

- If you are 60 years of age or older. Older adults may be more sensitive to the effects of this medicine.
- If you have diabetes.
- If you have intestinal ulcers leading to the narrowing of the stomach, small intestine or esophagus (stenosing peptic ulcer).
- If you have intestinal blockage (pyloral or duodenal blockage).
- If you have bladder neck blockage (vesical cervix blockage).
- If you have a history of difficulty breathing due to tightening of the lung muscles (bronchospasm).
- If you have problems with your liver, kidney, or bladder.

In addition, if you experience or you are diagnosed with any of the following conditions you should talk to your doctor or pharmacist as they may advise you to stop taking Oradus P tablets:

- High blood pressure.
- A fast or pounding heartbeat.
- Abnormal heart rhythm.
- Feeling sick and headache or increase headache while using Oradus P tablets.

If you are scheduled to have surgery, your doctor may advise you to stop taking Oradus P tablets 24 hours beforehand.

One of the active ingredients in Oradus P tablets, pseudoephedrine sulfate, has the potential to be abused and large doses of pseudoephedrine sulfate can be toxic. Continuous use may lead to taking more Oradus P tablets than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. If you suddenly stop treatment, depression may occur.

Laboratory tests

Stop taking Oradus P tablets at least 48 hours before you have any skin tests since antihistamines may influence the result of the skin test.

Athletes taking Oradus P tablets may have positive doping-tests.

Use in children and adolescents:

Do not give this medicine to children less than 12 years of age.

Other medicines and Oradus P

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking:

- Digitalis, a medicine used to treat certain heart disorders
- Medicines for blood pressure (e.g. α-methyldopa, mecamylamine, reserpine, veratrum alkaloids and guanethidine)
- Decongestants by oral or nasal route (such as phenylpropanolamine, phenylephrine, ephedrine, oxymetazoline, naphazoline)
- Diet pills (appetite suppressants)
- Amphetamines
- Medicines for migraines e.g. ergot alkaloids (such as, dihydroergotamine, ergotamine, or methylergometrine)
- Medicines for Parkinson's disease or for infertility e.g. bromocriptine, cabergoline, lisuride and pergolide
- Antacids for indigestion or stomach problems
- A medicine for diarrhea called kaolin
- Tricyclic antidepressants (such as fluoxetine), antihistamines (such as cetirizine and fexofenadine)

Oradus P with food

Oradus P tablets can be taken with or without food.

Oradus P with alcohol

Speak with your doctor or pharmacist regarding whether you can drink alcohol while taking Oradus P tablets. Drinking alcohol while taking Oradus P tablets is not recommended.

Pregnancy, 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.

Taking Oradus P tablets is not recommended if you are pregnant.

Decreased milk production in nursing mothers has been reported with pseudoephedrine sulfate, a component of Oradus P tablets. Desloratadine and pseudoephedrine sulfate are both excreted in human milk. If you are breast-feeding, taking Oradus P tablets is not recommended.

Fertility

There is no data available on male/female fertility.

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 medicinal product.

3- How to take Oradus P

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

Adults and adolescents 12 years of age and over

The recommended dose is one tablet twice daily with a glass of water, with or without food.

This medicine is for oral use.

Swallow the tablet whole; do not crush, break or chew the tablet before swallowing.

Do not take more tablets than recommended on the label. Do not take tablets more often than recommended.

Do not take this medicine for more than 10 days continuously unless your doctor tells you to do so.

If you take more Oradus P than you should

If you take more Oradus P tablets than you were told to, tell your doctor or pharmacist immediately.

If you forget to take Oradus P

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 P

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.

The following side effects have been commonly seen in studies: fast heartbeat, restlessness with increased body movement, dry mouth, dizziness, sore throat, decreased appetite, constipation, tiredness, headache, trouble sleeping, nervousness, and drowsiness.

Other side effects have been uncommonly reported: pounding or irregular heartbeat, increased body movement, flushing, hot flush, confusion, blurry vision, dry eye, nose bleeds, irritated nose, inflammation of the nose, runny nose, inflammation of the sinus, dry throat, stomach ache, stomach flu, feeling sick (nausea), abnormal stool, painful or difficult urination, sugar in urine, increased sugar in blood, thirst, problems urinating, changes in frequency of urination, itching, chills, decreased sense of smell, abnormal liver function tests, agitation, anxiety, irritability.

The following side effects have been rarely reported: severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling), rash, vomiting, diarrhea, hallucination, muscle pain, convulsion, liver inflammation, abnormal liver function tests.

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

5. How to store Oradus P

- 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 P contains

- The active substances are desloratadine and pseudoephedrine sulfate.
- Each tablet contains 2.5 mg of desloratadine and 120 mg of pseudoephedrine sulfate.
- The other ingredients are: microcrystalline cellulose, pregelatinized starch, disodium EDTA, citric acid, indigotine (E132), stearic acid, hypromellose, colloidal silicon dioxide, magnesium stearate.

What Oradus P looks like and contents of the pack

Oval bilayered tablets – containing desloratadine for immediate release in one layer and pseudoephedrine sulfate for extended release in the other layer, blue on one side and white on the other.

Oradus P is available in boxes containing 10 or 30 tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. N°. for Oradus P (30 tablets), Lebanon: 142114/1

Reg. N°. for Oradus P (10 tablets), Lebanon: 76420/1

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.