

GIAGRA TABLETS

(Sildenafil Citrate equivalent to Sildenafil 25mg, 50mg & 100 mg)

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What GIAGRA is used for

GIAGRA is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for GIAGRA to be effective, sexual stimulation is required.

How GIAGRA works

It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. GIAGRA will only help you to get an erection if you are sexually stimulated. You should not take GIAGRA if you do not have erectile dysfunction.

Before you use GIAGRA

- When you must not use it

Do not take GIAGRA

- If you are taking medicines called nitrates, as the combination may

Cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or "chest pain"). If you are not certain, ask your doctor or pharmacist.

- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are allergic (hypersensitive) to GIAGRA or any of the other ingredients of GIAGRA.
- If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as retinitis pigmentosa). If you have ever had loss of vision because of non-arteritic anterior ischaemic Optic neuropathy (NAION)

- 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)
- If you have a deformity of your penis or Peyronie's Disease.

- If you have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking GIAGRA and contact your doctor immediately.
- If you have suffered a myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months
- If you have resting hypotension (BP < 90/50) or hypertension (BP > 170/110)
- If you have retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases)

You should not use GIAGRA with any other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents

GIAGRA should not be given to individuals under the age of 18.

Special considerations for patients with kidney or liver problems

You should tell your doctor if You have kidney or liver problems. Your doctor may decide on a lower dose for you.

Pregnancy and Breast-feeding

GIAGRA is not indicated for use by women

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription. GIAGRA tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any healthcare professional treating your condition that you have taken GIAGRA and when you did. Do not take GIAGRA with other medicines unless your doctor tells you that you can.

You should not take GIAGRA if you are taking medicines called nitrates as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take GIAGRA if you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of GIAGRA.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking

GIAGRA with alpha-blockers. This is most likely to occur within 4 hours after taking GIAGRA. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start GIAGRA. Your doctor may start you on a lower dose (25 mg) of GIAGRA.

How to use GIAGRA

- How much to use

Always take GIAGRA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is 50 mg.

- When to use it

You should take GIAGRA about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

- How long to use it

This product does not require regular dosing and should be taken prior to sexual intercourse only.

- If you forget to use it

Not Applicable

- If you use too much (overdose)

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

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

Medicine, ask your doctor or pharmacist.

While you are using it

- Things you must do

If GIAGRA 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 to your doctor.

- Things you must not do

You should not take GIAGRA more than once a day.

- Things to be careful of

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

GIAGRA will only help you to get an erection if you are sexually stimulated. The amount of time GIAGRA takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that GIAGRA takes longer to work if you take it with a heavy meal.

If GIAGRA 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.

Driving and using machines

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

Taking GIAGRA with food and drink

GIAGRA can be taken with or without food. However, you may find that GIAGRA takes longer to start working if you take it with a heavy meal.

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

Side effects

Like all medicines, GIAGRA can cause side effects although not everybody gets them. The side effects reported in association with the use of GIAGRA are usually mild to moderate and of a short duration.

If you have chest pains during or after intercourse:

Get in a semi-sitting position and try to relax

Do not use nitrates to treat your chest pain

Contact your doctor immediately

All medicines including GIAGRA can cause allergic reactions. You should contact your doctor immediately.

If you experience any of the following symptoms after taking GIAGRA: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking GIAGRA. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking GIAGRA and contact your doctor immediately.

A very common side effect is headache.

Common side effects:
Dizziness, Visual disorders, Visual color distortion, Flushing, Nasal congestion, Dyspepsia, Diarrhea, Urinary tract infection.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -7 Reporting).

Storage and Disposal of GIAGRA

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Store in the original package, in order to protect from moisture.

Do not use GIAGRA 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

GIAGRA 25 TABLETS

Blue colored round, biconvex, film coated tablets, debossed

with 124 on one side and J on the other side. **Each film coated tablet contains Sildenafil Citrate 35.12mg is equivalent to Sildenafil 25mg**

GIAGRA 50 TABLETS

Blue colored round, biconvex, scored film coated tablets, debossed with 125 on one side and J on the other side with score line. **Each film coated tablet contains Sildenafil Citrate 70.24mg is equivalent to Sildenafil 50mg**

GIAGRA 100 TABLETS

Blue colored round, biconvex, scored film coated tablets, debossed with 126 on one side and J on the other side with score line. **Each film coated tablet contains Sildenafil Citrate 140.48mg is equivalent to Sildenafil 100mg**

- Ingredients
- Active ingredient (s)
Sildenafil Citrate
- Inactive ingredients cellulose, microcrystalline, calcium hydrogen phosphate anhydrous, croscarmellose sodium, magnesium stearate, opadry II blue, opadry clear & purified water.
- MAL Number:
- **GIAGRA 25-** MALxxxxxxxxxA
- **GIAGRA 50-** MALxxxxxxxxxA
- **GIAGRA 100-** MALxxxxxxxxxA

Manufactured by:

Hetero Labs Limited

Unit V, Sy.No. 439. 440, 441 & 458, TSIC SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana, India.

Product Registration Holder **Unimed Sdn Bhd**

No 53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara, 52200 Kuala Lumpur

Date of revision

- 13/11/2015