

Consumer Medicine Information

Rx

ORTREX[®] 200mg film coated Tablets

Contains the active ingredient voriconazole BP Tablets for oral administration

What is in this leaflet?

This leaflet answers some common questions about Ortrex (Voriconazole) it does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ortrex (Voriconazole) against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Read this leaflet carefully before taking Ortrex (Voriconazole) and keep this leaflet.

You may need to read it again.

What Ortrex (Voriconazole) is used for

Ortrex (Voriconazole) is used to treat fungal and yeast infections such as:

- invasive aspergillosis (as-pur-jilosis), a fungal infection caused by a fungus called Aspergillus (as-pur-jilus), which usually begins in the respiratory tract (in the nose, sinuses or lungs).

Aspergillus is harmless in most healthy people; however, in people with poor immune systems (such as people who have had organ transplants and people with cancer or HIV/AIDS) invasive aspergillosis can be serious and spread to other tissues and organs

- serious Candida (can-did-da) infections, including Candida infections of the food pipe and those that have spread into the blood stream or to other parts of the body
- serious fungal infections caused by Scedosporium (ski-doe-sporerium) species and Fusarium (fewsaa-rium) species.
- other serious fungal infections in patients who do not respond to, or cannot tolerate, other antifungal medicines.

This medicine belongs to a group of medicines called triazole antifungals.

This medicine works by preventing the growth of fungal and yeast organisms causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you start to use it

When you must not use it

Do not take Ortrex (Voriconazole) if you have ever had an allergy to:

- any medicine containing voriconazole
- any of the ingredients listed at the end of this leaflet

- any other similar medicines. Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives.

Do not take Ortrex (Voriconazole) if you are taking any of the following medicines:

- pimozone, a medicine used to treat mental illness
- quinidine, a medicine used to treat irregular heartbeat.
- Rifampicin, a medicine used to treat tuberculosis.
- Carbamazepine, a medicine used to treat Seizures
- Long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures.
- Ergotamine, or Dihydroergotamine, medicines used to treat migraine
- Sirolimus, a medicine used in transplant patients
- Efavirenz, a medicine used to treat HIV infection; some doses of efavirenz can be taken with Ortrex (Voriconazole), but you must check with your doctor first.
- Ritonavir, (a medicine used to treat HIV infection) in doses of 400 mg or more twice a day.
- St John's wort (a herbal medicine).

Ortrex (Voriconazole) should not be given to a child under the age of 2 years.

Safety and effectiveness in children younger than 2 years has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any foods, preservatives or dyes or any other medicines, especially antifungal medicines such as itraconazole, fluconazole or ketoconazole (not all brands given).

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- any problems affecting your kidneys
- any problems affecting your liver.

If you have liver disease your doctor may prescribe a lower dose

- Recent chemotherapy or stem cell transplant.

Tell your doctor if you are pregnant or plan to become pregnant.

Ortrex (Voriconazole) should not be taken during pregnancy, unless indicated by your doctor. Effective contraception should be used in women of childbearing potential. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

Ortrex (Voriconazole) should not be taken whilst breastfeeding, unless indicated by your doctor. It is not known if the active ingredient voriconazole passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell your doctor before you start taking Ortrex (Voriconazole).

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines should not be taken with Ortrex (Voriconazole) these include (not all brands given):

- pimozide, a medicine used to treat mental illness
- quinidine a medicine for irregular heartbeat.
- Rifampicin, a medicine used to treat tuberculosis.
- carbamazepine a medicine used to treat seizures.
- long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures.
- ergotamine or dihydroergotamine medicines used to treat migraine.
- Sirolimus, a medicine used in transplant patients.
- Ritonavir, (a medicine used to treat HIV infection) in doses of 400 mg or more twice a day.
- St John's wort, (a herbal medicine).

Some medicines and Ortrex (Voriconazole) may interfere with each other. These include (not all brands given):

- Efavirenz, a medicine used to treat HIV infection
- ritonavir (a medicine used to treat HIV infection) in doses of 100 mg twice a day
- warfarin, a medicine used to stop blood clots.
- Phenytoin, a medicine used to treat epilepsy
- cyclosporin a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system.

- sulphonylureas, medicines used to treat diabetes such as glibenclamide, gliclazide and glipizide.
- Rifabutin, an antibiotic.
- Theophylline, a medicine used to treat asthma.
- Benzodiazepines, medicines used to treat insomnia or anxiety.
- Statins, medicines used for lowering cholesterol.
- tacrolimus , a medicine used in patients who have had a liver or kidney transplant.
- indinavir and some other medicines used to treat HIV infection.
- omeprazole a medicine used to treat indigestion, reflux and stomach or duodenal ulcers.
- methadone (used to treat heroin addiction).
- oral contraceptives (the Pill).
- vincristine, vinblastine or vinorelbine, medicines used in treating cancer.
- strong pain killers such as Alfentanil, fentanyl and oxycodone.
- non-steroidal anti-inflammatory drugs, medicines used to treat pain and inflammation such as ibuprofen and diclofenac.

These medicines may be affected by Ortrex (Voriconazole) or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Ortrex (Voriconazole)

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much to take depending on your weight.

Adults

Treatment of invasive fungal Infections:

The usual dose of Ortrex (Voriconazole) Tablets in adults weighing greater than 40 kg is 400 mg (two 200 mg tablets twice a day) for the first day and then 200 mg to 300 mg twice a day thereafter.

In adults weighing less than 40 kg the dose of Ortrex (Voriconazole) Tablets halved.

Children

Ortrex (Voriconazole) should not be given to a child under the age of 2 years. Your doctor will determine the dose of Ortrex (Voriconazole) required for your child.

Depending on how serious the infection is and how your child reacts to the medicine, your doctor may increase or decrease the dose.

Adolescents (12-16 years of age)

Adolescents aged 12-16 years of age are usually given the same dose as adults.

How to take it

Ortrex (Voriconazole) needs to be taken regularly to be effective.

Ortrex Tablets Take Ortrex (Voriconazole) tablets at least one hour before or one hour after a meal. Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine regularly at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

The length of time you take Ortrex (Voriconazole) will depend on the type of infection you have.

If you have a weakened immune system or a difficult infection, you may need long-term treatment to prevent the infection from returning.

You may be switched from the injection to Ortrex Tablets once your condition improves.

Continue taking Ortrex for as long as your doctor or pharmacist recommends. Do not stop taking Ortrex because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to take it

If you forget to take one dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints. However, tell your doctor or pharmacist if you think that a dose has been forgotten.

***If you take too much
(Overdose)***

Immediately telephone your doctor or Poisons Information Centre for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Ortrex (Voriconazole) Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include upset stomach, diarrhoea, headache and sensitivity to light.

**While you are using Ortrex
(Voriconazole)**

Things you must do

Tell your doctor immediately if you develop a rash or blisters while taking Ortrex .

If this rash worsens, Ortrex (Voriconazole) may need to be stopped.

Avoid going out in the sun for long periods of time while you are taking Ortrex (Voriconazole)

Ortrex (Voriconazole) can cause sensitivity to light.

Tell your doctor if you notice any changes to your skin while you are taking Ortrex.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Make sure you follow your doctor's instructions and keep all appointments, including blood tests.

Your doctor should monitor the function of your liver and kidneys using blood tests. If you have liver disease, your doctor might lower your dose of Ortrex (Voriconazole) or stop your Ortrex

(Voriconazole) treatment. Your doctor might also monitor the function of your pancreas.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ortrex.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are a woman of childbearing age, you should avoid becoming pregnant while taking Ortrex (Voriconazole) If you become pregnant while taking Ortrex, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things you must not do

Do not take Ortrex to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else even if they have the same condition as you or if their symptoms seem similar to yours.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Things to be careful of

Be careful driving or operating machinery until you know how Ortrex affects you.

You may experience changes to your vision, such as blurriness, colour changes or uncomfortable sensitivity to light.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Do not drive at night.

Children should be careful when riding bicycles or climbing.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ortrex (Voriconazole).

This medicine helps most people with fungal infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following lists of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you notice any of the following and they worry you:

- changes to your vision, such as blurred vision, colour changes or sensitivity to light irregular heartbeat
- nausea or feeling sick, vomiting.
- headache
- stomach pain, indigestion,
- diarrhea
- back pain in middle or upper back
- swelling of the arms or legs
- soreness at the injection site.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips or
- tongue which may cause
- difficulty in swallowing or
- breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives or blisters
- fainting, seizures or fits
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice
- signs of frequent or worsening infections such as fever, severe chills, sore throat or mouth ulcers
- blood in urine
- signs of kidney failure such as tiredness, lack of appetite and reduced or greatly increased amount of urine
- convulsions, fits

These may be signs of a serious allergic reaction or side effect.

You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice any other side effects.

Other side effects not listed above may also occur in some people.

After using Ortrex (Voriconazole)

Storage

Ortrex (Voriconazole) Tablets Keep your tablets in the pack until it is time to use them.

If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Ortrex (Voriconazole) or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ortrex (Voriconazole) Tablets

- Ortrex (Voriconazole) Tablets come in two strengths, 50 mg and 200 mg.
- Ortrex (Voriconazole) 50 mg Tablets are white, round tablets marked EK50 on one side and 'TAJ' on the other.
- Ortrex (Voriconazole) 200 mg Tablets are white, capsule shaped tablets

marked EK200 on one side and 'TAJ' on the other.

Ingredients

Active Ingredients

Ortrex (Voriconazole) 50 mg Tablets contain 50 mg of voriconazole as the active ingredient.

Ortrex (Voriconazole) 200 mg Tablets contain 200 mg of voriconazole as the active ingredient.

Inactive Ingredients

The 50 mg and 200 mg tablets contain the following other ingredients:

- Lactose
- croscarmellose sodium
- magnesium stearate
- hypromellose
- titanium dioxide
- glycerol triacetate

Manufacturer:

Ortrex (Voriconazole) is made in India by: Taj Pharmaceuticals Limited.

Date of preparation

This leaflet was prepared in Jan. 2014.

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