

Package Information Leaflet

Comit-100 Tablets

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.

What is in this leaflet

1. What Comit-100 is and what it is used for
2. What you need to know before you take Comit-100
3. How to take Comit-100
4. Possible side effects
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1. What Comit-100 is and what it is used for

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 (PDE 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. Sildenafil will only help you to get an erection if you are sexually stimulated. You should not take Sildenafil if you do not have erectile dysfunction. You should not take Sildenafil if you are a woman. Sildenafil 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.

2. What you need to know before you take Comit-100

Do not take Comit-100:

- If you are allergic to sildenafil citrate or any of the other ingredients of this medicine.
- 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 have a severe heart or liver problem, recently had a stroke or a heart attack, or if you have low blood pressure, have certain rare inherited eye diseases (such as retinitis pigmentosa), 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.

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), deformity of your penis or Peyronie's Disease, problems with your heart.
- if you currently have a stomach ulcer, or a bleeding problem (such as haemophilia), you experience sudden decrease or loss of vision, stop taking Sildenafil and contact your doctor immediately. You should not use Sildenafil with any other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents

Sildenafil 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.

Other medicines and Sildenafil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

Sildenafil 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 Sildenafil and when you did.

You should not take Sildenafil 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 Sildenafil 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 Sildenafil.

Sildenafil with food and drink

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

Pregnancy, breast-feeding and fertility

Sildenafil is not indicated for use by women

Driving and using machines

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

Sildenafil contains lactose

Sildenafil film-coated tablets contain lactose monohydrate. 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 Comit-100

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

The usual starting dose is 50 mg.

You should not take Sildenafil more than once a day.

The dose increase should be done in a quantity of 50 mg. The maximum dose per day is 100 mg.

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

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

Sildenafil will only help you to get an erection if you are sexually stimulated. The amount of

time Sildenafil takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Sildenafil takes longer to work if you take it with a heavy meal.

If Sildenafil 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 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 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 Sildenafil can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Sildenafil: 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 Sildenafil. 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 Sildenafil and contact your doctor immediately.

A very common side effect (likely to occur in more than 1 in 10 patients) is headache. Common side effects (likely to occur in 1 to 10 patients in 100): 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 side effects (likely to occur in 1 to 10 patients in 1000) 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, watery eyes, irregular 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 side effects (likely to occur in 1 to 10 patients in 10000) include: high blood pressure, low blood pressure, fainting, stroke, heart attack, nosebleed and sudden decrease or loss of hearing.

Additional side effects reported from post-marketing experience include: pounding heartbeat, chest pain, sudden death or temporary decreased blood flow to parts of the brain.

Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Sildenafil. Cases of convulsions or seizures and serious skin reactions characterised by rash, blisters, peeling skin and pain which require immediate medical attention have also been reported.

5. How to store Comit-100

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the label, carton and blister after EXP. The expiry date refers to the last day of that month.

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 Comit-100 contains

- The active substance is sildenafil.

Each film-coated tablet contains 100 mg Sildenafil (as sildenafil citrate).

- The other ingredients are

Lactose, Maize starch, Anhydrous calcium hydrogen phosphate, Methyl paraben, Propyl paraben, Povidone, Croscarmellose sodium, Magnesium stearate, Purified talc, Sodium starch glycolate, Colloidal anhydrous silica, Wincoat Blue (WT 01215), Isopropyl alcohol, Dichloromethane.

What Sildenafil looks like and contents of the pack

Film-coated tablet

Comit-100 film-coated tablets

White tetragonal biconvex tablets having one side '100' embossed & other side in plain.

Comit-100 film-coated tablets are available as 4 Tablets in Aluminium blisters.

Marketing Authorization Holder

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