

## Package leaflet: Information for the patient

### Voriconazole Mylan 200 mg Film-coated Tablets

Voriconazole

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Voriconazole Mylan is and what it is used for
2. What you need to know before you take Voriconazole Mylan
3. How to take Voriconazole Mylan
4. Possible side effects
5. How to store Voriconazole Mylan
6. Contents of the pack and other information

#### 1. What Voriconazole Mylan is and what it is used for

Voriconazole Mylan contains the active substance voriconazole. Voriconazole Mylan is an antifungal medicine. It works by killing or stopping the growth of the fungi that cause infections.

It is used for the treatment of patients (adults and children over the age of 2) with:

- invasive aspergillosis (a type of fungal infection due to *Aspergillus* species),
- candidaemia (another type of fungal infection due to *Candida* species) in non-neutropenic patients (patients without abnormally low white blood cells count),
- serious invasive *Candida* species infections when the fungus is resistant to fluconazole (another antifungal medicine),
- serious fungal infections caused by *Scedosporium* species or *Fusarium* species

Voriconazole Mylan is intended for patients with worsening, possibly life-threatening, fungal infections.

Prevention of fungal infections in high-risk bone marrow transplant recipients.

This product should only be taken under the supervision of a doctor.

#### 2. What you need to know before you take Voriconazole Mylan

##### **Do not take Voriconazole Mylan:**

If you are allergic to voriconazole or any of the other ingredients of this medicine (listed in section 6).

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, or herbal medicines.

The medicines in the following list must not be taken during your course of **Voriconazole Mylan** treatment:

- Terfenadine (used for allergy)
- 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)
- Efavirenz (used for treating HIV) in doses of 400 mg and above once daily
- Carbamazepine (used to treat seizures)
- Phenobarbital (used for severe insomnia and seizures)
- Ergot alkaloids (e.g. ergotamine, dihydroergotamine; used for migraine)
- Sirolimus (used in transplant patients)
- Ritonavir (used for treating HIV) in doses of 400mg and more twice daily
- St John's wort (herbal supplement)

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking **Voriconazole Mylan** if:

- you have had an allergic reaction to other azoles.
- you are suffering from, or have ever suffered from liver disease. If you have liver disease, your doctor may prescribe a lower dose of **Voriconazole Mylan**. Your doctor should also monitor your liver function while you are being treated with **Voriconazole Mylan** by doing blood tests.
- you are known to have cardiomyopathy, irregular heart-beat, slow heart rate or an abnormality of electrocardiogram (ECG) called 'long QTc syndrome'.

You should 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. These precautions are also applicable to children.

While being treated with **Voriconazole Mylan**:

- tell your doctor immediately if you develop
  - sunburn
  - severe skin rash or blisters
  - bone pain.

If you develop skin disorders as described above, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you to be seen on a regular basis. There is a small chance that skin cancer could develop with long term use of **Voriconazole Mylan**.

Your doctor should monitor the function of your liver and kidney by doing blood tests.

### **Children and adolescents**

Voriconazole Mylan should not be given to children younger than 2 years of age.

### **Other medicines and Voriconazole Mylan**

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

Some medicines, when taken at the same time as Voriconazole Mylan may affect the way it works, or Voriconazole Mylan may affect the way they work.

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

- Rifabutin (used for treating tuberculosis). If you are already being treated with rifabutin your blood counts and side effects to rifabutin will need to be monitored.
- Phenytoin (used to treat epilepsy). If you are already being treated with phenytoin your blood concentration of phenytoin will need to be monitored during your treatment with Voriconazole Mylan, and your dose may be adjusted.

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

- Warfarin and other anticoagulants (e.g. phenprocoumon, acenocoumarol; used to slow down clotting of the blood)
- Ciclosporin (used in transplant patients)
- Tacrolimus (used in transplant patients)
- Sulfonylureas (e.g. tolbutamide, glipizide, and glyburide) (used for diabetes)
- Statins (e.g. atorvastatin, simvastatin) (used for lowering cholesterol)
- Benzodiazepines (e.g. midazolam, triazolam, alprazolam) (used for severe insomnia and stress)
- Omeprazole (used for treating ulcers)
- Oral contraceptives (if you take Voriconazole Mylan 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)
- Non-nucleoside reverse transcriptase inhibitors (e.g. efavirenz, delavirdine, nevirapine) (used for treating HIV) (some doses of efavirenz can NOT be taken at the same time as Voriconazole Mylan.)
- Methadone (used to treat heroin addiction)
- Alfentanil and fentanyl and other short acting opiates such as sufentanil (painkillers used for surgical procedures)
- Oxycodone and other long acting opiates such as hydrocodone (used for moderate to severe pain)

- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen, diclofenac) (used for treating pain and inflammation)
- Fluconazole (used for fungal infections)
- Everolimus (used for treating advanced kidney cancer and in transplant patients)

**Pregnancy and breast-feeding**

Voriconazole Mylan must not be taken during pregnancy, unless indicated by your doctor. Effective contraception must be used in women of childbearing potential. Contact your doctor immediately if you become pregnant while taking Voriconazole Mylan.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Voriconazole Mylan 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.

**Voriconazole Mylan contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to take Voriconazole Mylan**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose for adults (including elderly patients) is as follows:

	<b>Tablets</b>	
	Patients 40 kg and above	Patients less than 40 kg
<b>Dose for the first 24 hours</b> (Loading Dose)	400 mg every 12 hours for the first 24 hours	200 mg every 12 hours for the first 24 hours
<b>Dose after the first 24 hours</b> (Maintenance Dose)	200 mg twice a day	100 mg twice a day

Depending on your response to treatment, your doctor may increase the daily dose to 300 mg twice a day.

The doctor may decide to decrease the dose if you have mild to moderate cirrhosis.

## Use in children and adolescents

The recommended dose for children and teenagers is as follows:

	Tablets	
	Children aged 2 to less than 12 years and teenagers aged 12 to 14 years weighing less than 50 kg	Teenagers aged 12 to 14 years weighing 50 kg or more; and all teenagers older than 14
<b>Dose for the first 24 hours</b> (Loading Dose)	Your treatment will be started as an infusion	400 mg every 12 hours for the first 24 hours
<b>Dose after the first 24 hours</b> (Maintenance Dose)	9 mg/kg twice a day (a maximum dose of 350 mg twice daily)	200 mg twice a day

Depending on your response to treatment, your doctor may increase or decrease the daily dose.

Tablets must only be given if the child is able to swallow tablets.

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

If you or your child are taking Voriconazole Mylan for prevention of fungal infections, your doctor may stop giving you the medicine if you or your child develop treatment-related side effects.

### **If you take more Voriconazole Mylan 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 Voriconazole Mylan tablets with you. You may experience abnormal intolerance to light as a result of taking more Voriconazole Mylan than you should.

### **If you forget to take Voriconazole Mylan**

It is important to take your Voriconazole Mylan 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 a forgotten dose.

### **If you stop taking Voriconazole Mylan**

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 Voriconazole Mylan correctly, as described above.

Continue taking Voriconazole Mylan 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.

When Voriconazole Mylan treatment is stopped by your doctor you should not experience any effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

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

If any of the following happen, **stop taking Voriconazole Mylan and tell your doctor immediately or go to the nearest hospital emergency department:**

- Skin rash
- Yellowing of the skin or whites of the eyes (jaundice), changes in blood tests for liver function
- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)

**Some other side effects may need medical attention. Tell your doctor if you get any of the following:**

**Very common** (may affect more than 1 in 10 people):

- Severe breathing difficulties including shortness of breath and fast breathing, which may be caused by inflammation of the lungs

**Common** (may affect up to 1 in 10 people):

- A condition causing reduced levels of all types of blood cells (pancytopenia), causing frequent infections causing fever, chills, tiredness, sore throat or mouth ulcers (reduced white blood cells), tiredness, shortness of breath and pale skin (reduced red blood cells) and bleeding or bruising that is unexpected or lasts longer than usual (reduced platelets)
- Fluid build up in the lungs, causing difficulty breathing with fever, sweating, anxiety and cough, possibly with blood
- Bleeding in the back of the eye (retinal haemorrhage), causing changes in eyesight including loss of vision, which may happen suddenly
  - Fits (convulsion)
  - Liver failure or liver disease with the following symptoms; nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis)
  - Changes in urination, either in quantity or frequency, accompanied by feeling or being sick, loss of appetite, weight loss, blood in the urine, pain in the lower abdomen or back, which may be signs of kidney failure or other serious kidney problems

**Uncommon** (may affect up to 1 in 100 people):

- A widespread rash with blisters and peeling skin on much of the body (toxic epidermal necrolysis), or particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Unusual clotting of blood in the veins, reducing blood flow to parts of the body or severe and unexpected bleeding
- Severe skin reaction following exposure to light or sun (bullous photosensitivity)
- Very fast and fluttering heart rhythm (fibrillation)
  - Severe, persistent or bloody diarrhoea associated with abdominal pain or fever
- Reduced function of the adrenal gland which may cause low blood sugar, dehydration, weight loss, low blood pressure, feeling disoriented, weak and tired

- Swelling of the brain which can cause changes to the way you think or act, difficulty concentrating, feeling drowsy, uninterested and unenergetic
- Swelling of nerves at the back of the eye, causing sudden changes in eyesight including loss of vision, or pain when moving the eye
- Unusual and uncontrolled rolling or crossing of the eyes, which may be seen with uncontrolled movement of the neck, mouth or tongue, with eye pain

**Rare** (may affect up to 1 in 1,000 people):

- A serious allergic reaction (anaphylaxis) with symptoms such as swelling of the face, lips, mouth, tongue or throat causing difficulty breathing (angioedema)
- Changes to the heart's rhythm including 'missed' beats, which can cause light-headedness or fainting
  - Clouding of the cornea, causing reduction in eyesight or cloudy vision
  - Numbness, tingling, pain and weakness in the hands, feet, arms or legs, or in the back, which can lead to problems with movements, speech, eating or vision, and may be signs of a rare but dangerous immune response (Guillain-Barré syndrome)

**Not known** (frequency cannot be estimated from the available data):

- Pain, aching or tenderness of the muscles or bones (periostitis).
- Red, scaly patches on the skin or ring-shaped skin lesions, particularly on the face, which may be a sign of an autoimmune disease called cutaneous lupus erythematosus

There have been reports of skin cancer in patients treated with voriconazole for long periods of time.

### **Other possible side effects**

**Very common** (may affect more than 1 in 10 people):

- Visual impairment (changes in vision including blurred vision, changes to colour unusual sensitivity to light, colour blindness, halo vision, night blindness, unsteady or jumpy vision, seeing sparks, flashes or aura, unusual brightness, loss of part of the usual field of vision, spots of floaters before the eyes)
- Fever
- Nausea, vomiting, diarrhoea
- Headache
- Swelling of the hands or feet
- Stomach pains.
- Changes in blood tests for liver function

**Common** (may affect up to 1 in 10 people):

- Inflammation of the sinuses, chills, weakness
- Inflammation of the gums (gingivitis)
- Constipation, indigestion or heart burn, inflammation of the corners of the mouth and lips
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- Anxiety, depression, tingling, confusion, dizziness, agitation, trembling, hallucinations (seeing, hearing or feeling things that are not real) and other nervous symptoms
- Increase in muscle tone
- Feeling drowsy or sleepy, or difficulties sleeping
- Fainting
- Faster or slower heartbeat than normal
  - Low blood pressure
  - Chest pain
  - Low levels of sugar, potassium or sodium in the blood sugar
  - Hair loss
  - Back pain
  - Blood in the urine, changes in blood tests for kidney function
  - Inflammation of the gastrointestinal tract.

**Uncommon** (may affect up to 1 in 100 people):

- Other allergic reactions such as hives, itching and/or red skin
- Flu-like symptoms
  - Enlarged lymph glands, sometimes painful and possibly due to infection
  - Increase in a type of white blood cell which may be associated with allergic reaction
  - Problem with coordination
  - Double vision, pain and inflammation of the eyes and eyelids, involuntary movement of the eye
- Hearing problems, ringing in the ears
- Spinning sensation when sitting or standing still (vertigo)
- Inflammation of a vein (which may be associated with the formation of a blood clot)
  - Decreased sensitivity to touch
- Abnormal sense of taste
  - Inflammation of upper small intestine
  - Swelling and inflammation of the tongue
  - Enlarged liver, gallbladder disease, gallstones
  - Joint pain
  - Inflammation of the kidney, proteins in the urine
  - Raised levels of cholesterol or urea in the blood, which may be seen in a blood test

**Rare** (may affect up to 1 in 1,000 people):

- Red, scaly patches on the skin, especially on the face and scalp, sometimes thick or in the shape of a spike or “horn”
- Changes to your normal movements, including muscle spasms, shaking or shuffling similar to Parkinson’s disease, feeling restless or tense (extrapyramidal symptoms)
- Overactive or underactive thyroid gland

**Not known** (frequency cannot be estimated from the available data):

- Freckles or darker patches of skin

As voriconazole 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.

### **Side effects in children and adolescents**

Sunburn or severe skin reactions following exposure to light or sun has been seen more frequently in children. If you or your child develop a skin rash while taking this medicine speak to your doctor as soon as possible. You may be referred to a specialist, who may decide that it is important for you or your child to be seen on a regular basis.

Changes in blood tests for liver function have also been seen more frequently in children.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Voriconazole Mylan**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Voriconazole Mylan contains**

The active substance is voriconazole. Each tablet contains 200 mg voriconazole.

The other ingredients are:

Tablet core: Lactose monohydrate (see section 2 “Voriconazole Mylan contains lactose monohydrate”), croscarmellose sodium, pregelatinised maize starch, povidone and magnesium stearate.

Film-coating: Lactose monohydrate, hypromellose, titanium dioxide (E171) and triacetin.

### **What Voriconazole Mylan looks like and contents of the pack**

Voriconazole Mylan 200 mg film-coated tablets: a white to off-white film-coated, capsule shaped, biconvex tablet debossed with “M164” on one side of the tablet and blank on the other side.

Voriconazole Mylan is available in blister packs of:

14, 20, 28, 30, 90, 100, 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 100 x 1 for Voriconazole Mylan 200 mg film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

McDermott Laboratories Limited  
T/A Gerard Laboratories  
35/36 Baldoyle Industrial Estate  
Grange Road,  
Dublin 13,  
Ireland

### **Manufacturers**

Generics (UK) Limited, Station Close, Potters Bar, Herts EN6 1TL, United Kingdom.  
GE Pharmaceuticals Ltd., Industrial Zone, Chekanitza-South area, 2140 Botevgrad, Bulgaria.  
Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.  
Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium: Voriconazole Mylan 50 mg and 200 mg filmomhulde tabletten

Czech Republic: Vorikonazol Mylan 200 mg, potahované tablety

France: Voriconazole Mylan 50 mg and 200 mg, comprimé pelliculé

Germany: Voriconazol Mylan 50 mg and 200 mg Filmtabletten

Ireland : Voriconazole Mylan 200 mg film-coated Tablets

Italy: Voriconazolo Mylan 50 mg and 200 mg compresse rivestite con film

Luxembourg: Voriconazole Mylan 50 mg and 200 mg comprimés pelliculés

Poland: Voriconazole Mylan

Portugal: Voriconazol Mylan

Spain: Voriconazol MYLAN 50 mg and 200 mg comprimidos recubiertos con película EFG

The Netherlands: Voriconazol Mylan 50 mg and 200 mg, filmomhulde tabletten

United Kingdom :Voriconazole 50 mg and 200 mg film-coated Tablets

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