

# Voriconazole APOTEX Tablets

Contains the active ingredient voriconazole

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## Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

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### What is in this leaflet

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#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about voriconazole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

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### What this medicine is used for

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The name of your medicine is Voriconazole APOTEX tablets. It contains the active ingredient voriconazole.

It is used to treat fungal and yeast infections such as:

- invasive aspergillosis (as-pur-jilosis), a fungal infection caused by a fungus called *Aspergillus* (as-pur-jilus), which usually begins in the respiratory tract (in the nose, sinuses or lungs). *Aspergillus* is harmless in most healthy people; however, in people with poor immune systems (such as people who have had organ transplants and people with cancer or HIV/AIDS) invasive aspergillosis can be serious and spread to other tissues and organs.
- serious *Candida* (can-did-da) infections, including *Candida* infections of the oesophagus (food pipe or gullet) and those that have spread into the blood stream or to other parts of the body.
- serious fungal infections caused by *Scedosporium* (ski-doe-spore-rium) species and *Fusarium* (few-saa-rium) species.
- other serious fungal infections in patients who do not respond to, or

cannot tolerate, other antifungal medicines.

Voriconazole is also used to prevent invasive fungal infections in patients who are at risk of developing such infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

#### How it works

This medicine belongs to a group of medicines called triazole antifungals.

This medicine works by preventing the growth of fungal and yeast organisms causing your infection.

There is no evidence that this medicine is addictive.

#### Use in children

**This medicine should not be given to children under the age of 2 years.**

Safety and effectiveness in children younger than 2 years has not been established.

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### Before you take this medicine

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*When you must not take it*

**Do not take this medicine if:**

- **You are taking any of the following medicines:**
  - pimozide, a medicine used to treat mental illness
  - quinidine, a medicine used to treat irregular heartbeat
  - rifampicin, a medicine used to treat tuberculosis and other infections
  - carbamazepine, a medicine used to treat seizures
  - long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures
  - rifabutin, an antibiotic
  - ergotamine or dihydroergotamine, medicines used to treat migraine
  - sirolimus, a medicine used in transplant patients
  - efavirenz (a medicine used to treat HIV infection) in doses of 400 mg or more once a day
  - ritonavir (a medicine used to treat HIV infection) in doses of 400 mg or more twice a day
  - St John's Wort (a herbal medicine)
- **You are hypersensitive to, or have had an allergic reaction to, voriconazole or any of the ingredients listed at the end of this leaflet or to any other similar medicines.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

### *Before you start to take it*

#### **Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines, especially antifungal medicines such as itraconazole, fluconazole, posaconazole or ketoconazole
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - heart problems
  - any problems affecting your kidneys
  - any problems affecting your liver. If you have liver disease, your doctor may prescribe a lower dose
  - recent chemotherapy or stem cell transplant.
3. You are currently pregnant or you plan to become pregnant. This medicine should not be taken during pregnancy, unless indicated by your doctor. Effective contraception should be used in women of childbearing potential. Your doctor can discuss with you the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. This medicine should not be taken whilst breastfeeding, unless indicated by your doctor. It is not known if the active ingredient voriconazole passes into breast milk. Your doctor can discuss with you the risks and benefits involved.
5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

### *Taking other medicines*

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

**Some medicines should not be taken with voriconazole. Do not take voriconazole if you are taking the following:**

- pimozide, a medicine used to treat mental illness.
- quinidine, a medicine for irregular heartbeat.
- rifampicin, a medicine used to treat tuberculosis and other infections.
- carbamazepine, a medicine used to treat seizures.
- long-acting barbiturates such as phenobarbitone, medicines used to treat severe insomnia and seizures.
- rifabutin, an antibiotic.
- ergotamine or dihydroergotamine, medicines used to treat migraine.
- sirolimus, a medicine used in transplant patients.
- efavirenz (a medicine used to treat HIV infection) in doses of 400 mg or more once a day.
- ritonavir (a medicine used to treat HIV infection) in doses of 400 mg or more twice a day.
- St John's Wort (a herbal medicine).

Other medicines may also interact with voriconazole. These include:

- efavirenz (a medicine used to treat HIV infection) in doses below 400 mg once a day
- ritonavir (a medicine used to treat HIV infection) in doses of 100 mg twice a day
- warfarin, a medicine used to stop blood clots
- everolimus, a medicine used to treat cancer
- fluconazole, a medicine used to treat fungal infections
- phenytoin, a medicine used to treat epilepsy

- cyclosporin, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system.
- sulphonylureas, medicines used to treat diabetes such as glibenclamide, gliclazide and glipizide
- some antihistamines, medicines used to treat hayfever, allergic skin reactions, itching
- benzodiazepines, medicines used to treat insomnia or anxiety
- statins, medicines used for lowering cholesterol
- tacrolimus, a medicine used in patients who have had a liver or kidney transplant
- indinavir and some other medicines used to treat HIV infection
- omeprazole, a medicine used to treat indigestion, reflux and stomach or duodenal ulcers
- methadone (used to treat heroin addiction)
- oral contraceptives (the Pill)
- vincristine, vinblastine or vinorelbine, medicines used in treating cancer
- strong pain killers such as alfentanil, fentanyl and oxycodone
- non-steroidal anti-inflammatory drugs, medicines used to treat pain and inflammation such as ibuprofen and diclofenac

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with voriconazole.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

### *How much to take*

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

#### **Adults**

##### **Treatment of invasive fungal infections**

The usual dose of voriconazole tablets in adults weighing 40 kg and greater is 400 mg (two 200 mg tablets every 12 hours twice a day) for the first day and then 200 mg to 300 mg twice a day thereafter.

In adults weighing less than 40 kg the dose of voriconazole tablets is halved.

##### **Prevention of invasive fungal infections**

The usual dose in adults weighing 40 kg and greater is one 200 mg to 300 mg tablet every 12 hours twice a day.

In adults weighing less than 40 kg the dose of voriconazole tablets is halved.

#### **Children**

Voriconazole should not be given to a child under the age of 2 years.

Your doctor will determine the dose of voriconazole required for your child.

Depending on how serious the infection is and how your child reacts to the medicine, your doctor may increase or decrease the dose.

#### **Adolescents (12-16 years of age)**

Adolescents aged 12-16 years of age are usually given the same dose as adults.

### *How to take it*

Voriconazole needs to be taken regularly to be effective.

Swallow the tablets whole with a full glass of water.

### *When to take it*

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

Take voriconazole tablets at least one hour before or one hour after a meal.

### *How long to take it for*

The length of time you take this medicine will depend on the type of infection you have.

If you have a weakened immune system or a difficult infection, you may need long-term treatment to prevent the infection from returning.

Continue taking this medicine for as long as your doctor or pharmacist recommends. Do not stop taking this medicine because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

### *If you forget to take it*

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

#### **Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

### *If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident**

**and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

Symptoms of an overdose may include upset stomach, diarrhoea, headache and sensitivity to light.

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## While you are taking this medicine

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### *Things you must do*

While you are taking this medicine, tell your doctor if:

- you develop a rash or blisters while taking voriconazole. If this rash worsens, this medicine may need to be stopped.
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are about to have any blood tests. It may interfere with the results of some tests
- you are going to have surgery or are going into hospital. It may affect other medicines used during surgery.

**Avoid going out in the sun for long periods of time while you are taking this medicine.**

Voriconazole can cause sensitivity to sunlight.

**Tell your doctor if you notice any changes to your skin while you are taking this medicine.**

**If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.**

**Make sure you follow your doctor's instructions and keep all appointments, including blood tests.**

Your doctor should monitor the function of your liver and kidneys using blood tests. If you have liver disease, your doctor might lower your dose of this medicine or stop your treatment. Your doctor might

also monitor the function of your pancreas.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### *Things you must not do*

**Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

### *Things to be careful of*

Be careful when driving or operating machinery until you know how this medicine affects you.

Avoid going out in the sun for long periods of time while you are taking this medicine. This medicine can cause sensitivity to sunlight.

Tell your doctor if you notice any changes to your skin while you are taking this medicine.

You may experience changes to your vision, such as blurriness, colour changes or uncomfortable sensitivity to light. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Do not drive at night.

Children should be careful when riding bicycles or climbing.

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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking voriconazole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor if you notice any of the following:**

- changes to your vision, such as blurred vision, colour changes or sensitivity to light
- irregular heartbeat
- nausea or feeling sick, vomiting
- headache
- stomach pain, indigestion, diarrhoea
- back pain in the middle or upper back
- swelling of the arms or legs
- rash
- changes to your skin, such as skin eruptions or small lumps on the skin.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives or blisters
- fainting, seizures or fits
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice
- signs of frequent or worsening infections such as fever, severe chills, sore throat or mouth ulcers
- blood in urine
- signs of kidney failure such as tiredness, lack of appetite and reduced or greatly increased amount of urine.

Other side effects not listed above may occur in some patients.

### *Allergic reactions*

**If you think you are having an allergic reaction to voriconazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and disposal

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### *Storage*

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### *What Voriconazole APOTEX looks like*

#### **50 mg tablet:**

White coloured, round-shaped, film-coated tablets, engraved with "APO" on one side and "VOR" over "50" on the other side.

#### **200 mg tablet:**

White coloured, modified oval-shaped, biconvex film-coated tablets, engraved with "APO" on one side and "VOR 200" on the other side.

Blister pack of 56 tablets

\* Not all strengths may be available.

### *Ingredients*

Each tablet contains 50 mg or 200 mg of voriconazole as the active ingredient.

It also contains the following inactive ingredients:

- Lactose monohydrate
- Croscarmellose sodium
- Magnesium stearate
- Polyvinyl alcohol
- Macrogol 8000
- Talc
- Titanium dioxide

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

### *Australian Registration Numbers*

Voriconazole APOTEX 50 mg tablets (blister): AUST R 218362.

Voriconazole APOTEX 200 mg tablets (blister): AUST R 218361.

### *Sponsor*

Apotex Pty Ltd  
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