

VIAGRA®

sildenafil (as citrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Viagra.

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 Viagra against the benefits they expect it will have for you.

It should be used only under strict medical supervision.

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 Viagra is used for

Viagra 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.

Viagra 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.

Viagra will work only if you are sexually excited.

Viagra will not increase your sex drive.

Viagra is not for use in women.

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

Before you take Viagra

YOU MUST NOT TAKE VIAGRA 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 VIAGRA.

When you must not take it

Do not take Viagra 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, Lycinate and Nitrostat; patches such as Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitran; sprays such as Nitrolingual and Glytrin and injections such as Gliceryl 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 Viagra if you:

- are using amyl nitrite
- have heart or blood vessel problems that make sexual intercourse inadvisable
- have suffered a heart attack or stroke in the last 6 months
- have severe liver problems
- blood pressure is unusually high or low or is not effectively treated
- have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)
- have an eye disease called retinitis pigmentosa.

Do not take Viagra if you have an allergy to Viagra or similar medicines or any of the ingredients listed at the end of this leaflet

An allergic reaction can include:

- hives, itching or skin rash
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing.

Do not take Viagra if the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright.

Do not take Viagra if the expiry date on the pack has passed.

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 any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
- have any other heart or blood vessel problems.
- have previously had sudden loss of eyesight in one or both eyes.
- have any of the following medical conditions:
 - 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.
- are taking or using any other treatment for impotence.
- are taking medicines to treat 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 or pharmacist about any of the above, tell them before you start taking Viagra.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a

pharmacy, supermarket or health food shop.

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

Some medicines and Viagra 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
- some protease inhibitors such as ritonavir and saquinavir for the treatment of HIV infection
- medicines called alpha-blockers. These 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).

You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Viagra.

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

How to take Viagra

Take Viagra exactly as your doctor has prescribed.

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 pack, 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 dose of Viagra a day.

When to take it

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

Viagra tablets

Swallow the tablet whole with a full glass of water.

Viagra orally disintegrating tablets

Make sure your hands are dry before taking the tablet from the blister. Immediately place the tablet on your tongue. The tablet will break into pieces on your tongue. Allow the tablet to dissolve completely then swallow it with your saliva.

Do not chew, bite or break the tablet.

Take your tablet on an empty stomach. You can take the tablet with water if you prefer.

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

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

Viagra will work only if you are sexually excited.

If you take too much (Overdose)

If you take too much, you are more likely to experience side effects.

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have taken too much Viagra. Do this even if there are no signs of discomfort.

While you are taking it

Things you must do

Stop taking Viagra 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 Viagra 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.

If you are about to start taking any new medicines, especially nitrates, tell your doctor and pharmacist that you are taking Viagra.

See "Before you take Viagra" for a list of common nitrate medications.

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

Things you must not do

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

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 Viagra.

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

Things to be careful of

Be careful drinking alcohol while taking Viagra.

Drinking alcohol can temporarily impair the ability to get an erection.

Do not drink large amounts of alcohol before sexual activity.

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

Side effects

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

While Viagra helps most people it can cause some unwanted side effects in a few people. All medicines have side effects. If unwanted effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

You may not get any of them.

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

- headache, dizziness
- flushing
- hot flushes
- indigestion
- 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.

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
- 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.

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 shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts
- chest pain
- increased hear rate
- sudden decrease or loss of hearing
- seizures, fits or convulsions
- your erection be increased, painful or 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). If you lose eyesight in one or more eyes or experience changes in vision such as blurring, a blue colour to your vision or a greater awareness of light, seek medical attention urgently
- changes to your normal vision such as:
 - red or yellow colour tinges to your vision or colourless objects appear coloured
 - you see a halo around lights, sparks or lights when your eyes are closed.

This is not a complete list of all possible side effects. Others may occur in some people and there may be side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

After taking Viagra

Storage

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.

Keep Viagra in a cool, dry place where the temperature stays below 30°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 windowsills.

Heat and dampness can destroy some medicines.

Keep the tablets in their pack until it is time to take them. If you take your tablets out of the pack they will not keep as well.

Disposal

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

Product description

What it looks like

Viagra tablets:

- 25 mg - blue, rounded-diamond shaped tablets marked VGR 25 on one side and PFIZER on the other.
- 50 mg - blue, rounded-diamond shaped tablets marked VGR 50 on one side and PFIZER on the other.
- 100 mg - blue, rounded-diamond shaped tablets marked VGR 100

on one side and PFIZER on the other.

All strengths are available in a box of 4 tablets. The 100 mg tablets are also available in a box of 12 tablets.

*Viagra orally disintegrating tablets:

- 50 mg - blue, rounded-diamond shaped tablets marked VR 50 on one side.

They are available in a box of 4 tablets.

*Viagra orally disintegrating tablets is not currently available.

Ingredients

Viagra tablets contain:

Active ingredients

- 25 mg - sildenafil (as citrate) 25 mg.
- 50 mg - sildenafil (as citrate) 50 mg.
- 100 mg - sildenafil (as citrate) 100 mg.

Other ingredients

- microcrystalline cellulose
- calcium hydrogen phosphate anhydrous
- croscarmellose sodium
- magnesium stearate
- hypromellose
- titanium dioxide (E171)
- lactose
- glycerol triacetate
- indigo carmine aluminium lake (E132)
- PF0102.

Viagra orally disintegrating tablets contain:

Active ingredients

- 50 mg - sildenafil (as citrate) 50 mg.

Other ingredients

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- colloidal anhydrous silica

- indigo carmine aluminium lake
- sucralose
- ludiflash
- sweetness enhancer 586220 TP0551
- special compound 501438 AP1051
- lemon flavour 501051 TP0551.

Supplier

Viagra is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia.

Toll Free number: 1800 675 229.

Viagra is supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland, New Zealand.

Toll Free number: 0800 736 363.

Australian Registration Numbers

Viagra tablets:

25 mg - AUST R 64434.

50 mg - AUST R 64435.

100 mg - AUST R 64436.

Viagra orally disintegrating tablets:

50 mg - AUST R 200061 .

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