

VTTACK

Voriconazole, Tablet, film coated, 50 mg and 200 mg



What is in this leaflet

This leaflet answers some common questions about VTTACK.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What VTTACK is used for

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

- invasive aspergillosis, a fungal infection caused by a fungus called *Aspergillus*, which usually begins in the respiratory tract (in the nose, sinuses or lungs) and can spread to other tissues and organs
- serious *Candida* (yeast) infections, including infection of the food pipe and those that have spread into the blood stream or other parts of the body
- serious fungal infections
- other serious fungal infections in patients who do not respond to, or cannot tolerate, other antifungal medicines

VTTACK is also used to prevent invasive fungal infections in patients

who are at risk of developing such infections.

VTTACK contains the active ingredient voriconazole. It belongs to a group of medicines called triazole antifungals.

It works by killing or stopping the growth of fungal and yeast organisms that cause the infection.

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

Your doctor may have prescribed it for another reason.

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

There is not enough information to recommend the use of this medicine for children under the age of 2 years.

Before you take VTTACK

When you must not take it

Do not take VTTACK if you have an allergy to:

- any medicine containing voriconazole
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take VTTACK 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
- ivabradine (used to slow the heart rate)
- rifampicin, used to treat tuberculosis and other infections
- certain anti-seizure medicines, such as carbamazepine
- long-acting barbiturates such as phenobarbitone, used to treat severe insomnia and seizures
- rifabutin, an antibiotic
- medicines used to treat migraine headaches, such as ergotamine and dihydroergotamine
- sirolimus, a medicine used following organ transplants to prevent organ rejection
- certain medicines used to treat HIV infections, such as ritonavir and efavirenz, in doses of 400 mg once daily or higher
- St John's Wort (a herbal medicine)
- naloxegol, used to treat constipation caused by opioids
- tolvaptan, used to treat low blood sodium levels or for kidney problems
- venetoclax (used to treat blood cancers)
- lurasidone used to treat schizophrenia and bipolar disorder

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives, dyes or any other azole antifungal medicines such as itraconazole, fluconazole, posaconazole or ketoconazole.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- any problems affecting your kidneys
- any problems affecting your liver
- recent chemotherapy or stem cell transplant

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

VTTACK should not be taken during pregnancy or breast-feeding, unless indicated by your doctor. Effective contraception should be used in women of childbearing potential.

If you have not told your doctor about any of the above, tell him/her before you start taking VTTACK.

Taking other medicines

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

See 'When you must not take it' section above for medicines that should not be taken while taking VTTACK.

Some medicines and VTTACK may interfere with each other. These include:

- fluconazole, a medicine used to treat other fungal infections

- letermovir, an antiviral medicine
- ivacaftor, used to treat cystic fibrosis
- phenytoin, a medicine used to prevent seizures
- short and long acting opiates that are used to treat pain, including alfentanil, fentanyl and oxycodone
- methadone, a medicine used to treat drug addiction
- medicines used following organ transplants to prevent organ rejection, such as ciclosporin and tacrolimus
- warfarin and other blood thinning medications that are used to prevent blood clots
- sulphonylureas, medicines used to treat diabetes such as glibenclamide, gliclazide and glipizide
- statins, medicines used to lower cholesterol levels
- non-steroidal anti-inflammatory medications, including ibuprofen and diclofenac, used to treat pain and inflammation
- omeprazole, a medicine used to treat indigestion, reflux and stomach ulcers
- vinca alkaloids, such as vincristine and vinblastine, medicines used in treating cancer
- oral contraceptive pill
- benzodiazepines, such as midazolam, triazolam and alprazolam, medicines used for sedation or anxiety
- everolimus, a medicine used to treat cancer
- other cancer drugs such as glasdegib, axitinib, bosutinib, cabozantinib, ceritinib, cobimetinib, dabrafenib, dasatinib, nilotinib, sunitinib ibrutinib, ribociclib
- tretinoin (used for the treatment of acne and acute promyelocytic leukemia)
- some antihistamines (used to treat hayfever, allergic reactions or itching)
- theophylline (used to treat asthma)
- eszopiclone (used to treat insomnia)

- indinavir (used to treat HIV infection)

These medicines may be affected by VTTACK or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take VTTACK

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many VTTACK tablets to take, and for how long.

The usual doses are shown below but your doctor may decide to adjust them to your individual needs.

The usual dose of VTTACK tablets in adults weighing 40 kg or above is 400 mg (two 200 mg tablets) twice a day for the first day and then 200 mg twice a day thereafter.

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

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

How to take it

VTTACK tablets are to be taken at least one hour before or one hour following a meal. Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

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

How long to take it

The length of time you take VTTACK 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 your medicine for as long as your doctor tells you.

Continue taking your medicine until you finish the pack. Do not stop taking VTTACK 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 for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at

the nearest hospital, if you think that you or anyone else may have taken too much VTTACK. 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.

While you are taking VTTACK

Things you must do

Always follow your doctor's instructions carefully.

If symptoms of your infection do not improve over time, or if they become worse, tell your doctor.

Avoid going out in the sun for long periods of time while you are taking VTTACK. VTTACK can cause sensitivity to light.

Tell your doctor immediately if you develop a rash or blisters while taking VTTACK. If this rash worsens, VTTACK may need to be stopped.

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VTTACK.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Tell your doctor if you suffer from chronic, or long-lasting fatigue, muscle weakness, loss of appetite, weight loss or abdominal pain while on VTTACK.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are a woman of childbearing age, you should avoid becoming pregnant while taking VTTACK. If you become pregnant while taking VTTACK, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. Tests may be carried out to monitor liver and kidney function as the activity of these organs can alter the effectiveness of the medicine.

Things you must not do

Do not take VTTACK to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without 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 driving or operating machinery until you know how VTTACK affects you.

This medicine may cause changes to vision, including blurring, altered perception, increased sensitivity to light and sudden dimming or loss of vision in some people. 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VTTACK.

This medicine helps most people with fungal infections but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- changes to your vision, such as blurred vision, colour changes or sensitivity to light
- fever, chills, rash or itching
- nausea, vomiting or loss of appetite
- diarrhoea or stomach pain
- headache, dizziness or tremor
- swelling of the face, hands, ankles, feet, legs or arms
- back pain in middle or upper back
- indigestion

The above list includes the more common side effects of your medicine. They are usually mild to moderate.

Tell your doctor as soon as possible if you notice any of the following:

- hallucinations, confusion, depression or anxiety
- painful/swollen joints
- ringing of the ear
- blood in urine
- flaking of the skin
- asthma, wheezing, shortness of breath
- irregular heart beat

- signs of frequent or worsening infections such as fever, severe chills, sore throat or mouth ulcers
- signs of kidney failure such as tiredness, lack of appetite and reduced or greatly increased amount of urine

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain or breathing difficulties
- abnormal tiredness, loss of appetite, dark urine, pale stools, yellowing of the skin or eyes
- a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters)
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or difficulty breathing, wheezing
- seizures, convulsions, fits or fainting
- changes to your skin, such as skin eruptions or small lumps on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Some of these side effects (for example, changes in blood pressure, blood sugar or iron levels and liver/renal function) can only be found when your doctor does tests from time to time to check your progress.

After taking VTTACK

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store VTTACK 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

VTTACK 50 mg tablets are white to off-white, film coated, oval tablets printed with "V26" on one side and blank on the other side.

VTTACK 200 mg tablets are white to off-white, film coated, oval tablets printed with "V164" on one side and blank on the other side.

Ingredients

VTTACK contains either 50 mg or 200 mg of voriconazole as the active ingredient.

It also contains:

- lactose
- pregelatinised starch
- croscarmellose sodium
- povidone
- magnesium stearate
- hypromellose
- titanium oxide
- triacetin

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Viatrix Ltd,
PO Box 11183,
Ellerslie,
AUCKLAND

www.viatrix.co.nz

Telephone 0800 168 169

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