

Vedafil

sildenafil (as citrate)

CONSUMER MEDICINE INFORMATION

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 benefits and risks. Your doctor has weighed the risks of you taking Vedafil against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Vedafil is used for

The name of your medicine is Vedafil. It contains the active ingredient called sildenafil citrate.

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 belongs to a group of medicines called phosphodiesterase type 5 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.

Vedafil is not for use in women.

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

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

Before you take Vedafil

BECAUSE SEXUAL ACTIVITY MAY PLACE A STRAIN ON YOUR HEART, YOUR DOCTOR WILL NEED TO CHECK WHETHER YOU ARE FIT ENOUGH TO TAKE VEDAFIL.

When you must not take it

DO NOT TAKE VEDAFIL IF YOU ARE TAKING ANY NITRATE OR NITRITE MEDICATIONS, USED TO TREAT ANGINA (CHEST PAIN) OR OTHER HEART CONDITIONS. IT MAY LEAD TO A SEVERE DROP IN YOUR BLOOD PRESSURE, WHICH MAY BE DIFFICULT TO TREAT.

Nitrate medicines include:

- glyceryl trinitrate (also called nitroglycerin).
- tablets; such as Anginine, Lycinate, Nitrostat, Imdur Durules, Monodur durules, Sorbidin, Isordil, Corangin, ISMO 20, Imtrate, Duride, Isomonit, Ikorel and Sodium Nitroprusside

- patches such as Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitran
- sprays such as Nitrolingual and Glytrin
- injections such as Gliceryl trinitrate concentrate

There may be other tradenames for nitrate medicines not listed above.

Do not take Vedafil if you are taking guanylate cyclase stimulators (GCS), such as Adepmas (riociguat).

GCS is a type of medicine used to treat high blood pressure in the blood vessels in the lungs (chronic thromboembolic pulmonary hypertension, CTEPH) or narrowing of the vessels that carry blood from the heart to the lungs (pulmonary arterial hypertension or PAH).

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

Do not take Vedafil if you have suffered a heart attack or stroke in the last 6 months.

Do not take Vedafil if you are taking amyl nitrate (sometimes called 'poppers').

Do not take VEDAFIL if you have or have had any of the following medical conditions:

- heart or blood vessel problems that make sexual intercourse inadvisable
- severe liver problems
- blood pressure is unusually high or low or is not effectively treated
- loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)
- 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.

Before you start to take it

Tell your doctor if you:

- Have allergies to any other medicines, foods, preservatives or dyes.
- Have or have had any other heart or blood vessel problems.
- Have ever had sudden loss of eyesight in one or both eyes.
- Have or have had any of the following medical conditions:
 - diabetes
 - eye problems
 - kidney or liver problems
 - leukaemia (cancer of the blood cells)
 - multiple myeloma (cancer of the bone marrow)
 - any disease or deformity of the penis
 - any bleeding disorder such as haemophilia
 - stomach ulcer
 - a disease of the blood called sickle cell anaemia
 - problems with colour vision
 - a sudden decrease or loss of hearing

Tell your doctor or pharmacist if you are receiving any other treatment for impotence or high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension) including Revatio or Tracleer (bosentan).

Tell your doctor if you have any other medical conditions

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

Taking other medicines

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

Do not take VEDAFIL if you are using nitrate medicines for angina.

Do not take VEDAFIL if you are taking guanylate cyclase stimulators (GCS), such as Adepmas (riociguat).

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

- cimetidine, a medicine used to treat ulcers
- medicines used to treat fungal infections, such as ketoconazole and itraconazole
- antibiotics, such as erythromycin and rifampicin
- protease inhibitors, such as ritonavir and saquinavir, used in the treatment of HIV infection
- alpha-blockers, medicines used to treat high blood pressure or prostate problems
- medicines used to treat high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension) including Tracleer (bosentan).

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

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 and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor 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.

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

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your prescribed dose about one hour before you intend to have sex.

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 heavy meal.

VEDAFIL will only work if you are sexually excited.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 Vedafile.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Vedafile

Things you must do

Stop using Vedafile if you experience any of the following:

- loss of eyesight in one or both eyes
- hearing loss
- an erection that persists more than 4 hours.

You may require urgent medical attention.

Tell your doctor if Vedafile does not help you get an erection or if your erection does not last long enough to complete sexual intercourse.

Your doctor may decide that you need a higher dose.

If you are about to start taking any new medicine, especially any nitrate medication or Adepmas (riociguat), remind your doctor and pharmacist that you are taking Vedafile.

Check the list of common nitrate medications listed under "Before you take Vedafile".

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Vedafile.

Things you must not do

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

Do not use the drug amyl nitrite (sometimes called "poppers") while you are taking Vedafile.

If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctor knows you are taking Vedafile.

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

Things to be careful of

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

This medicine may cause dizziness and changes in vision in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

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.

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

Alcohol can temporarily impair the ability to get an erection.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in some 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 list 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
- dizziness
- flushing
- hot flushes
- indigestion, an uncomfortable feeling in the stomach or belching after eating
- heartburn
- nasal congestion
- sinus congestion
- swelling of your nose
- diarrhoea
- rash
- dry mouth or dry throat
- dry nose
- dry eye
- tightness in your throat
- feeling hot or irritable
- redness in your mouth or tongue

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

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

- a fast or irregular heart beat
- urinary tract infection (stinging or burning urine, more frequent need to pass urine)
- blood in the urine
- persistent headache or fainting
- bleeding from the nose
- pain or tingling in your hands, toes or feet
- decreased sensitivity or numbness in your mouth

- irritation or feeling of having something in the eye
- swollen or puffy eye(s)
- fatigue, pain in or around the eyes
- "red eye" due to swollen blood vessels in the white part of the eye and in the eyelids
- changes in vision such as blurring, a coloured tinge to your vision or a greater awareness of light

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:

- signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing
- chest pain, an uncomfortable feeling in the chest (often spreading to the arms, neck and sometimes to the shoulders and back) or a feeling of tightness, pressure or heaviness in the chest
- increased heart rate
- sudden decrease or loss of hearing
- seizures, fits or convulsions
- an erection which persists for four hours, or a painful erection
- loss of eyesight in one or both eyes, blurring, a blue colour to your vision or greater awareness of light
- changes to your normal vision such as red or yellow colour tinges to your vision or colourless objects appear coloured or you see halo around lights, sparks or lights when your eyes are closed.

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

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

Other side effects not listed above may also occur in some people.

After taking VEDAFIL

Storage

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.

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

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

Keep VEDAFIL 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 in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking VEDAFIL or the tablets have passed their expiry date, ask your pharmacist what to do with the amount left over.

Product description

What it looks like

VEDAFIL 25 mg

Blue, round-shaped tablets marked 'M' on one side and 'SL over 25' on the other.

Each blister pack contains 4 tablets.

VEDAFIL 50 mg

VEDAFIL 50 mg are blue, round-shaped tablets marked 'M' on one side and 'SL over 50' on the other.

Each blister pack contains 4 tablets.

VEDAFIL 100 mg

VEDAFIL 100 mg are blue, round-shaped tablets marked 'M' on one side and 'SL over 100' on the other.

Each blister pack contains 4 or 12 tablets.

Ingredients

The active ingredient in VEDAFIL is sildenafil citrate.

VEDAFIL tablets also contain:

- microcrystalline cellulose
- calcium hydrogen phosphate anhydrous
- croscarmellose sodium
- magnesium stearate

The tablet coating is Opadry Blue 03K80846 (ID No. 106239).

Supplier

Alphapharm Pty Limited

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW
www.mylan.com.au

Australian registration numbers:

VEDAFIL 25 mg - AUST R 162807

VEDAFIL 50 mg - AUST R 162805

VEDAFIL 100 mg - AUST R 162806

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