

Package leaflet: Information for the user

Sildenafil Teva 50 mg chewable tablets

Sildenafil Teva 100 mg chewable tablets

Sildenafil

(only applicable to those applications where a trademark is proposed)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What *Sildenafil teva* is and what it is used for
2. What you need to know before you take *Sildenafil teva*
3. How to take *Sildenafil teva*
4. Possible side effects
5. How to store *Sildenafil teva*
6. Contents of the pack and other information

1. What *Sildenafil teva* is and what it is used for

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 (PDE5) 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. Sildenafil will only help you to get an erection if you are sexually stimulated.

Sildenafil teva 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. You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take *Sildenafil teva*

Do not take Sildenafil teva :

- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall 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 medicines known as nitric oxide donors such as amyl nitrite (“poppers”), as the combination may also lead to a dangerous fall in your blood pressure.
- 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 due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions Talk to your doctor or pharmacist before taking Sildenafil teva

- 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 carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Sildenafil teva and contact your doctor immediately.

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

You should not take Sildenafil teva if you do not have erectile dysfunction.

You should not take Sildenafil teva if you are a woman.

Children and adolescents

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

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.

Other medicines and Sildenafil teva

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Sildenafil teva chewable tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken Sildenafil teva and when you did. Do not take Sildenafil teva with other medicines unless your doctor tells you that you can.

You should not take Sildenafil teva if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse 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 Sildenafil teva if you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a dangerous fall 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 Sildenafil teva.

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 Sildenafil teva with alpha-blockers. This is most likely to happen within 4 hours after taking Sildenafil teva. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil teva. Your doctor may start you on a lower dose (25 mg) of Sildenafil teva.

Sildenafil teva with food, drink and alcohol

Sildenafil teva can be taken with or without food. However, you may find that Sildenafil teva 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 Sildenafil teva.

Pregnancy, breast-feeding and fertility

Sildenafil teva is not indicated for use by women.

Driving and using machines

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

Sildenafil teva chewable tablets contain aspartame, a source of phenylalanine. If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism) you should take this into account. Sildenafil teva chewable tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take *Sildenafil teva*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose is 50 mg.

You should not take Sildenafil teva more than once a day.

You should take Sildenafil teva about one hour before you plan to have sex. The tablet should be chewed whole.

If you feel that the effect of Sildenafil teva is too strong or too weak, talk to your doctor or pharmacist.

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

If Sildenafil teva 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 take more Sildenafil teva than you should

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. The side effects reported in association with the use of Sildenafil teva 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.**

If you experience any of the following serious side effects stop taking Sildenafil teva and seek medical help immediately:

- An allergic reaction (this occurs rarely). Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat. Sildenafil teva Sildenafil teva
- Prolonged and sometimes painful erections (frequency unknown) Sildenafil teva. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision, stop taking Sildenafil teva and contact your doctor immediately.
- Serious skin reactions (frequency unknown). Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits (frequency unknown)

Very common (may affect more than 1 in 10 people):
Headache.

Common (may affect up to 1 in 10 people) include:
Facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness.

Uncommon (may affect up to 1 in 100 people) include:
Vomiting, skin rash, bleeding at the back of the eye, eye irritation, bloodshot eyes /red eyes, eye pain, double vision, abnormal sensation in the eye, pounding or rapid heartbeat, muscle pain, feeling sleepy,

reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, penile bleeding, presence of blood in semen and/or urine, chest pain and feeling tired.

Rare (may affect up to 1 in 1,000 people) include:

High blood pressure, low blood pressure, fainting, stroke, heart attack, irregular heartbeat, nosebleed and sudden decrease or loss of hearing.

Not known (frequency cannot be estimated from the available data):

Additional side effects reported from post-marketing experience include: unstable angina (a heart condition), sudden death, temporary decreased blood flow to parts of the brain. Most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Sildenafil teva.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sildenafil teva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP.

The expiry date refers to the last day of that month.

Store in the original container in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sildenafil teva contains

- The active substance is sildenafil. Each tablet contains 50 mg or 100 mg sildenafil.
- The other ingredients are: polacrillin potassium, silica colloidal anhydrous, lactose monohydrate, povidone K-30, aspartame (E951), croscarmellose sodium, peppermint flavour, magnesium stearate, potassium hydroxide (for pH adjustment) or hydrochloric acid (for pH adjustment).

What Sildenafil teva looks like and contents of the pack

50 mg: White, triangular, biconvex, embossed with “50” on one side.

100 mg: White, triangular, biconvex, embossed with “100” on one side

Blisters in packages of:

50 mg: 2, 4, 8, 12, 24 chewable tablets
100 mg: 2, 4, 8, 12, 24 chewable tablets

Not all pack sizes may be marketed.

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This medicinal product is authorised in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product}
{Name of the Member State} {Name of the medicinal product}

This leaflet was last revised in March 2014