

Voriconazole APOTEX Powder for Injection

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 this medicine. 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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

Voriconazole APOTEX 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 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-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 APOTEX 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/is not addictive.

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

Before you are given this medicine

When you must not be given it

Do not take this medicine if you have an allergy to:

- Any medicine containing Voriconazole.
- Any of the ingredients listed at the end of this leaflet.
- Any other similar medicines.

Some of the 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.
- Rash, itching or hives on the skin.

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

Voriconazole APOTEX should not be used 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 APOTEX should not be used 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.

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

Safety and effectiveness in children younger than 2 years have 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 first.

Before you start to take it

Tell your doctor if you have allergies to foods, preservatives or dyes, or any other medicines, especially antifungal medicines such as itraconazole (Sporanox), fluconazole (Diflucan), Posaconazole (Noxafil) or Ketoconazole (Nizoral) (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.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines should not be taken with Voriconazole APOTEX. These include (not all brands given):

- Cisapride (e.g. Prepulsid) a medicine used for treating stomach problems.
- Pimozide (e.g. Orap), a medicine used to treat mental illness.
- Quinidine (e.g. Kinidin Durules), a medicine for irregular heartbeat.
- Ivabradine, a medicine used to treat heart problems.
- Rifampicin (e.g. Rifadin, Rimycin), a medicine used to treat tuberculosis and other infections.
- Carbamazepine (e.g. Tegretol, Teril), a medicine used to treat seizures.
- Long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures.
- Rifabutin (e.g. Mycobutin) an antibiotic.
- Ergotamine (e.g. Cafergot) or dihydroergotamine (e.g. Dihydergot), medicines used to treat migraine.
- Sirolimus (e.g. Rapamune) a medicine used in transplant patients.
- Efavirenz (e.g. Stocrin) (a medicine used to treat HIV infection) in doses of 400 mg or more once a day.
- Ritonavir (e.g. Norvir, Kaletra) (a medicine used to treat HIV infection) in doses of 400 mg or more twice a day.
- St John's Wort, (a herbal medicine).

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

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

- Efavirenz (e.g. Stocrin) (a medicine used to treat HIV

infection) in doses below 400 mg once a day.

- Ritonavir (e.g. Norvir, Kaletra) (a medicine used to treat HIV infection) in doses of 100 mg twice a day.
- Warfarin (e.g. Marevan, Coumadin), a medicine used to stop blood clots.
- Everolimus (e.g. Afinitor, Certican), a medicine used to treat cancer.
- Venetoclax (e.g., Venclexta), a medicine used to treat blood cancers.
- Naloxegol, (e.g., Movantik), a medicine used to treat constipation caused by opioids (narcotic pain medicines).
- Ivacaftor, (e.g., Kalydeco, Orkambi, Symdeko), a medicine used to treat cystic fibrosis.
- Fluconazole (e.g. Diflucan), a medicine used to treat fungal infections.
- Phenytoin (e.g. Dilantin), a medicine used to treat epilepsy.
- Ciclosporin (e.g. Sandimmun, Neoral), 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 (e.g. Daonil, Diamicon, Minidiab).
- Some antihistamines, medicines used to treat hayfever, allergic skin reactions, itching.
- Theophylline (e.g. Nuelin), a medicine used to treat asthma.
- Benzodiazepines (e.g. Valium), medicines used to treat insomnia or anxiety.
- Statins (e.g. Zocor, Lipitor, Crestor), medicines used for lowering cholesterol.
- Tacrolimus (e.g. Prograf), a medicine used in patients who have had a liver or kidney transplant.

- Indinavir (e.g. Crixivan) and some other medicines used to treat HIV infection.
- Omeprazole (e.g. Losec), 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 (e.g. Vepesid).
- Strong pain killers such as alfentanil (e.g. Rapifen), fentanyl (e.g. Durogesic, Actiq, Sublimaze) and oxycodone (e.g. Endone, Proladone).
- Non-steroidal anti-inflammatory drugs, medicines used to treat pain and inflammation such as ibuprofen and diclofenac (e.g. Nurofen, Advil, Voltaren).
- Tolvaptan (e.g., Jinarc, Samsca) used to treat low levels of sodium in your blood or for kidney problems).
- Letermovir (e.g., Prevymis) used to prevent viral infections after bone marrow transplant).

These medicines may be affected by Voriconazole APOTEX 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 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 APOTEX should not be given to a child under the age of 2 years.

Your doctor will determine the dose of Voriconazole APOTEX 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 take too much (overdose)

As Voriconazole APOTEX 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 'Side Effects' section but are usually of a more severe nature.

While you are using this medicine

Things you must do

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.

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

It may affect other medicines used during surgery.

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

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

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.

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 Voriconazole APOTEX or stop your Voriconazole APOTEX treatment. Your doctor might also monitor the function of your pancreas.

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking Voriconazole APOTEX. If you become pregnant while taking Voriconazole APOTEX, tell your doctor immediately.

Things you must not do

Do not use Voriconazole APOTEX 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 when driving or operating machinery until you know how this medicine 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 this medicine.

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, 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 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.
- Severe skin reaction such as painful red areas, large blisters, flaking of your skin, and bleeding in the lips, eyes, mouth, nose and genitals.
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

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.

AUST R 265660.

Ingredients

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

This medicine also contains the following:

- Hydroxypropylbetadex
- Sodium chloride
- Hydrochloric acid for pH adjustment.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes (include any that are appropriate).

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Tel: 1800 195 055

This leaflet was prepared in November 2020.