PATIENT INFORMATION VFEND ® (VEE-fend) (voriconazole IV injection, tablets, liquid)

Read the Patient Information that comes with VFEND before you start taking it and each time you get a refill. There may be new information. This information does not replace talking with your doctor about your condition or treatment.

What is VFEND?

VFEND is a prescription medicine that treats certain serious fungal infections in your blood and body; these infections are called "aspergillosis," "esophageal candidiasis," "Scedosporium," "Fusarium," and "candidemia.".

VFEND is for adults and children over 12 years of age.

What should I tell my doctor before taking VFEND?

Tell your doctor about all your health conditions, including if you:

- have or ever had an abnormal heart rate or rhythm. Your doctor may order a test to check your heart (EKG) before starting VFEND.
- have liver or kidney problems. Your doctor may do blood tests to make sure you can take VFEND.
- have trouble digesting dairy products, lactose, or regular table sugar. VFEND tablets contain lactose (milk sugar). VFEND liquid contains sucrose (table sugar).
- had an allergic reaction to any other medicine, such as hives, wheezing, or swelling of your face or throat.
- are pregnant or planning to become pregnant while taking this medication. VFEND can harm your unborn baby. Women who can become pregnant should use effective birth control while taking VFEND.
- **are breast-feeding.** It is not known if VFEND passes into breast milk. You and your doctor will need to decide if VFEND is right for you while you are nursing.

Know what medications you are taking. Be sure to tell your doctor about all the medications that you are taking, including prescription medicines, non-prescription medicines, vitamins, and herbal remedies. Keep a list of them with you to show your doctor or pharmacist.

Who should not take VFEND?

Do NOT take VFEND if you are taking the medicines listed below. Serious or life-threatening side effects from these medicines, or a decrease in the effect of VFEND could result if any of these medicines are taken together with VFEND. Tell your doctor right away if you are taking

any of these medications:

- terfenadine (Seldane[®]) astemizole (Hismanal[®])
- cisapride (Propulsid[®])
 pimozide (Orap[®])
- sirolimus (Rapamune®)
- carbamazepine (Tegretol®) rifampin (Rifadin®)
- rifabutin (Mycobutin®)
- quinidine (like Quinaglute[®])
- ergotamine, dihydroergotamine, methysergide (Sansert®), and bromocriptine (Parlodel®)
- long-acting barbiturates like phenobarbital (Luminal®)
- ritonavir (Norvir ®) and efavirenz (Sustiva®) (Some doses of ritonavir and efavirenz can be taken at the same time as VFEND, but you must check with your doctor first)

If you have questions or are uncertain about your medications, talk with your doctor or pharmacist.

Do not take VFEND if you are allergic to anything in it. The active ingredient is voriconazole. There is a list of what is in VFEND at the end of this leaflet.

Can I take other medicines with VFEND?

VFEND and many medicines can interact with each other and some should not be taken together (see "Who should not take VFEND?"). Other medicines may need the dose adjusted when taken with Vfend. Knowing the medicines that you are taking is important. Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. Keep a list of them with you to show your doctor or pharmacist. Do not take any new medicine without talking with your doctor.

How do I take VFEND?

- VFEND comes in I.V. (intravenous) form, or as a tablet or liquid.
- **VFEND I.V.** Your doctor or nurse may give you VFEND through a needle in your vein (intravenous, I.V.). It takes 1 to 2 hours to get each dose.
- **VFEND tablets.** Take the tablets as your doctor tells you. Take your dose at least 1 hour before or at least 1 hour after meals.
- **VFEND liquid**. Take the liquid as your doctor tells you. Take it at least 1 hour before or at least 1 hour after meals.
- VFEND is usually taken every 12 hours. Follow your doctor's instructions on when to take it. If you miss a dose of VFEND, take it as soon as you remember. If it is more than 6 hours since you missed your dose, <u>wait</u>. Do not take the missed dose. Take VFEND at the next regular dosing time. Do not take double doses.
- If you take too much VFEND or develop serious reactions, call your doctor or poison control center, or go to the nearest emergency room.

What should I avoid while taking VFEND?

Avoid night driving, because VFEND may cause vision problems like blurry vision.

Avoid all driving or using dangerous machinery, **if** you have any change in your eyesight. Avoid bright sunlight. Your skin may burn more easily. Your eyes may hurt in bright sunlight.

What are possible side effects of VFEND?

VFEND may cause serious or life threatening side effects. Call your doctor right away if you have any of the following symptoms:

Serious changes in heart rate or rhythm, including heart stopping (cardiac arrest). People who have certain heart conditions or who take certain other medicines have a higher chance for this problem.

Eyesight (vision) changes. These changes include blurred vision, color vision change, and being sensitive to light while you are taking VFEND. These changes are generally mild. Your doctor should monitor your eyesight if you take VFEND for more than 28 days.

Liver problems. VFEND can cause liver problems that usually go away when you stop VFEND. It can also cause very serious liver problems. Your doctor should test your liver function while you are taking VFEND. Call your doctor if you have any of these symptoms of liver problems, you:

- itch, or your skin or eyes turn yellow
- feel more tired than usual
- feel like you have the flu
- have nausea or vomiting

Kidney problems. Your doctor may check your kidney function while you are taking VFEND. Your doctor will decide if you can keep taking it or if you need a lower dose. Call your doctor if you have any of these symptoms of kidney problems:

• no appetite, feeling very tired changes in thinking, seizures, or trouble breathing nausea and vomiting, or itching

Serious allergic reactions can happen with VFEND injection. These include sweating, fast heartbeats, chest tightness, trouble breathing, nausea, itching, and rash. Your doctor should stop your VFEND infusion if you have any of these symptoms.

Serious skin reactions. If you get a skin rash or hives, sores in your mouth, or your skin blisters and peels, stop using VFEND. Call your doctor right away.

Common side effects with VFEND include eyesight changes, rash, vomiting, nausea, diarrhea, headache, chills, fever, infection in your blood, swelling in your arms and legs, stomach pains, and breathing problems.

These are not all the side effects with VFEND. For more information, ask your doctor or pharmacist.

How do I store VFEND?

- Store VFEND tablets and liquid at room temperature, 59° to 86° F (15° to 30°C). Do not refrigerate or freeze. The liquid should be discarded after 14 days. Keep all containers tightly closed.
- I.V. VFEND should be given by your nurse or doctor.
- Keep VFEND, as well as all other medicines, out of the reach of children.

General information about VFEND

Doctors can prescribe medicines for conditions that are not in this leaflet. Use VFEND only for what your doctor prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives the most important information about VFEND. For more information, talk with your doctor. You can ask your doctor or pharmacist for information about VFEND that is written for health professionals.

What is in VFEND?

Active ingredient: voriconazole

Inactive ingredients:

VFEND IV: sulfobutyl ether beta-cyclodextrin sodium

VFEND tablets: lactose monohydrate, pregelatinized starch, croscarmellose sodium, povidone, magnesium stearate, and a coating containing hypromellose, titanium dioxide, lactose monohydrate, and triacetin

VFEND liquid: colloidal silicon dioxide, titanium dioxide, xanthan gum, sodium citrate dihydrate, sodium benzoate, anhydrous citric acid, natural orange flavor, and sucrose



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