

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VFEND?

VFEND contains the active ingredient voriconazole. VFEND is used to treat fungal and yeast infections.

For more information, see Section [1. Why am I using VFEND?](#) in the full CMI.

2. What should I know before I use VFEND?

Do not use if you have ever had an allergic reaction to voriconazole, any similar medicines, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, or are breastfeeding. VFEND should NOT be used during pregnancy or breastfeeding, unless indicated by your doctor. Effective contraception should be used in women of childbearing potential.

For more information, see Section [2. What should I know before I use VFEND?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VFEND and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VFEND?

- Your doctor will prescribe the amount required of VFEND tablets, oral suspension or powder for injection. More instructions can be found in Section [4. How do I use VFEND?](#) in the full CMI.

5. What should I know while using VFEND?

Things you should do	- Advise any doctor or dentist you visit that you are using VFEND and remind them of this if they ask you to have a blood test. - Avoid going out in the sun for long periods while you are taking VFEND. VFEND can cause sensitivity to sunlight. - Advise your doctor immediately if you notice any changes to your skin including a rash or blisters, or suffer from long-lasting fatigue, muscle weakness, loss of appetite, weight loss or abdominal pain. - Use an effective method of contraception if you are a woman of childbearing potential. - Inform your doctor immediately if you become pregnant while using Vfend. - Make sure you follow your doctor's instructions and keep all appointments, including blood tests.
Things you should not do	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.
Driving or using machines	- Be careful before you drive or use any machines or tools until you know how VFEND affects you. - You may experience changes to your vision, such as blurriness, colour changes or uncomfortable sensitivity to light.
Looking after your medicine	- VFEND Tablets: Keep your tablets in the pack until it is time to take them, and stored below 30°C. - VFEND Oral Suspension: Store prepared suspension below 30°C. - VFEND Powder for Injection: this will be stored in the hospital and is kept below 30°C.

For more information, see Section [5. What should I know while using VFEND?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include pain at injection site, headache, nausea or rash. More serious side effects may include sudden skin symptoms or changes, allergic reaction (difficulty breathing; swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives), changes to urine colour or seizures. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VFEND®

Active ingredient(s): *VORICONAZOLE* (vori-con-a-zole)

Consumer Medicine Information (CMI)

This leaflet provides important information about using VFEND. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VFEND.**

Where to find information in this leaflet:

- [1. Why am I using VFEND?](#)
- [2. What should I know before I use VFEND?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VFEND?](#)
- [5. What should I know while using VFEND?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VFEND?

VFEND contains the active ingredient voriconazole.

VFEND belongs to a group of medicines called triazole antifungals.

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

VFEND 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-jilus), which usually begin 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-spore-rium) species and *Fusarium* (few-saa-rium) species.
- other serious fungal infections in patients who do not respond to, or cannot tolerate, other antifungal medicines.

2. What should I know before I use VFEND?

Warnings

Do not use VFEND if:

- you are allergic to voriconazole, any similar medicines, 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 or other parts of the body; skin rash, itching or hives.

- Always check the ingredients to make sure you can use this medicine.
- Do not use VFEND if you are taking any of the following medicines:
 - Certain medicines to treat mental illness including depression, schizophrenia and bipolar disorder:
 - pimozide; lurasidone; or St John's Wort (a herbal medicine).
 - Certain medicines used to manage heart problems:
 - quinidine or ivabradine.
 - Certain medicines used to treat other infections including but not limited to tuberculosis and HIV:
 - rifampicin; rifabutin; efavirenz; or ritonavir (in doses of 400 mg or more once a day).
 - Certain medicines used for seizures, insomnia or migraines
 - carbamazepine; phenobarbitone; ergotamine; dihydroergotamine; lemborexant.
 - Other medicines:
 - sirolimus, used in transplant patients.
 - naloxegol, used to treat constipation caused by opioids (narcotic pain medicines).
 - tolvaptan used to treat low levels of sodium in your blood or for kidney problems.
 - venetoclax, used to treat blood cancers.
 - finerenone, a medicine used to treat chronic kidney disease and type 2 diabetes.

VFEND 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 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.

Check with your doctor if you:

- have any other medical conditions, including:
 - heart problems.
 - any problems affecting your kidneys.
 - any problems affecting your liver.
 - recent chemotherapy or stem cell transplant.
 - take any medicines for any other condition
- have allergies to foods, preservatives or dyes or any other medicines, especially antifungal medicines such as itraconazole, fluconazole, posaconazole or ketoconazole (not all brands given).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

VFEND 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.

VFEND 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.

3. What if I am 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 VFEND. Please see Section 2 above for a list of those medicines.

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

- Medicines used to treat infections including fungal, bacterial and HIV infections:
 - fluconazole; flucloxacillin; indinavir.
- Medicines used for cancer treatment:
 - everolimus; glasdegib; axitinib; bosutinib; cabozantinib; ceritinib; cobimetinib; dabrafenib; dasatinib; nilotinib; sunitinib; ibrutinib; ribociclib; dasatinib; sunitinib, vincristine; vinblastine; vinorelbine; tretinoin.
- Medicines used in management of organ or bone marrow transplant:
 - ciclosporin; tacrolimus; letermovir.
- Medicines for management of diabetes glibenclamide; gliclazide and glipizide.
- Medicines for management of heart-related conditions:
 - Statins (used for lowering cholesterol).
- Medicines used to prevent blood clots:
 - warfarin (e.g. Marevan, Coumadin).
- Medicines used for severe acne:
 - tretinoin.
- Medicines for management of mental health including insomnia and anxiety:
 - benzodiazepines; eszopiclone.
- Medicines used for pain management:
 - 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.

- Other medicines:
 - ivacaftor, used to treat cystic fibrosis.
 - phenytoin, used to treat epilepsy.
 - some antihistamines, used to treat hayfever, allergic skin reactions, itching.
 - theophylline, used to treat asthma.
 - omeprazole, used to treat indigestion, reflux and stomach or duodenal ulcers.
 - methadone, used to treat heroin addiction.
 - oral contraceptives (the Pill).
 - methotrexate, a medicine used to treat arthritis and cancers.

These medicines may be affected by VFEND or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I use VFEND?

How much to take

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

Adults

Treatment of invasive fungal infections

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

The usual dose of VFEND Oral Suspension in adults weighing 40 kg and greater is 10 mL twice a day for the first day and then 5 mL twice a day.

In adults weighing less than 40 kg the dose of VFEND Tablets and Oral Suspension is halved.

The usual dose of VFEND Powder for Injection 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.

Children

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

Your doctor will determine the dose of VFEND 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 VFEND

VFEND Tablets

Swallow the tablets whole with a full glass of water.

VFEND Oral Suspension

Your pharmacist should advise you how to measure VFEND Oral Suspension using the multi-dosing syringe provided in the pack.

VFEND Oral Suspension should not be mixed with any other medication.

Please see instructions below before using VFEND Oral Suspension.

1. Shake the bottle well before use.
2. Remove cap and insert the tip of the syringe into the adaptor while the bottle is upright.
3. Turn the bottle upside down while holding the syringe in place. Slowly pull back the plunger of the syringe until the required amount of VFEND Oral Suspension is withdrawn from the bottle.
4. If large bubbles can be seen, slowly push the plunger back into the syringe. This will force the medicine back into the bottle. Repeat step 3 again.
5. Turn the bottle back upright and then remove the syringe.
6. Put the tip of the syringe into the mouth and point towards the inside of the cheek. SLOWLY push down the plunger of the syringe. Do not squirt the suspension out quickly.

If the medicine is to be given to a child, make sure the child is sitting or is held upright.

7. Replace the bottle cap.

Cleaning and storing the syringe:

1. The syringe should be rinsed after each dose. Pull the plunger out of the syringe and wash both parts by holding under warm running water.
2. Dry the two parts. Push the plunger back into the syringe. Keep it in a clean safe place with the medicine.

VFEND Powder for Injection

VFEND Powder for Injection is made into a solution and then given as an intravenous infusion by a doctor or trained nurse.

When to take / use VFEND

VFEND Tablets and Oral Suspension

- Take your medicine 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.
- Take your medicine 1 hour before food or after a meal.

How long to take it

- The length of time you take VFEND 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 VFEND Tablets or Oral Suspension once your condition improves.

Continue taking VFEND for as long as your doctor or pharmacist recommends. Do not stop taking VFEND 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 VFEND

If it is almost time for your next 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 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.

VFEND 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 take too much VFEND

If you think that you have taken too much VFEND, you may need urgent medical attention.

You should immediately:

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

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

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

5. What should I know while using VFEND?

Things you should do

- Remind any doctor or dentist you visit that you are using VFEND.
- 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.
- Avoid going out in the sun for long periods of time while you are taking VFEND. VFEND can cause sensitivity to sunlight.
- 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 VFEND

or stop your VFEND 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.

Call your doctor straight away if you:

- notice any changes to your skin while you are taking VFEND.
- develop a rash or blisters while taking VFEND. If this rash worsens, VFEND may need to be stopped.
- suffer from chronic, or long-lasting fatigue, muscle weakness, loss of appetite, weight loss or abdominal pain while on VFEND.
- notice the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- become pregnant while taking VFEND. If you are a woman of child-bearing age, you should avoid becoming pregnant while taking VFEND.

Things you should not do

- 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
- Do not use VFEND 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VFEND 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

VFEND Tablets

Keep your tablets in the pack until it is time to take 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 use this medicine after the expiry date.

VFEND Oral Suspension

Your pharmacist will store VFEND Oral Suspension in a powder form at 2°C to 8°C in the refrigerator before reconstitution.

Store the prepared suspension in a cool dry place where the temperature stays below 30°C.

Discard suspension 14 days after preparation.

VFEND Powder for Injection

VFEND Powder for Injection will be stored in the hospital and is kept below 30°C.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any 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

Symptoms at injection site:	What to do:
• soreness at the injection site	Speak to your doctor if you have any of these less serious side effects and they worry you.
Gastrointestinal symptoms: • stomach pain, indigestion, diarrhoea • nausea or feeling sick, vomiting	
Pain: • headache	
Vision and skin symptoms: • changes to your vision, such as blurred vision, colour changes or sensitivity to light • rash	

Serious side effects

Skin changes:	What to do:
• sudden or severe itching, skin rash, hives or blisters • severe skin reaction such as painful red areas, large blisters, flaking of your skin	Call your doctor straight away, or go straight to the Emergency

- yellowing of the skin or eyes, also called jaundice - changes to your skin, such as skin eruptions or small lumps on the skin Urine and kidney related effects: - blood in urine - signs of kidney failure such as tiredness, lack of appetite and reduced or greatly increased amount of urine Allergic reaction related symptoms: - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing - asthma, wheezing, shortness of breath Other: - fainting, seizures, convulsions or fits - bleeding in the lips, eyes, mouth, nose and genitals. - signs of frequent or worsening infections such as fever, severe chills, sore throat or mouth ulcers - irregular heartbeat - back pain in middle or upper back - swelling of the arms or legs	Department at your nearest hospital if you notice any of these serious side effects.
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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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to Medsafe. By reporting side effects, you can help provide more information on the safety of this medicine.

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

7. Product details

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

What VFEND contains

Active ingredient (main ingredient)	<u>Tablets:</u> VFEND 50 mg Tablets - 50 mg of voriconazole. VFEND 200 mg Tablets - 200 mg of voriconazole.
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	<u>Oral suspension:</u> VFEND Oral Suspension - 40 mg/mL of voriconazole. <u>Powder for injection:</u> VFEND Powder for Injection - 200 mg of voriconazole in each 30 mL vial.
Other ingredients (inactive ingredients)	The 50 mg and 200 mg <u>tablets</u> contain the following other ingredients: - lactose monohydrate - maize starch (pregelatinised) - croscarmellose sodium - povidone - magnesium stearate - hypromellose - titanium dioxide - triacetin. VFEND <u>Oral Suspension</u> contains the following other ingredients: - sucrose - colloidal anhydrous silica - titanium dioxide - sodium citrate dihydrate - xanthan gum - sodium benzoate - citric acid - natural orange flavour. VFEND <u>Powder for Injection</u> contains the following other ingredients: - water for injections - sulfobutyl betadex sodium (SBCD).

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

What VFEND looks like

VFEND Tablets

VFEND 50 mg Tablets are white, round tablets engraved Pfizer on one side and VOR50 on the other (registration number TT50-6696).

VFEND 200 mg Tablets are white, capsule shaped tablets engraved Pfizer on one side and VOR200 on the other (registration number TT50-6696a).

VFEND Oral Suspension

Once reconstituted, VFEND Oral Suspension is a white to off-white orange flavoured suspension. Each bottle

contains 70 mL of suspension (registration number TT50-6696/2).

VFEND Powder for Injection

White to off white powder in a clear, colourless, glass vial which contains 200 mg of voriconazole (registration number TT50-6696/1).

Who distributes VFEND

Pfizer New Zealand Limited

PO Box 3998

Auckland.

Toll Free Number: 0800 736 363.

www.pfizermedicalinformation.co.nz

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