SILDEGRA®

Sildenafil citrate (100 mg tablets)

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What Sildegra is used for

Sildegra is a treatment for 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 Sildegra works

Sildegra 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. Sildegra will only help you to get an erection if you are sexually stimulated. You should not take Sildegra if you do not have erectile dysfunction. You should not take Sildegra if you are a woman.

Before you use Sildegra

- *When you must not take it*

Do not take Sildegra

- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of Sildegra.
- If you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrite ("poppers"). These medicines are often given for relief of angina pectoris (or "chest pain"). Sildegra can cause a serious increase in the effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- 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) 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 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 disorder (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Sildegra and contact your doctor immediately.
- You should not use Sildegra with any other treatment for erectile dysfunction.

Special considerations for children

Sildegra should not be given to children 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 lactation

Sildegra 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.

Sildegra tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell anyone treating your condition that you have taken Sildegra.

Do not take Sildegra with other medicines unless your doctor tells you that you can.

Sildegra may cause a serious increase in the effects of medicines called nitrates, and nitric oxide donors such as amyl nitrite ("poppers"). These are often used for the relief of angina pectoris (or "chest pain"). You should NOT take Sildegra if you are taking these medicines.

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

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate problems may experience dizziness or light-headedness upon standing. These are symptoms of postural hypotension that is low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Sildegra with alpha- blockers. This is most likely to occur within 4 hours after taking Sildegra. 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 Sildegra. Your doctor may start you on a 25 mg dose of Sildegra.

How to use Sildegra

- *How much to use*

Always take Sildegra 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.

- *When to use it*

You should take Sildegra about one hour before sexual activity.

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Swallow the tablet whole with some water.
If you have the impression that the effect of Sildegra is too strong or too weak, talk to your doctor or pharmacist.

- *How long to use it*

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

You should not use Sildegra more than once a day.

- *If you forget to use it*

Please take Sildegra as prescribed. However, if you miss a dose, you should take the next dose about one hour before sexual activity.

- *If you use too much (overdose)*

Contact your doctor immediately.

While you are using it

- *Things you must do*

- It is important that you take Sildegra as directed by your doctor or pharmacist.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Sildegra.

- *Things you must not do*

- You should not use Sildegra more than once a day.
- Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

- *Things to be careful of*

Driving and using machines

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

Side effects

Like all medicines, Sildegra can cause side effects although not everybody gets them.

Very common side effect is headache.

Other common side effects are dizziness, effects on vision (including visual colour distortion, increased brightness of light or blurred vision), flushing, hot flush, stuffy nose, nausea and indigestion.

While the uncommon and rare side effects are running nose, allergic reactions, difficulty sleeping, decreased sense of touch, eye disorders such as eye pain and inflammation of eye, vertigo, ringing in the ears, low or high blood pressure, pounding heart, chest pain, fainting, tiredness and irritability.

You may experience prolonged and sometimes painful erections after taking Sildegra and if you have such an erection that lasts continuously for more than 4 hours, you should contact a doctor immediately.

If you have chest pains during or after intercourse, you should not use nitrates but you should contact your doctor immediately.

Muscle aches can occur if Sildegra is taken more frequently than once a day.

Tell your doctor or pharmacist if you develop any unusual symptoms, or if any known symptom continues or worsens.

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 Sildegra

- *Storage*

Keep out of the reach and sight of children.
Do not use this medicine after the expiry date that is stated on the carton.
Store below 30°C.

- *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*

Sildegra 100 mg tablets are light blue round slightly dotted tablets, with cross breaking notch on both sides and debossment “100” on one side.
The tablet can be divided into equal quarters.

- *Ingredients*

Active ingredient
Sildenafil citrate

Inactive ingredients
Microcrystalline cellulose
Calcium hydrogen phosphate anhydrous
Copovidone
Croscarmellose Sodium
Magnesium stearate
Indigo carmine (E132) aluminium lake
Saccharin-Sodium

- *MAL number*

Sildegra 100mg tablets
MAL15045134AZ

Manufacturer

Sandoz Private Limited, Kalwe
Plot No. 8-A/2 & 8-B,
TTC Industrial Area,
Kalwe Block, Village-Dighe,
Navi Mumbai 400708,
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Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
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