

VFEND[®] FILM COATED TABLETS

Voriconazole (50 mg, 200 mg)

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What VFEND is used for

VFEND is used to treat and prevent fungal infections. VFEND is also used for prevention of breakthrough fungal infections who are at risk of developing such infections.

VFEND should be administered primarily to individuals with impaired immune system with progressive, possibly life-threatening infections.

How VFEND works

VFEND is a triazole antifungal agent. It kills or stops the growth of fungi that cause infections.

Before you use VFEND

- When you must not use it

Voriconazole is contraindicated in individuals with known hypersensitivity to voriconazole or to any of the ingredients.

VFEND should not be taken with the following medicines:

- Terfenadine
- Astemizole
- Cisapride
- Pimozide
- Quinidine
- Ivabradine
- Sirolimus
- Rifabutin
- Rifampicin
- Carbamazepine
- Phenobarbital

- Efavirenz (400 mg and above once daily)
- Ritonavir (400 mg and above twice daily)
- Ergot alkaloids (ergotamine, dihydroergotamine)
- St. John's Wort
- Naloxegol
- Tolvaptan
- Finerenone
- Eplerenone
- Voclosporin
- Venetoclax
- Lurasidone
- Lemborexant

Pregnancy and lactation

VFEND must not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the fetus.

Do not take VFEND if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take VFEND if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor before taking VFEND if you:

- have had allergic reactions to other azoles
- have liver problems like hepatitis (inflammation of the liver), cholestasis (impaired flow of bile from the liver to the duodenum), or liver failure
- have kidney problems
- suffer from heart diseases such as cardiomyopathy, irregular heartbeat, slow heart rate or an abnormality in electrocardiogram (ECG) results
- develop severe skin reactions. Your doctor may advise you to avoid any sunlight and sun exposure while being treated. It is important to

cover sun exposed areas of skin and use sunscreen with high sun protection factor (SPF), as an increased sensitivity of skin to the sun's UV rays can occur. This may be further increased by other medicines that sensitise the skin to sunlight, like methotrexate. These precautions are also applicable to children.

- have electrolyte disturbances like decreased levels of potassium, magnesium or calcium in the blood
- have visual disturbances
- have any pancreatic disorders

There is a small chance that skin cancer and periostitis (inflammation of the band of tissue that surrounds bones) could develop with long-term use of VFEND.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking:

- Astemizole, terfenadine (used for allergy)
- Cisapride (used to treat stomach problems)
- Pimozide (used to treat mental illness)
- Quinidine (used to treat irregular heartbeat)
- Ivabradine (used to treat heart failure)
- Carbamazepine, phenobarbital (used to treat seizures)
- Efavirenz (used to treat HIV infection)
- Glasdegib (used to treat acute myeloid leukaemia)
- Flucloxacillin (used to treat infections)
- Lemborexant (used to treat difficulty falling asleep)

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- Ergot alkaloids such as ergotamine, dihydroergotamine (used to treat migraine)
- Lurasidone (used for treating schizophrenia)
- Finerenone (used to treat chronic kidney disease)
- Voclosporin (used to treat kidney disease)
- Eplerenone (used to treat heart function problems)
- Rifabutin, rifampicin (used for treating tuberculosis)
- Ritonavir (used for treating HIV)
- St. John's Wort (a herbal medicine)
- Everolimus (used for treating advanced kidney cancer and in transplant individuals)
- Fluconazole (used for fungal infections)
- Phenytoin (used to treat epilepsy)
- Warfarin and other anticoagulants such as phenprocoumon, acenocoumarol (used to slow down clotting of the blood)
- Tyrosine kinase inhibitors such as axitinib, bosutinib, cabozantinib, ceritinib, cobimetinib, dabrafenib, dasatinib, nilotinib, sunitinib, ibrutinib, ribociclib
- Benzodiazepines such as midazolam, triazolam, alprazolam (used for severe insomnia and stress)
- Eszopiclone (used to treat insomnia)
- Sirolimus (used in transplant individuals)
- Ciclosporin (a medicine used to prevent organ transplant rejection)
- Tacrolimus (used in transplant individuals)
- Oxycodone (used for moderate to severe pain)
- Tretinoin (used to treat acne)
- Methadone (used to treat heroin addiction)
- Non-steroidal anti-inflammatory drugs (e.g., ibuprofen, diclofenac) (used for treating pain and inflammation)
- Omeprazole (used to treat indigestion, reflux and ulcers)
- Sulphonylureas such as tolbutamide, glipizide, and glyburide (used for diabetes)
- Statins (e.g., lovastatin) (used for lowering cholesterol)
- Vinca alkaloids such as vincristine, vinblastine (used in treating cancer)
- Oral contraceptives (norethisterone/ethinylestradiol)
- Alfentanil, fentanyl (painkillers used for surgical procedures)
- Corticosteroids such as prednisolone, budesonide (used to treat wheezing and shortness of breath)
- Venetoclax (used to treat certain types of blood cancer)
- Naloxegol (used to treat constipation caused by narcotic pain medications)
- Letemovir (used to treat viral infections)
- Ivacaftor (used for the management of Cystic Fibrosis)
- Tolvaptan (treat low levels of sodium in the blood)

How to use VFEND

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose for adults is:

- 200 mg to 300 mg every 12 hours (for individuals 40 kg and above)
- 100 mg to 150 mg every 12 hours (for individuals less than 40 kg)

If individuals are unable to tolerate treatment at these higher doses, reduce the oral maintenance dose by 50 mg steps to a minimum of 200 mg every 12 hours or to a minimum of 100 mg every 12 hours (for individuals less than 40 kg).

Voriconazole is not recommended for children less than 2 years of age. Use in children aged 2 to <12 years with liver or kidney impairment has not been studied.

- When to use it

Use as directed by your doctor or pharmacist.

VFEND are to be taken at least one hour before, or one hour following a meal.

- How long to use it

Continue taking VFEND for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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Taking too many tablets may cause discomfort to eye with the exposure to light.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking VFEND.

Tell your doctor immediately if you become pregnant while taking this medication.

Tell your doctor if you develop signs and symptoms of Cushing's syndrome or adrenal insufficiency.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give VFEND to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If it makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

VFEND may cause transient and reversible changes to vision, including blurring, altered/enhanced visual perception, and/or discomfort to the eyes on light exposure. You must avoid potentially hazardous tasks, such as driving or operating machinery while experiencing these

symptoms. You should not drive at night while taking VFEND.

Side Effects

Like all medicines, VFEND can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common and common side effects experienced by consumers while taking VFEND are as follows:

- Headache
- Visual disturbance (including altered/enhanced visual perception, blurred vision, color vision change, discomfort to the eyes on light exposure, night blindness)
- Nausea, vomiting, diarrhea, stomach pain
- Rash
- Fever, swelling of the legs and feet
- Sinusitis
- Decrease in platelets, white blood cells and red blood cells
- Decreased electrolytes (potassium and sodium), decreased glucose in the blood
- Hallucinations, confusion, depression, anxiety, agitation, difficulty sleeping
- Dizziness, tremor, altered sensations, sleepiness, loss of consciousness, increased muscle rigidity and spasticity
- Retinal bleeding
- Abnormal rate and rhythm of the heart
- Low blood pressure, inflammation of blood vessels (phlebitis)
- Inflammation of the lips, indigestion, constipation, inflammation of the gums
- Respiratory distress syndrome, fluid accumulation in the lungs
- Abnormal liver function tests, jaundice, cholestatic jaundice, inflammation of the liver
- Face swelling, itching, hair loss, scaling of skin

- Back pain
- Creatinine increased, acute kidney failure, passing blood in urine
- Chills, asthenia (lack of energy), chest pain

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of VFEND

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

VFEND 50 mg:

The film-coated tablets are white, round tablets, debossed "Pfizer" on one side and "VOR50" on the reverse.

VFEND 200 mg:

The film-coated tablets are white, capsule-shaped tablets, debossed "Pfizer" on one side and "VOR200" on the reverse.

PVC/Aluminium blister in cartons of 10 and 20. Not all pack sizes may be marketed.

- Ingredients

- Active ingredient
Voriconazole

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- Inactive ingredients

Tablet core:

Lactose Monohydrate,
Pre-gelatinised Starch,
Croscarmellose Sodium,
Povidone, Magnesium Stearate.

Film-coat:

Hypromellose, Titanium Dioxide
(E171), Lactose Monohydrate,
Glycerol Triacetate (Triacetin).

- MAL numbers:

VFEND 50 mg tablet:

MAL20040542ARZ

VFEND 200 mg: tablet:

MAL20040543ARZ

Manufacturer

Pfizer Italia S.R.L.,
Ascoli Piceno, Italy

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
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Wisma Averis, Tower 2,
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