

VIAGRA® TABLETS

Sildenafil Citrate (50 mg, 100 mg)

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What VIAGRA is used for

VIAGRA is a treatment for adult men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

How VIAGRA works

VIAGRA contains the active substance sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. VIAGRA will only help you to get an erection if you are sexually stimulated.

Before you use VIAGRA

When you must not use it

- If you are taking medicines containing nitrates, nitrites or nitric oxide donors.
- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of VIAGRA.
- If you are taking riociguat. This medicine is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in

the lungs caused by blood clots).

Pregnancy and lactation

VIAGRA is not indicated for use by women.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow) or any disease or deformity of your penis. These conditions may require special care when taking medicines for erectile dysfunction.
- If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.
- If you have obstruction with the pumping chambers of your heart.
- If you currently have a stomach ulcer, or a bleeding disorder (such as haemophilia).
- If you have or ever had a sudden decrease or loss of vision because of a problem with blood flow to the nerve in the eye called non-arteritic anterior ischaemic optic neuropathy (NAION).
- If you have low blood pressure at rest.
- If you have a rare inherited degenerative eye disease (retinitis pigmentosa).
- If you are on any other treatment for erectile dysfunction.
- If you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Special considerations for children:

VIAGRA should not be given to children under the age of 18.

- Taking other medicines

VIAGRA tablets may interfere with some medicines. In the event of a medical emergency, you should tell anyone treating your condition that you have taken VIAGRA. Do not take VIAGRA with other medicines unless your doctor tells you that you can.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly any of the following:

- Medicines containing nitrates, nitrites, and nitric oxide donors. Combination of this medicine and VIAGRA may lead to low blood pressure.
- Protease inhibitors, such as ritonavir and saquinavir used for the treatment of HIV. Your doctor may start you on the lowest dose (25 mg) of VIAGRA.
- Alpha-blocker therapy (e.g. doxazosin) for the treatment of high blood pressure or prostate problems as the combination of the two medicines may cause symptoms such as dizziness or light-headedness upon standing.
- Ketoconazole used to treat fungal infections.
- Erythromycin and rifampicin used to treat bacterial infections.
- Cimetidine used to treat and prevent certain types of ulcer.
- Bosentan and riociguat, used to treat high blood pressure.

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Taking VIAGRA with food and drink

When VIAGRA is taken with high fat food, it may take a little longer for VIAGRA to work.

How to use VIAGRA

- How much to use

Always take VIAGRA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 50 mg. The maximum recommended daily dose is 100 mg and minimum dose is 25 mg.

VIAGRA will only help you to get an erection if you are sexually stimulated. The amount of time VIAGRA takes to work varies from person to person. You should not use VIAGRA more than once a day.

- When to use it

You should take VIAGRA about one hour before sexual activity. Swallow the tablet whole with some water.

- How long to use it

Continue taking VIAGRA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

A dose above 100 mg does not increase the efficacy. However, it will result in an increase in undesirable effects and their severity. You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

If VIAGRA does not help you to get an erection or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

If you have the impression that the effect of VIAGRA is too strong or too weak, talk to your doctor or pharmacist.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

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

Drinking alcohol can temporarily impair the ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink large amounts of alcohol before taking VIAGRA.

- Things to be careful of

Driving and using machines

The effect of VIAGRA on the ability to drive and use machinery has not been studied.

VIAGRA can cause dizziness and can affect vision. You should be aware of how you react to VIAGRA before you drive or use machinery.

Side effects

Like all medicines, VIAGRA can cause side effects although not everybody gets them. These effects are normally mild to moderate.

If any of the following happen, stop taking VIAGRA and tell your doctor immediately:

- Headache
- Dizziness
- Vision blurred
- Visual disturbance
- A disorder of the vision causing all objects to appear blue (Cyanopsia)
- Hot flush and flushing
- Nasal congestion
- Nausea
- Indigestion

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of VIAGRA

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Keep tablets in the original package, protected from moisture.

Do not use VIAGRA after the expiry date which is stated on the carton. The expiry date refers to the last day of the month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

VIAGRA film-coated tablets are blue, rounded-diamond shaped. They are marked "VIAGRA" on one side and "VGR 50" or "VGR 100" on the other side. The tablets are provided in PVC/Aluminium foil blisters in cartons of 1 or 4 tablets.

Not all pack sizes and strengths may be marketed.

- Ingredients

- Active ingredient

The active substance is sildenafil. Each tablet contains 50 mg or 100 mg of sildenafil (as the citrate).

- Inactive ingredients

Microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, hydroxypropyl methylcellulose (hypromellose), titanium dioxide (E171), lactose, triacetin, FD & C Blue #2 aluminum lake (indigo carmine aluminium lake (E132))

- MAL Numbers

Product name	Registration number
Viagra 50 mg Tablet	<u>MAL20012710ACRZ</u>
Viagra 100 mg Tablet	<u>MAL20012711ACRZ</u>

Manufacturer

Viagra 50 mg and 100 mg:
Fareva Amboise,
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Product Registration Holder

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Date of Revision

27/05/2024

Serial Number

NPRA(R1/4)10062024/111

PLD-VIAGRA-0524