

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

VFEND 50 mg film-coated tablets

VFEND 200 mg film-coated tablets

Voriconazole

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

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

VFEND has been prescribed for you personally and you should not share your medicine with other people.

It may harm them, even if their symptoms are the same as yours.

1. WHAT VFEND CONTAINS:

The active ingredient in this medicine is called voriconazole.

VFEND 50 mg and 200 mg Tablets: Each tablet contains 50 mg and 200 mg voriconazole respectively.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone and pregelatinised starch, and which make up the tablet core and glycerol triacetate, hypromellose, lactose monohydrate and titanium dioxide, which make up the film-coat.

2. WHAT VFEND IS USED FOR:

VFEND belongs to a group of medicines called triazole antifungal agents. These medicines are used to treat a wide variety of fungal infections. VFEND works by killing or stopping the growth of the fungi that cause infections.

VFEND has been prescribed for you. Do not allow anyone else to take it.

VFEND should only be taken under the supervision of a doctor.

3. BEFORE YOU TAKE VFEND:

Do not take VFEND if you are allergic to voriconazole or any of the other ingredients.

A list of the medicines that may affect VFEND is shown in the section 'Taking other medicines with VFEND'.

However, the medicines in the following list must not be taken during your course of VFEND treatment:

- Astemizole (used for allergy)
- Cisapride (used for stomach problems)
- Pimozide (used for treating mental illness)
- Quinidine (used for irregular heart beat)
- Rifampicin (used for treating tuberculosis)
- Carbamazepine (used to treat seizures)
- Phenobarbital (used for severe insomnia and seizures)
- Ritonavir (used for treating HIV) in doses of 400 mg and more twice daily
- Ergot alkaloids (e.g. ergotamine, dihydroergotamine; used for migraine)
- Sirolimus (used in transplant patients)
- Rifabutin (used for treating tuberculosis)
- St John's Wort (herbal supplement)

VFEND cannot be used to treat patients who

- are pregnant or breastfeeding
- have 'long QT syndrome' (an abnormality of the electrocardiogram (ECG))
- have severe impairment of hepatic (liver) function.

Take special care with VFEND:

Before being treated with VFEND, tell your doctor if:

- you have had an allergic reaction to other azoles, antifungals.
- you are suffering from, or have ever suffered from liver disease. If you have liver disease, your doctor may prescribe a lower dose of VFEND. Your doctor should also monitor your liver function while you are being treated with VFEND by doing blood tests.
- you are suffering from, or have ever suffered from kidney disease. Dependent upon the degree of kidney disease the doctor may decide to give you VFEND tablets. Your doctor should monitor your renal function while you are being treated with VFEND by doing blood tests.

While being treated with VFEND:

- tell your doctor immediately if you develop a severe skin rash or blisters.
- avoid sunlight while being treated with VFEND, as an increased sensitivity of skin to the sun's UV rays can occur.
- your doctor should monitor the function of your liver and kidneys by doing blood tests.

Taking VFEND with food and drink:

VFEND tablets must be taken at least one hour before or one hour after a meal.

Pregnancy and Breastfeeding:

VFEND must not be taken during pregnancy. Effective contraception must be used in women of childbearing potential. Contact your doctor immediately if you become pregnant while taking VFEND.

VFEND must not be taken during breastfeeding.

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machinery:

VFEND may cause blurring of vision or uncomfortable sensitivity to light. While affected, do not drive or operate any tools or machines. Contact your doctor if you experience this.

Important information about some of the ingredients of VFEND:

VFEND tablets contain lactose and should not be given to patients with an intolerance to some sugars (i.e. rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption).

Taking other medicines with VFEND:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those that are obtained without a prescription.

Some medicines, when taken at the same time as VFEND, may affect the way VFEND works or VFEND may affect the way they work. Tell your doctor if you are taking any of the following medicines, as VFEND must not be taken if you are already taking any of these medicines:

- Astemizole (used for allergy)
- Cisapride (used for stomach problems)
- Pimozide (used for treating mental illness)
- Quinidine (used for irregular heart beat)
- Rifampicin (used for treating tuberculosis)
- Carbamazepine (used to treat seizures)
- Phenobarbital (used for severe insomnia and seizures)
- Ritonavir (used for treating HIV) in doses of 400 mg and more twice daily
- Ergot alkaloids (e.g. ergotamine, dihydroergotamine; used for migraine)

- Sirolimus (used in transplant patients)
- St John's Wort (herbal supplement)

Tell your doctor if you are taking the following medicine, as treatment with VFEND at the same time should be avoided if possible:

- Ritonavir (used for treating HIV) in doses of 100 mg twice daily

Tell your doctor if you are taking either of the following medicines, as treatment with VFEND at the same time should be avoided if possible, and a dose adjustment of voriconazole may be required:

- Rifabutin (used for treating tuberculosis)
- Phenytoin (used to treat epilepsy)

Tell your doctor if you are taking any of the following medicines, as a dose adjustment or monitoring may be required to check that they are still having the desired effect:

- Warfarin (used to slow down clotting of the blood)
- Ciclosporin (used in transplant patients)
- Tacrolimus (used in transplant patients)
- Sulphonylureas (e.g. tolbutamide, gliclazide, and glyburide) (used for diabetes)
- Statins (used for lowering cholesterol)
- Benzodiazepines (e.g. midazolam, triazolam and alprazolam) (used for severe insomnia and stress)
- Omeprazole (used for treating ulcers)
- Oral contraceptives (if you take VFEND whilst using oral contraceptives, you may get side effects such as nausea and menstrual disorders)
- Vinca alkaloids (e.g. vincristine and vinblastine) (used in treating cancer)
- Indinavir and other HIV protease inhibitors (used for treating HIV)
- Other Non-nucleoside reverse transcriptase inhibitors (e.g. delavirdine, nevirapine) (used for treating HIV)

- Methadone (used to treat heroin addiction)
- Efavirenz (used for treating HIV) (some doses of efavirenz cannot be taken at the same time as VFEND)
- Alfentanil , fentanyl and other opiates (painkillers used for surgical procedures)
- Oxycodone and other long acting opiates
- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen, diclofenac) (used for treating pain and inflammation)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of VFEND with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE VFEND:

Do not share medicines prescribed for you with any other person.

Always take VFEND exactly as directed by your doctor. You should check with your doctor or pharmacist if you are unsure.

Your doctor will determine your dose depending on your weight and the type of infection you have.

Take your tablet at least one hour before, or one hour after a meal. Swallow the tablet whole with some water.

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.

If you think that the effect of VFEND is too strong, or that it does not seem to be working, tell your doctor or pharmacist.

If you take more VFEND than you should:

If you take more tablets than prescribed (or if someone else takes your tablets) you must seek medical advice or go to the nearest hospital casualty department immediately. Take your box of VFEND tablets with you.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take VFEND Tablets:

It is important to take your VFEND tablets regularly at the same time each day. If you forget to take one dose, take your next dose when it is due. Do not take a double dose to make up for the forgotten dose.

Effects when treatment with VFEND is stopped:

It has been shown that taking all doses at the appropriate times may greatly increase the effectiveness of your medicine. Therefore unless your doctor instructs you to stop treatment, it is important to keep taking VFEND correctly, as described above.

When VFEND treatment is stopped by your doctor you should not experience any effects. However if you were taking medicines containing ciclosporin or tacrolimus you must mention this to your doctor, as the dose will need to be adjusted.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for VFEND are included in this leaflet. Should your general health worsen while taking VFEND, please consult your doctor, pharmacist or other healthcare professional for advice.

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.

Frequent side effects are:

- Visual disturbances (change in vision)
- Fever
- Rash
- Nausea, vomiting, diarrhoea
- Headache
- Swelling of the extremities
- Stomach pains
- Flu-like symptoms, sinusitis, chills, weakness
- Anaemia, low numbers of cells called platelets that help the blood to clot, low numbers of some types of white blood cells or of all types of blood cells, red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- Low blood sugar, low blood potassium
- Anxiety, depression, tingling, confusion, dizziness, agitation, trembling, hallucinations and other nervous symptoms
- Low blood pressure, inflammation of a vein (which may be associated with the formation of a blood clot)
- Breathing difficulty, chest pain, fluid accumulation in the lungs
- Jaundice, redness of the skin
- Swelling of the lips or face
- Allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe skin reaction following exposure to light or sun
- Itchiness
- Hair loss
- Back pain
- Kidney failure, blood in the urine, changes in blood tests of kidney function

- Inflammation at injection sites
- Changes in blood tests of liver function

Less frequent side effects are:

- Enlarged lymph glands (sometimes painful)
- Increase in a type of white blood cell which may be associated with allergic reaction, disorder of blood clotting system
- Heart rhythm problems including very fast heartbeat, very slow heartbeat, fainting
- Depressed function of the adrenal gland
- Problem with coordination
- Manifestation (signs) of swelling of the brain
- Double vision pain and inflammation of the eyes and eyelids, involuntary movement of the eye
- Decreased sensitivity to touch
- Constipation, inflammation of upper small intestine, dyspepsia (heartburn/indigestion), pancreatitis (inflammation of the pancreas), peritonitis (inflammation of the lining of the abdominal cavity)
- Gingivitis (inflammation of the gums)
- Swelling and inflammation of the tongue
- Enlarged liver, hepatitis, liver failure, gallbladder disease, gallstones
- Joint pain
- Inflammation of the kidney, proteins in the urine
- Abnormal electrocardiogram (ECG)
- Blood chemistry changes
- Inability to sleep
- Hearing difficulties, ringing in the ears
- Abnormal sense of taste
- Increase in muscle tone, muscle weakness caused by an abnormal immune system response
- Abnormal brain function, Parkinson-like symptoms, convulsion
- Sleepiness during infusion

As VFEND has been known to affect the liver and the kidney, your doctor should monitor the function of your liver and kidney by doing blood tests. Please advise your doctor if you have any stomach pains or if your stools have a different consistency.

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

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF VFEND:

Keep all medicines out of the reach and sight of children.

VFEND tablets must be stored below 25 °C.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF VFEND:

VFEND tablets are available in plastic bottles or in cardboard cartons. The opaque plastic bottles are available in pack sizes of 2, 30 or 100 tablets.

The cardboard cartons contain tablets in blister packs with pack sizes of 2, 10, 14, 20, 28, 30, 50, 56 or 100 tablets.

8. IDENTIFICATION OF VFEND:

VFEND 50 mg tablets are white to off-white, round convex tablets, engraved with “Pfizer” on one side and “VOR50” on the other.

VFEND 200 mg tablets are white to off-white, capsule-shaped tablets, engraved with “Pfizer” on one side and “VOR200” on the other.

9. REGISTRATION NUMBERS:

VFEND 50mg tablets: 36/20.1.7/0106

VFEND 200 mg tablets: 36/20.1.7/0107

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION:

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