

PART III: CONSUMER INFORMATION**PrVFEND**

voriconazole tablets
voriconazole powder for oral suspension
voriconazole for injection

This leaflet is part III of a three-part "Product Monograph" published when VFEND was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VFEND. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

ABOUT THIS MEDICATIONWhat VFEND is used for:

VFEND is prescribed by your doctor to treat certain fungal infections, specifically Aspergillus or Candida infections.

What VFEND does:

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

When it should not be used:

- If you are allergic to voriconazole or any of the other ingredients of VFEND (see below, under "What are the nonmedicinal ingredients").
- If you are taking other medication that must not be taken with VFEND (see listing under "Interactions with this medication")

What is the medicinal ingredient of VFEND and what dosage forms does it come in:

- Voriconazole tablets, 50 mg and 200 mg
- Voriconazole powder for oral suspension, 40 mg per mL
- Voriconazole for injection, 200 mg per vial

What are the nonmedicinal 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- β -cyclodextrin sodium (SBECD)

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 doctor.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- Some medications should not be taken during VFEND treatment (see listing under "Interactions with this medication")
- VFEND may cause irregular heartbeat and rarely cardiac arrest and death
- VFEND may cause disturbances in vision
- VFEND may cause liver problems
- VFEND may cause severe skin reactions
- VFEND may cause harm to the fetus in pregnant woman

For more information, see warnings below and "Side Effects and what to do about them"

Take special care with VFEND:Before being treated with VFEND, tell your doctor if:

- you have any of the following conditions: history of heart disease, or an irregular heart beat.
- you have had any drug allergies including allergic reactions to other azoles.
- you are suffering from, or have ever suffered from liver disease.
- you are suffering from, or have ever suffered from kidney disease.
- you are already being treated with certain medication (See "Interactions with this medication")
- you think you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, please check with your doctor before starting to take VFEND tablets since they contain lactose monohydrate.
- you think you have sucrose intolerance, fructose intolerance, sucrase-isomaltase deficiency or glucose-galactose malabsorption, please check with your doctor before starting to take VFEND powder for oral suspension since it contains sucrose.
- you are pregnant: VFEND must not be taken during pregnancy, unless indicated by your doctor. Effective contraception must be used in women of child-bearing potential. Contact your doctor immediately if you become pregnant while taking VFEND.
- you are breast-feeding: VFEND must not be taken during breast feeding. Ask your doctor or pharmacist for advise before taking any medicine while breast feeding.

While being treated with VFEND:

- tell your doctor immediately if you develop serious skin reactions such as rash, red skin, blistering of lips, eyes or mouth, skin peeling accompanied by fever.
- strong sunlight should be avoided while being treated with **VFEND**. Tell your doctor if you develop an increased sensitivity of skin to the sun.
- your doctor may wish to monitor the function of your liver and kidney by doing blood tests.

INTERACTIONS WITH THIS MEDICATION

Taking other medicines with VFEND:

It is very important that you inform your doctor or pharmacist if you are taking or have taken any other medicines, even those that are obtained without a prescription. Some medicines affect the way **VFEND** works and dosage adjustments or monitoring may be necessary, such as for the following:

- Cyclosporine (a medicine used in transplant patients)
- Tacrolimus (a medicine used in transplant patients)
- Tricyclic antidepressants
- Antiarrhythmics (drugs that stabilize heart function such as procainamide, amiodarone, quinidine, sotalol)
- Antipsychotic drugs
- HIV protease inhibitors
- Macrolide antibiotics
- Methadone
- Oral contraceptives
- Short-acting opiates (e.g. alfentanil, sufentanil)
- Long-acting opiates (e.g. oxycodone, fentanyl)
- Some oral anticoagulants (e.g. warfarin, coumarin)
- Fluconazole (used for fungal infections)
- Everolimus (used for treating advanced kidney cancer and in transplant patients)
- Benzodiazepines (e.g. midazolam, triazolam, alprazolam)
- Calcium channel blockers (heart medications)
- Sulfonylureas (e.g. glyburide, glipizide)
- Letermovir (used to treat viral infections)
- Tolvaptan (used to treat low sodium levels)
- Ivacaftor (used to treat cystic fibrosis)
- Corticosteroids (e.g. prednisolone, budesonide)

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

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

- Terfenadine[†] (a medicine for allergy)
- Astemizole[†] (a medicine for allergy)
- Cisapride[†] (a medicine for stomach problems)
- Pimozide (a medicine for treating mental illness)
- Quinidine (a medicine for irregular heart beat)
- 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: ergotamine and dihydroergotamine (a medicine for migraines)
- Ritonavir (doses of 400mg twice daily or higher) and efavirenz (doses of 400mg once daily or higher) (medicines for the treatment of HIV)
- Naloxegol (used to treat constipation caused by opioid use)
- St John's Wort (*Hypericum perforatum*)
[†] Not marketed in Canada

PROPER USE OF THIS MEDICATION

Usual Adult dose:

Your doctor 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 doctor. You should check with your doctor or pharmacist if you are unsure. Never change the dose yourself.

Your doctor will prescribe a higher dose of **VFEND** on your first day of treatment to more quickly obtain an effective blood level of the antibiotic in your body.

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		400mg		

It has been shown that taking all doses at the appropriate times may greatly increase the effectiveness of your medicine.

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 doctor may prescribe a lower dose of **VFEND**.

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

Continue taking **VFEND** until your doctor 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:

In case of drug overdose, contact a health care practitioner, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, **VFEND** can have side effects. If any side effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side effects are visual disturbances (blurring of vision, reduced vision, colour vision change and increased sensitivity to light), fever, rash, nausea, vomiting, diarrhea, headache, swelling of the extremities and stomach pains.

Other reported side effects include: changes in heart rate or rhythm, changes in blood pressure, blood cell changes, blood chemistry changes, dizziness, itchiness, weakness, back pain, chest pain, flu-like symptoms, facial swelling, hallucinations and other nervous symptoms, tingling, cough, breathing difficulty, hair loss, pain and irritation of the eyes, joint pain.

The following side effects have also been reported with the use of **VFEND**: peripheral neuropathy (nerve damage) with symptoms such as a burning pain, tingling, numbness, sensitivity to touch and weakness, and hyponatremia (low levels of sodium in the blood) with symptoms such as nausea, vomiting, confusion, weakness, fatigue, cramps, decreased consciousness and seizures.

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.

Check with your doctor immediately if chills, fever, flushing, sweating, muscle aches or pains, or other flu-like symptoms occur, especially if they occur shortly before, or together with a skin rash. Also, contact your doctor in case of a fast heartbeat, chest tightness or faintness. Very rarely, these effects may be the first signs of a serious reaction to this medication.

Contact your doctor if you suffer persistent abdominal pain and tenderness or vomiting as this may be a sign of a serious condition (pancreatitis).

If you develop bone pain during treatment, contact your doctor.

Driving and using machines

VFEND may cause changes to vision, including blurring and/or photophobia (sensitivity to light). The majority of visual symptoms appeared to spontaneously resolve within 60 minutes. While being treated with **VFEND** you must avoid potentially hazardous tasks, such as driving or operating machinery if you perceive any change in vision. You should not drive at night while taking **VFEND**.

If any of these side effects persist or are troublesome, please tell your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Heart failure			√
	Irregular heartbeat			√
	Visual disturbances		√	
	Severe skin reactions		√	
	Liver problems (yellowing of the eyes or skin, itching, feeling more tired than usual or like you have the flu, stomach pains or nausea and vomiting)			√

This is not a complete list of side effects. If you notice any unexpected side effects while using **VFEND**, please contact your doctor or pharmacist.

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HOW TO STORE IT

- Keep **VFEND** out of the reach and sight of children.
- Store **VFEND** Tablets at room temperature (15° to 30°C). Do not use after the expiry date stated on the label.
- Store **VFEND** Oral Suspension at room temperature (15° to 30°C) for up to 14 days. Do not refrigerate or freeze. Keep the container tightly closed. Discard remaining suspension 14 days after constitution.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at**
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program**
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada ULC, at 1-800-463-6001 (Medical Information).

This leaflet was prepared by Pfizer Canada ULC.