

VASAFIL

sildenafil (as citrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VASAFIL.

It does not contain all of 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 VASAFIL against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine,

Keep this leaflet with your medicine.

You may need to read it again.

What VASAFIL is used for

VASAFIL is used to treat erectile dysfunction, also commonly called impotence, in men. This is when a man cannot get, or keep, a hard erect penis, suitable for sexual activity.

It 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.

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

It is not for use in women.

It is available only with a doctor's prescription.

Before you take it

YOU MUST NOT TAKE VASAFIL 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 WILL NEED TO CHECK WHETHER YOU ARE FIT ENOUGH TO TAKE VASAFIL.

When you must not take it

Do not take VASAFIL if you are allergic to medicines containing sildenafil citrate or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take VASAFIL if you are being treated for angina (chest pain) or other heart conditions with certain medicines called nitrates.

Nitrate medicines include glyceryl trinitrate (also called nitroglycerin). Common tradenames include tablets; such as Anginine, Lycinat and Nitrostat; patches such as Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitran; sprays such as

Nitrolingual and Glytrin and injections such as Glyceryl trinitrate concentrate. Common tradenames for other nitrate preparations include tablets such as Imdur Durules, Monodur durules, Sorbidin, Isordil, Corangin, ISMO 20, Imtrate, Duride, Isomonit, Ikorel and Sodium Nitroprusside. There may be other tradenames not listed here.

Do not take VASAFIL if you are using amyl nitrate.

Do not take it if you have:

- heart or blood vessel problems that make sexual intercourse inadvisable
- suffered a heart attack or stroke in the last 6 months
- have severe liver problems
- Unusually high or low blood pressure that 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)
- an eye disease called retinitis pigmentosa.

Do not take VASAFIL if the expiry date (Exp.) printed on the pack has passed.

Do not take VASAFIL if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you: -

- **have any allergies to any other medicines, foods, dyes or preservatives.**
- **have any other heart or blood vessel problems.**

- **have previously had sudden loss of eyesight in one or both eyes.**

Tell your doctor if you have any medical conditions, especially the following:

- 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
- previous experience of a sudden decrease or loss of hearing

Tell your doctor if you are receiving any other treatment for impotence.

If you have not told your doctor about any of the above, tell them before you start taking VASAFIL.

Taking other medicines

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

Some medicines may be affected by VASAFIL, or may affect how well it works. 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
- some protease inhibitors such as ritonavir and saquinavir for the treatment of HIV infection
- medicines called alpha-blockers, that are 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).

Your doctor can tell you what to do if you are taking any of these medicines.

Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines.

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

How to take it

How much to take

The dose varies from patient to patient.

Your doctor will decide the correct dose for you depending on your condition and response.

Your doctor may instruct you to take 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 dose of VASAFIL a day.

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

How to take it

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

Swallow the tablets with a glass of water.

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

You may find Vasafil takes longer to work if you take it with or soon after a heavy meal.

VASAFIL will work only if you are sexually excited.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much VASAFIL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking VASAFIL.

See "Before you take VASAFIL" for a list of common nitrate medications. You should not take it if you are taking any of the medications on this list.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking VASAFIL.

Stop using it 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 it does not help you get an erection or if your erection does not last long enough to complete sexual intercourse, tell your doctor.

In these cases, your doctor may decide that you need a higher dose.

Things you must not do

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

Do not use it to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

If you experience changes in vision, or dizziness, when taking VASAFIL, you should not drive or operate machinery.

Be careful when drinking alcohol while taking it.

If you are affected by alcohol, your ability to get and maintain an erection can be affected.

Do not drink large amounts of alcohol before sexual activity.

Side effects

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

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- headache, dizziness
- flushing
- indigestion
- nasal congestion
- diarrhoea
- rash
- dry mouth, throat, nose or eye

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

- unusual heart beat
- urinary tract infection (stinging or burning urine, more frequent need to pass urine)

- blood in the urine
- changes in vision such as blurring, a blue colour to your vision or a greater awareness of light
- 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 pain in or around eyes.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of allergy such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts
- chest pain
- sudden decrease or loss of hearing
- seizures, fits or convulsions

Very rarely your erection may persist for longer than usual. If your erection continues for four hours, or sooner if there is pain, you should seek medical attention urgently.

Rarely men have lost eyesight some time after taking drugs to treat erectile dysfunction (known as impotence). It is not known at this time if VASAFIL causes this. If you lose eyesight in one or more eyes, seek medical attention urgently.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

Keep VASAFIL 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 a cool dry place where the temperature stays below 25°C.

Do not store it 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 VASAFIL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

VASAFIL comes in 3 strengths of tablets:

- VASAFIL 25 – oval, green tablet marked ‘SD 25’ on one side
- VASAFIL 50 – oval, green tablet marked ‘SD 50’ on one side
- VASAFIL 100 – oval, green tablet marked ‘SD 100’ on one side

All strengths come in packs of 4 tablets. VASAFIL 100 also comes in a pack of 12 tablets.

Ingredients

The active ingredient in VASAFIL is sildenafil (as citrate):

- each VASAFIL 25 tablet contains 25mg of sildenafil
- each VASAFIL 50 tablet contains 50mg of sildenafil

- each VASAFIL 100 tablet contains 100mg of sildenafil.

The tablets also contain:

- microcrystalline cellulose
- calcium hydrogen phosphate
- croscarmellose sodium
- magnesium stearate
- Opadry II 85F60888 Blue (ARTG 106662).

The tablets do not contain gluten or lactose.

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:
VASAFIL 25 - AUST R 172073
VASAFIL 50 - AUST R 172074
VASAFIL 100 – AUST R 172068

Date of preparation: March 2017.