

Voriconazole – AFT

Voriconazole

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about VFEND. 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 VFEND 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 Voriconazole – AFT is used for?

Voriconazole – AFT contains the active ingredient voriconazole. Voriconazole – AFT 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-ri-um) species.
- other serious fungal infections in patients who do not respond to, or cannot tolerate, other antifungal medicines.

Voriconazole-AFT 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 start to use Voriconazole – AFT?

When you must not use it

Do not use Voriconazole – AFT if you have ever had allergy to:

- any medicine containing voriconazole or any other similar medicines
- 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 or other parts of the body; skin rash, itching or hives.

Do not use Voriconazole – AFT if you are taking any of the following medicines:

- pimozide (e.g., Orap), a medicine used to treat mental illness.
- quinidine (e.g., Kinidin Durules), a medicine used to treat 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., Dihyergot), 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).
- naloxegol, (e.g., Movantik), a medicine used to treat constipation caused by opioids (narcotic pain medicines).
- tolvaptan (e.g., Jinarc) used to treat low levels of sodium in your blood or for kidney problems).
- venetoclax (e.g., Venclexta), a medicine used to treat blood cancers.
- lurasidone, a medicine to treat schizophrenia and bipolar disorder.

Voriconazole – AFT 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 use Voriconazole – AFT after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use the medicine if the packaging is torn or shows signs of tampering.

Before you start to use it

Check with 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 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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Voriconazole – AFT 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Voriconazole – AFT 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.

Taking other medicines

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

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

- 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 (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).
- tolvaptan (e.g., Jinarc) used to treat low levels of sodium in your blood or for kidney problems).
- lurasidone, a medicine to treat schizophrenia and bipolar disorder.
- 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).

Some medicines may interfere with Voriconazole – AFT. These medicines may be affected by Voriconazole – AFT, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. These medicines include:

- efavirenz (Stocrin) (a medicine used to treat HIV infection) in doses below 400 mg once a day.
- ritonavir (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.
- other cancer drugs such as glasdegib, axitinib, bosutinib, cabozantinib, ceritinib, cobimetinib, dabrafenib, dasatinib, nilotinib, sunitinib, ibrutinib, ribociclib.
- tretinoin, a medicine used for the treatment of acne and acute promyelocytic leukemia.
- ivacaftor, (e.g., Kalydeco), 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, medicines used to treat insomnia or anxiety.

- eszopiclone, a medicine used to treat insomnia.
- 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).
- letermovir (e.g., Prevymis) used to prevent viral infections after bone marrow transplant.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Voriconazole – AFT.

How to use Voriconazole – AFT?

How to use it

Voriconazole – AFT powder for Injection is given as an intravenous infusion by a doctor or trained nurse.

Voriconazole – AFT powder for Injection is a powder which is mixed with Water for Injections and then diluted by your pharmacist or doctor. It is then given as an intravenous infusion into a vein.

How much to take

The usual dose of Voriconazole-AFT Powder for Infusion 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.

When to use Voriconazole – AFT

Voriconazole – AFT injections are given by doctors or nurses in hospital. If you are not sure when to receive it, ask your doctor or pharmacist.

How long to use Voriconazole – AFT

The length of time you take Voriconazole – AFT 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 intravenous infusion to oral therapy once your condition improves.

If you forget to use Voriconazole – AFT

Voriconazole – AFT powder for injection will be given to you under close medical supervision. It is unlikely that a dose would be missed.

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

If you use too much Voriconazole – AFT

As Voriconazole – AFT is given to you under the supervision of your doctor, it is unlikely that you will have too much.

However, if you experience any side effects after being given Voriconazole - AFT, **you should immediately:**

- contact your doctor, or
- go to the Emergency Department at your nearest hospital, or
- phone the Poisons Information Centre (**0800 POISON or 0800 764 766**)

You should do this even if there are no signs of discomfort or poisoning.

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

While you are using Voriconazole – AFT

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Voriconazole – AFT.

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

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

It may affect other medicines used during surgery.

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

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

Avoid going out in the sun for long periods of time while you are given Voriconazole – AFT as the medicine can cause sensitivity to sunlight. Tell your doctor if you notice any changes to your skin while you are using the medicine.

Tell your doctor if you suffer from chronic, or long-lasting fatigue, muscle weakness, loss of appetite, weight loss or abdominal pain while on Voriconazole – AFT.

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 – AFT or stop your 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 on this medicine, tell your doctor immediately.

If you are a woman of childbearing age, you should avoid becoming pregnant while using Voriconazole – AFT.

Things you should be careful of

Driving or using machines

Be careful driving or operating machinery until you know how Voriconazole – AFT 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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Vision – related:</p> <ul style="list-style-type: none"> changes to your vision, such as blurred vision, colour changes or sensitivity to light <p>Skin – related:</p> <ul style="list-style-type: none"> changes to your skin, such as skin eruptions or small lumps on the skin rash <p>Pain/ swelling – related:</p> <ul style="list-style-type: none"> stomach pain headache back pain in middle or upper back soreness at the injection site swelling of arms or legs <p>Body as a whole:</p> <ul style="list-style-type: none"> irregular heartbeat nausea or feeling sick vomiting indigestion, diarrhea 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Breathing – related:</p> <ul style="list-style-type: none"> swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing asthma, wheezing, shortness of breath <p>Skin – related:</p> <ul style="list-style-type: none"> sudden or severe itching, skin rash, hives or blisters 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 <p>Body as a whole:</p> <ul style="list-style-type: none"> fainting, convulsions, seizures or fits 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These may be signs of a serious allergic reaction or side effect. You may need urgent medical attention or hospitalization. These side effects are rare.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

After using Voriconazole-AFT

Storage

Voriconazole – AFT powder for Injection will be stored in the pharmacy or in the hospital ward and is kept below 30 °C.

Product description

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

Voriconazole - AFT is a white or almost white lyophilized cake or powder which provides a clear solution upon reconstitution.

Voriconazole – AFT contains

Active ingredient (main ingredient)	Voriconazole
Other ingredients (inactive ingredients)	Sulfobutyl betadex sodium (SBECD), water for injection
Potential allergens	Nil

Do not take this medicine if you are allergic to any of these ingredients.

Supplier

AFT Pharmaceuticals Ltd., Auckland, New Zealand

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