

Voriconazole Kabi

[Voriconazole]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Voriconazole Kabi. It does not contain all the available information. It does not take the place of talking to your doctor.

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

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet. You may need to read it again.

What Voriconazole Kabi is used for

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 oesophagus (food pipe or gullet) 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.

Voriconazole is also used to prevent invasive fungal infections in patients who are at risk of developing such infections.

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 are given Voriconazole Kabi

When you must not be given it

Do not be given Voriconazole Kabi 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 be given Voriconazole Kabi if you are taking any of the following medicines:

- pimozide, a medicine used to treat mental illness.
- quinidine, a medicine used to treat irregular heartbeat.
- rifampicin, a medicine used to treat tuberculosis and other infections.
- carbamazepine, a medicine used to treat seizures.
- long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures.
- rifabutin, an antibiotic.
- ergotamine or dihydroergotamine, medicines used to treat migraine.
- sirolimus, a medicine used in transplant patients.
- efavirenz (a medicine used to treat HIV infection) in doses of 400 mg or more once a day.
- 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).

Voriconazole Kabi 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 be given 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 being given this medicine, talk to your doctor first.

Before you start to be given 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, posaconazole or ketoconazole.

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.

Voriconazole should not be given 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.

Voriconazole should not be given whilst breastfeeding, unless indicated by your doctor. It is not known if 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 Voriconazole Kabi.

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 voriconazole. These include:

- pimozide, a medicine used to treat mental illness.
- quinidine, a medicine for irregular heartbeat.
- rifampicin, a medicine used to treat tuberculosis and other infections.
- carbamazepine, a medicine used to treat seizures.
- long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures.
- rifabutin an antibiotic.
- ergotamine or dihydroergotamine, medicines used to treat migraine.
- Sirolimus, a medicine used in transplant patients.
- efavirenz (a medicine used to treat HIV infection) in doses of 400 mg or more once a day.
- 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 voriconazole may interfere with each other. These include:

- efavirenz (a medicine used to treat HIV infection) in doses below 400 mg once a day.
- ritonavir (a medicine used to treat HIV infection) in doses of 100 mg twice a day.
- warfarin, a medicine used to stop blood clots.
- everolimus, a medicine used to treat cancer.
- fluconazole, a medicine used to treat fungal infections.
- 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.
- some antihistamines, medicines used to treat hayfever, allergic skin reactions, itching.
- 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 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 has more information on medicines to be careful with or avoid while taking this medicine.

How Voriconazole Kabi is given

How much is given

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

Adults

Treatment of invasive fungal infections

The usual dose is 6 mg/kg every 12 hours for the first day. The dose is then adjusted to 3 mg/kg or 4 mg/kg every 12 hours, depending on the type of infection you have.

Prevention of invasive fungal infections

The usual dose is 6 mg/kg every 12 hours for the first day, given by injection. The dose is then adjusted to 4 mg/kg every 12 hours by injection.

Children

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

Your doctor will determine the dose 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 it is given

Voriconazole Kabi is given as an injection by a doctor or trained nurse.

It is a powder which is mixed with Water for Injections and then diluted by your pharmacist or doctor. It is then given by injection into a vein.

How long to take it

The length of time you take Voriconazole Kabi 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 voriconazole tablets or oral suspension once your condition improves.

If you forget to take it

Voriconazole Kabi will be given to you under close medical supervision. It is unlikely that a dose would be missed.

However, tell your doctor or medical staff if you think that a dose has been forgotten.

If you take too much (overdose)

As Voriconazole Kabi is given to you in a hospital under the supervision of your doctor or medical staff, it is very unlikely that you will receive an overdose. You will be closely monitored while in the hospital so that any unwanted side effects can be treated. However, if you experience severe side effects contact medical or nursing staff immediately.

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

While you are being given Voriconazole Kabi

Things you must do

Tell your doctor or medical staff immediately if you develop a rash or blisters while being given Voriconazole Kabi.

If this rash worsens, Voriconazole Kabi may need to be stopped.

Tell your doctor or medical staff if you notice any other changes to your skin.

Avoid going out in the sun for long periods of time while you are being given Voriconazole Kabi.

Voriconazole can cause sensitivity to sunlight.

Things to be careful of

Be careful when driving or operating machinery until you know how Voriconazole Kabi 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 medical staff as soon as possible if you do not feel well while you are being given Voriconazole Kabi.

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 to answer any questions you may have.

Tell your doctor or medical staff 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, diarrhoea
- back pain in middle or upper back
- swelling of the arms or legs
- rash
- changes to your skin, such as skin eruptions or small lumps on the skin
- soreness at the injection site.

If any of the following happen, tell your doctor or medical staff immediately:

- 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. 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 Voriconazole Kabi

Storage

Voriconazole Kabi will be stored in the pharmacy or on the hospital ward and is kept below 25°C.

Disposal

Voriconazole Kabi is used for one dose in one patient only. Any remaining contents should be discarded.

Product Description

What it looks like

White to off-white powder.

Ingredients

Each vial contains 200 mg of voriconazole as the active ingredient.

It also contains the following inactive ingredients:

- hydroxypropylbetadex
- arginine
- sodium chloride (for pH adjustment)
- hydrochloric acid (for pH adjustment)

Australian Registration Number

AUST R 303750

Supplier

Australia:

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Mount Kuring-gai NSW 2080

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