

Voriconazole APOTEX Powder for Injection

Contains the active ingredient voriconazole

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is Voriconazole APOTEX powder for injection. It contains the active ingredient voriconazole.

It is used to treat fungal and yeast infections such as:

- invasive aspergillosis (as-pur-ji-lo-sis), a fungal infection caused by a fungus called *Aspergillus* (as-pur-ji-lus), 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-di-da) infections, including those that have spread into the blood stream or to other parts of the body.
- serious fungal infections caused by *Scedosporium* (ski-doe-spore-ri-um) species and *Fusarium* (few-saa-ri-um) 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.

Ask your doctor if you have any questions about why this medicine has been chosen for you. Your doctor may have given you this medicine for another reason.

How it works

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.

There is no evidence that this medicine is addictive.

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

Before you are given this medicine

When you must not be given it

- **You must not be given this medicine 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 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)

- **You are hypersensitive to, or have had an allergic reaction to, voriconazole or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, contact the medical or nursing staff immediately.

- **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.
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you are given it

Your doctor must know about all the following before you are given this medicine.

You must tell your doctor if:

1. You have allergies to:
 - any other medicines, especially antifungal medicines such as

itraconazole, fluconazole, posaconazole or ketoconazole

- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - 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
 3. You are currently pregnant or you plan to become pregnant, or are breastfeeding.

This medicine 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.

This medicine 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.

4. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with voriconazole. Do not take voriconazole if you are taking the following:

- 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).

Other medicines may also interact with voriconazole. 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, a medicine 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

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with voriconazole.

How this medicine is given

How much of this medicine is given

Your doctor will tell you how much will be given, as it depends 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 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 of voriconazole required and the most suitable dosage form 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 old)

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

How it is given

This medicine is given as an injection into a vein.

This medicine must only be given by a physician or nurse.

If you receive too much (overdose)

As voriconazole 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 your medical or nursing staff immediately.

Symptoms of an overdose may include the side effects listed below in the 'Possible Side Effects' section but are usually of a more severe nature.

While you are using this medicine

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Avoid going out in the sun for long periods of time while you are taking this medicine. This medicine can cause sensitivity to sunlight.

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

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well after you have been given voriconazole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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 the 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 you experience any of the following, contact the medical or nursing staff immediately.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to voriconazole, contact your medical or nursing staff immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

After using this medicine

Storage

This medicine will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 25°C.

After sterile Water for Injections is added to this medicine it may be stored in a fridge at 2°C to 8°C for up to 24 hours prior to use. Do not freeze.

Disposal

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

Product description

What Voriconazole APOTEX powder for injection 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:

- hydroxypropyl betadex
- sodium chloride
- hydrochloric acid for pH adjustment.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Voriconazole APOTEX 200 mg powder for injection (glass vial): AUST R 265660.

Sponsor

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