

VEDAFIL®

Sildenafil citrate 25 mg, 50 mg and 100 mg



What is in this leaflet

This leaflet answers some common questions about VEDAFIL.

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 or pharmacist has weighed the risks of you taking VEDAFIL 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 VEDAFIL is used for

VEDAFIL is used to treat erectile dysfunction, more commonly known as impotence, in men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.

VEDAFIL contains the active ingredient sildenafil citrate, which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

It works by relaxing the blood vessels in your penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection in the natural way.

VEDAFIL will work only if you are sexually excited. VEDAFIL will not increase your sex drive.

This medicine is available with a doctor's prescription or from a trained pharmacist without a doctor's prescription if you meet certain criteria.

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

VEDAFIL is not to be used in women or in children.

Before you take VEDAFIL

You must not take VEDAFIL if you are taking any nitrate medication. It may lead to a severe drop in your blood pressure, which may be difficult to treat.

Because sexual activity may place a strain on your heart, your doctor or pharmacist will need to check whether you are fit enough to take VEDAFIL.

When you must not take it

Do not take VEDAFIL if:

- you have an allergy to
 - any medicine containing sildenafil citrate
 - any of the ingredients listed at the end of this leaflet

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.

- you are being treated for angina (chest pain) or other heart conditions with nitrate medication (either via tablets, injections, patches or spray)

e.g. glyceryl trinitrate, isosorbide, sodium nitroprusside, nicorandil, or organic nitrates.

- you are using amyl nitrite
- you are taking a class of medicines called guanylate cyclase stimulators, e.g. riociguat
- you have heart or blood vessel problems that make sexual intercourse inadvisable
- you have suffered a heart attack or stroke in the last six months
- you have severe liver problems
- your blood pressure is unusually high or low or is not effectively treated
- you have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)
- you have an eye disease called retinitis pigmentosa

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 or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are receiving any other treatment for erectile dysfunction (impotence) or taking medicines for the treatment of high blood

pressure in the blood vessels between the heart and the lungs.

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

- heart problems
- high blood pressure
- smoker
- diabetes, especially if you also have eye problems
- kidney or liver problems
- leukaemia (cancer of the blood cells)
- multiple myeloma (a cancer of the bone marrow)
- any disease or deformity of your penis
- any bleeding disorder such as haemophilia
- stomach ulcer
- a disease of the blood called sickle cell anaemia
- colour vision problems
- previously experienced sudden decrease or loss of hearing
- previously experienced sudden loss of vision in one or both eyes

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

Taking other medicines

You must not take VEDAFIL if you are taking any nitrate medication or if you are taking any guanylate cyclase stimulators e.g riociguat.

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.

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

- cimetidine, a medicine used to treat ulcers
- some medicines used to treat fungal infections including ketoconazole and itraconazole
- some antibiotics

including erythromycin and rifampicin

- medicines used for treatment of HIV infection, such as ritonavir and saquinavir
- medicines called alpha-blockers, used to treat high blood pressure or prostate problems
- bosentan, a medicine used for the treatment of high blood pressure in the blood vessels between the heart and the lungs

These medicines may be affected by VEDAFIL 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 VEDAFIL

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 or pharmacist will decide the correct dose for you depending on your condition and response.

This can be one 25 mg tablet a day or one 50 mg tablet a day or one 100 mg tablet a day. The maximum dose is 100 mg.

Do not take more than one dose of VEDAFIL a day.

When to take it

Take the VEDAFIL tablet about one hour before you intend to have sex.

VEDAFIL will work only if you are sexually stimulated.

Swallow the tablet whole with a full glass of water.

The amount of time VEDAFIL takes to start working varies from person to person, but it normally takes between half an hour and one hour.

You may find VEDAFIL takes longer to work if you take it with a meal.

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

While you are using VEDAFIL

Things you must do

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

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

Stop using VEDAFIL if you have a loss of eyesight in one or both eyes, experienced loss of hearing or have an erection that persists more than 4 hours. Seek medical attention urgently.

If VEDAFIL does not help you get an erection or if your erection does not last long enough to complete sexual intercourse, tell your doctor or pharmacist. In these cases, your doctor or pharmacist may decide that you need a higher dose.

Things you must not do

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

Do not alter the dosage without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how VEDAFIL affects you.

This medicine may cause temporary visual disturbances and dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Avoid consuming large amounts of alcohol before sexual activity, as you may have difficulty getting an erection and side effects such as visual disturbances and dizziness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people with erectile dysfunction, 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:

- headache
- flushing
- nasal congestion
- indigestion
- diarrhoea
- dizziness
- thirst
- chills
- pins and needles sensation or numbness in hands and feet
- nausea and vomiting
- stomach pain
- cough
- vertigo
- tremor
- sleepiness
- unable to sleep (insomnia)
- abnormal dreams
- muscle ache
- sweating
- pain
- dry mouth

The above list includes the more mild side effects of your medicine.

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

- abnormal vision e.g. blurring, increased sensitivity to light, colour tinge to vision
- urinary tract infection (stinging or burning sensation when urinating, greater urgency to urinate)
- blood in urine
- fainting
- nosebleed
- hallucinations
- depression
- impaired co-ordination or difficulty moving limbs
- discharge with itching of the eyes and crusty eyelids
- bleeding, tender or enlarged gums
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- painful, swollen joints
- excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak,

depressed, irritable and generally unwell, and passing large amounts of urine

- sweating, weakness, hunger, dizziness, trembling, headache,
- flushing or paleness, numbness, having a fast, pounding heart beat

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

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

- unusual heartbeat
- palpitations
- chest pain
- seizures, fits or convulsions
- prolonged erection
- decreased or loss in vision in one or both eyes
- decreased or loss in hearing
- rash, increased sensitivity of the skin to sun, hives, skin blistering, skin ulcers
- bleeding from the rectum
- an allergic reaction such as shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body

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.

This is not a complete list of side effects. Other side effects not listed above may also occur in some people.

After using VEDAFIL

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 VEDAFIL 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

VEDAFIL 25 mg tablets are blue, film-coated, round biconvex tablets debossed with 'M' on one side and 'SL over 25' on other side.

VEDAFIL 50 mg tablets are blue, film-coated, round biconvex tablets debossed with 'M' on one side and 'SL over 50' on other side.

VEDAFIL 100 mg tablets are blue, film-coated, round biconvex tablets debossed with 'M' on one side and 'SL over 100' on other side

Ingredients

VEDAFIL contains 25 mg, 50 mg or 100 mg of sildenafil citrate as the active ingredient.

It also contains:

- hydrogen phosphate anhydrous
- croscarmellose sodium
- magnesium stearate
- hypromellose
- titanium dioxide
- indigo carmine (FD&C)
- 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

VEDAFIL is supplied in New Zealand by:

Viatrix Ltd,
PO Box 11-183,
Ellerslie,
Auckland
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

20 August 2021
(Based on datasheet dated 20 August 2021)

VEDAFIL[®] is a Viatrix company trade mark.