

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrVFEND®**

**Voriconazole tablets**

**Voriconazole powder for oral suspension**

**Voriconazole for injection**

Read this carefully before you start taking **VFEND** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VFEND**.

#### **Serious Warnings and Precautions**

- Some medications should not be taken during VFEND treatment (see listing under the “following may interact with this medication” section)
- VFEND may cause irregular heartbeat and rarely cardiac arrest (when the heart suddenly stops beating) and death
- VFEND may cause problems with your vision
- VFEND may cause liver problems
- VFEND may cause severe skin reactions
- VFEND may cause harm to the fetus (unborn baby) in pregnant women
- VFEND may cause changes to the appearance of your teeth and pain affecting your joints, bones, or muscles.

For more information, see the “To help avoid side effects and ensure proper use...” and the “Serious side effects and what to do about them” sections below.

#### **What is VFEND used for?**

- **VFEND** is used to treat certain fungal infections, specifically Aspergillus or Candida infections.

#### **How does VFEND work?**

**VFEND** works by killing or interfering with the growth of fungi which helps stop the infection.

#### **What are the ingredients in VFEND?**

Medicinal ingredients: voriconazole

Non-medicinal ingredients:

Voriconazole tablets: croscarmellose sodium, Hypromellose, lactose monohydrate, magnesium stearate, povidone, pregelatinized starch, titanium dioxide and triacetin

Voriconazole powder for oral suspension: anhydrous citric acid, colloidal silicon dioxide, natural orange flavor, sodium benzoate, sodium citrate dihydrate, sucrose, titanium dioxide, and xanthan gum.

Voriconazole for injection: sulphobutylether- $\beta$ -cyclodextrin sodium (SBECD)

**VFEND comes in the following dosage forms:**

Voriconazole tablets, 50 mg and 200 mg

Voriconazole powder for oral suspension, 40 mg per mL

Voriconazole for injection, 200 mg per vial

**Do not use VFEND if:**

- You are allergic to voriconazole or any of the other ingredients of **VFEND** (see Non-medicinal ingredients)
- You are taking other medication that must not be taken with **VFEND** (see the following may interact with this medication)

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VFEND. Talk about any health conditions or problems you may have, including if you:**

- have history of heart disease, or an irregular heartbeat
- have had any drug allergies including allergic reactions to other drugs known as “azoles”
- have or had liver problems
- have or had kidney problems
- think you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, please check with your healthcare professional before starting to take **VFEND** tablets since they contain lactose monohydrate
- think you have sucrose intolerance, fructose intolerance, sucrase-isomaltase deficiency or glucose-galactose malabsorption, please check with your healthcare professional before starting to take **VFEND** powder for oral suspension since it contains sucrose
- are pregnant: Do not take **VFEND** while you are pregnant unless your healthcare professional tells you to do so. Use effective contraception methods if you are of childbearing age. Contact your healthcare professional right away if you become pregnant while taking **VFEND**.
- are breast-feeding: do not take **VFEND** during breast feeding. It is not known if **VFEND** passes in breast milk. Ask your healthcare professional for advice before taking any medicine while breast feeding

**Other warnings you should know about:**

**While being treated with VFEND:**

- tell your healthcare professional immediately if you develop serious skin reactions such as rash, red skin, blistering of lips, eyes or mouth, skin peeling accompanied by fever, and skin lesions.

- avoid strong sunlight while being treated with **VFEND**. Wear protective clothing and use sunscreen. Tell your healthcare professional if your skin becomes more sensitive to the sun.
- your healthcare professional may wish to monitor the function of your liver and kidney by doing blood tests.
- **VFEND** may affect your vision (e.g. make your eyes blurry). Do not drive or perform complex tasks if you have problems with your eyes. You should not drive at night while taking **VFEND**.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **Serious Drug Interactions**

The following list of medicines must not be taken during your course of **VFEND** treatment:

- Pimozide (a medicine for treating mental illness)
- Quinidine (a medicine for irregular heartbeat)
- Rifampin (a medicine for treating tuberculosis)
- Carbamazepine (a medicine used to treat seizures)
- Long acting barbiturates (medicines for severe insomnia and seizures) such as phenobarbital
- Sirolimus (used in transplant patients)
- Rifabutin (a medicine for fungal infections)
- Ergot Alkaloids: dihydroergotamine (a medicine for migraines)
- Ritonavir (doses of 400 mg twice daily or higher) and efavirenz (doses of 400 mg once daily or higher) (medicines for the treatment of HIV)
- Naloxegol (used to treat constipation caused by opioid use)
- Ivabradine (used to treat heart failure)
- St John's Wort (*Hypericum perforatum*)
- Venetoclax (used to treat Leukemia and Lymphoma)
- Eszopiclone, if you are 65 years of age or older (used to treat insomnia)
- Lovastatin, Simvastatin (used to treat high cholesterol levels)
- Triazolam (used to treat insomnia)
- Tolvaptan (used to treat low sodium levels)
- Lurasidone (used to schizophrenia and bipolar disorder)
- Glasdegib (used to treat acute myeloid leukemia)
- Tretinoin (used to treat acute promyelocytic leukemia)
- Tyrosine kinase inhibitors (e.g. axitinib, bosutinib) – used to treat cancer

### **The following may interact with VFEND:**

- Cyclosporine (a medicine used in transplant patients)
- Tacrolimus (a medicine used in transplant patients)
- Tricyclic antidepressants (medicines used to treat depression)

- Antiarrhythmics (medicines that stabilize heart function such as procainamide, amiodarone, quinidine, sotalol)
- Antipsychotic drugs (medicines used to treat psychotic disorders)
- HIV protease inhibitors (medicines used to treat HIV)
- Macrolide antibiotics (medicines used to treat bacterial infections)
- Methadone (medicine used to treat pain)
- Oral contraceptives (medicines used for birth control)
- Short-acting opiates (medicines used to treat pain, e.g. alfentanil, sufentanil)
- Long-acting opiates (medicines used to treat pain, e.g. oxycodone, fentanyl)
- Some oral anticoagulants (medicines used to prevent blood clots, e.g. warfarin, coumarin)
- Fluconazole (medicine used for fungal infections)
- Everolimus (medicine used for treating advanced kidney cancer and in transplant patients)
- Benzodiazepines (medicine used to treat anxiety, insomnia and seizures, e.g. midazolam, alprazolam)
- Calcium channel blockers (medicines used to treat heart conditions)
- Sulfonylureas (medicine used to treat diabetes, e.g. glyburide, glipizide)
- Letemovir (medicine used to treat viral infections)
- Ivacaftor (medicine used to treat cystic fibrosis)
- Corticosteroids (medicine used to treat inflammation, e.g. prednisolone, budesonide)
- Lemborexant (medicine used to treat insomnia)

Tell your healthcare professional if you are taking non-steroidal anti-inflammatories (NSAIDs) (used for treating pain and inflammation) including ibuprofen and diclofenac, as the NSAID dose may have to be adjusted.

#### **How to take VFEND:**

**VFEND has been prescribed for you. Do not allow anyone else to take it.** This product should only be taken under the supervision of a healthcare professional.

#### **Usual dose:**

##### Usual Adult dose:

Your healthcare professional will determine your dose depending on your weight and the type of infection (or suspected infection) you have.

Always take **VFEND** exactly as directed by your healthcare professional. You should check with your healthcare professional if you are unsure. Never change the dose yourself.

Your healthcare professional will prescribe a higher dose of **VFEND** on your first day of treatment. This will help your body quickly obtain an effective blood level of the antifungal.

#### **VFEND Injection:**

During the first 24 hours, you will be administered 2 doses of 6 mg/kg (12 hours apart).

After the first 24 hours:

- If you have an Aspergillus infection, you will be administered 4 mg/kg, twice a day.
- If you have a Candida infection, you will be administered 3 mg/kg or 4 mg/kg, twice a day.

#### VFEND Tablets:

Infection	First 24 hours (2 doses 12 hours apart)		After the first 24 hours	
	40 kg or more	Less than 40 kg	40 kg or more	Less than 40 kg
Aspergillus	400 mg	200 mg	200 mg twice a day	100 mg twice a day
Candida		400 mg		

**VFEND** tablets must be taken at least one hour before or two hours after a meal. Swallow the tablet whole with some water.

**VFEND** Oral Suspension must be taken one hour before or following a meal. Shake the closed bottle for approximately 10 seconds before each use. The suspension should only be administered using the oral dispenser supplied with each pack.

**VFEND** Oral Suspension should NOT be mixed with any other medication or flavoring agent and should not be further diluted with water or any other drinks.

If you have liver disease, your healthcare professional may prescribe a lower dose of **VFEND**.

Your healthcare professional may order periodic blood tests to monitor your liver function during **VFEND** treatment.

Continue taking **VFEND** until your healthcare professional tells you to stop. Do NOT stop treatment early because your infection may not be cured. Patients with a weakened immune system or those with difficult infections may require long term treatment to prevent the infection from returning.

#### Overdose:

If you think you, or a person you are caring for, have taken too much **VFEND**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Take your box of **VFEND** tablets or bottle of **VFEND** oral suspension with you.

#### Missed Dose:

If you miss taking a dose of **VFEND**, just take the next dose when it is due. Do NOT take a double dose to make up for the forgotten dose.

### What are possible side effects from using VFEND?

These are not all the possible side effects you may have when taking **VFEND**. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- fever
- rash
- nausea
- vomiting
- diarrhea
- headache
- swelling of the extremities (hands and feet)
- stomach pain
- dizziness
- itchiness
- weakness
- back pain
- chest pain
- flu-like symptoms
- facial swelling
- tingling
- cough
- hair loss
- pain and irritation of the eyes
- sensitivity to light and sun (photosensitivity)

Patients taking **VFEND** alone or taking **VFEND** along with corticosteroids long-term have experienced adrenal problems with symptoms of dizziness, fatigue, loss of appetite, nausea and vomiting.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Heart failure</b> (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			
<b>Irregular heartbeat</b>			√
<b>Visual disturbances</b> (eye problems): blurring of vision, reduced vision, colour vision change and increased sensitivity to light		√	
<b>Severe Cutaneous Adverse Reactions (SCAR):</b> severe skin reactions that may also affect other organs: <ul style="list-style-type: none"> <li>• Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish)</li> <li>• Swelling and redness of eyes or face</li> <li>• Flu-like feeling, fever, chills, body aches, swollen glands, cough</li> <li>• Shortness of breath, chest pain or discomfort</li> </ul>			√
<b>Liver problems:</b> yellowing of the skin, itching, feeling more tired than usual or like you have the flu, stomach pains or nausea and vomiting			√
<b>Kidney problems:</b> nausea, vomiting, fever, swelling of hands and feet, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, drowsiness, confusion			√
<b>Peripheral neuropathy</b> (nerve damage): burning pain, tingling,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
numbness, sensitivity to touch, weakness			
<b>Hyponatremia</b> (low levels of sodium in the blood): nausea, vomiting, confusion, weakness, fatigue, cramps, decreased consciousness, seizures			√
<b>Pancreatitis</b> (inflammation of the pancreas): persistent abdominal pain and tenderness, vomiting			√
<b>Bone and joint pain</b>		√	
<b>Hallucination</b>		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

Keep out of reach and sight of children

Store **VFEND** tablets at room temperature (15 °C to 30 °C). Do not use after the expiry date stated on the label.

Store **VFEND** reconstituted oral suspension at room temperature (15 °C to 30 °C) for up to 14 days. Do not refrigerate or freeze. Keep the container tightly closed. Discard remaining suspension 14 days after reconstitution.

**If you want more information about VFEND:**



- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.pfizer.ca](http://www.pfizer.ca) or by calling 1-800-463-6001.

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