ELONZA 100MG TABLET

Sildenafil citrate eq. to sildenafil (100mg)

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What Elonza is used for

Elonza is used in treatment of men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

In order for Elonza to be effective, sexual stimulation is required.

How Elonza works

Sidenafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Sildenafil is an oral therapy for erectile dysfunction. In the natural setting, i.e. with sexual stimulation, it restores impaired erectile function by increasing blood flow to the penis. 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.

Before you use Elonza

- When you must not use it

- If you are allergic (hypersensitive) to Sildenafil citrate
- If you are allergic (hypersensitive) to any of the other ingredients of Elonza
- If you are taking medicines called "Nitrates"
  - Nitrates are usually given for relief of angina pectoris (or "chest pain")
  - Sildenafil if taken in combination with nitrates may lead to a dangerous fall in your blood pressure.
- 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 problem
- If you have a severe liver disorder
  - Sildenafil should not be used unless when clearly indicated and prescribed by doctor. Your doctor may decide to give a lower dose for you.
- 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).
- You must not take Elonza in combination with any other oral or local treatments for erectile dysfunction
- If you do not have erectile dysfunction
- If you are a woman

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking Elonza.

- Before you start to use it

Inform your doctor in cases of:

- 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 problem (such as hemophilia)
- If you have kidney problems
  - Your doctor may decide to give a lower dose for you.

- Taking other medicines

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

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Carbamazepine
- Phenytoin
- Phenobarbital
- St. John's wort
- Rifampicin
- Ketoconazole
- Itraconazole
- Ritonavir
- Clarithromycin
- Telithromycin
- Nefazodone
- Erythromycin
- Saquinavir
- Nicorandil and other nitrate containing medicines
- Nitric oxide donors such as Amyl nitrite ("poppers")

How to use Elonza

- How much to use

Oral

Use in adults

The recommended dose is 50 mg taken as needed approximately one hour before sexual activity. Based on efficacy and toleration, the dose may be increased to 100 mg or decreased to 25 mg. The maximum recommended dosing frequency is once per day.

Use in the elderly

Dosage adjustments are not required in elderly patients.

Use in patients with kidney problem

The dosing recommendations described in "Use in adults" apply to patients with mild to moderate kidney impairment. Since Sildenafil clearance is reduced in patients with severe kidney problem, a 25mg dose should be considered.

Use in patients with liver problem

Since Sildenafil clearance is reduced in patients with liver problem (e.g. cirrhosis), a 25 mg dose should be considered.

Use in children

Elonza is not indicated for individuals below 18 years of age.

Use in patients using other medicines

Your doctor may recommend a lower dose of Sildenafil if you are taking other medicines as well. Therefore, it is important to tell your doctor the medicines that you are taking or about to take before starting Elonza.

- When to use it

It is recommended to take Elonza on an empty stomach. Onset of activity is delayed when taken with food.

Take Elonza about one hour before you plan to have sex.

- How long to use it

Do not take Elonza more than once a day. Elonza is intended for use prior to anticipated sexual activity and is not

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for continuous daily use.

- If you forget to use it

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take Elonza more than once a day.

- If you use too much (Overdose)

In case you yourself or anyone accidentally consume too much Elonza, call your doctor immediately or go to the nearest Emergency Department of a hospital. In case of overdose, you may feel headache, flushing, dizzy, indigestion, nasal congestion or altered vision.

While you are using it

- Things you must do

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

- Things you must not do

- Drinking alcohol before taking Elonza. Drinking alcohol can temporarily impair your ability to get an erection.

- Things to be careful of

- Activities requiring mental alertness: Do not drive a car or operate a potentially dangerous tools or machines until you know how sildenafil affects you. Sildenafil can cause dizziness and can affect vision.

Side effects

As with all drugs, Elonza is likely to have undesirable effects, although not everybody gets them.

- Headache
- Flushing
- Eye disorders (altered vision and chromatopsia)
- Dizziness
- Palpitations
- Nasal congestion
- Dyspepsia

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist.

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 Elonza

- Storage

Store at temperature of not more than 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?

Royal blue, rhombic, biconvex, film coated tablet with engraved 100 on one side and scored on the other

-Ingredients

- Active ingredient:
Sildenafil citrate

-Inactive ingredients:
Microcrystalline cellulose, Dibasic calcium phosphate compacted, Ludipress, Croscarmellose sodium, Povidone K 90, Isopropyl alcohol, Purified water, Talc, Magnesium stearate, Hydroxypropyl methylcellulose 2910, Polyethylene glycol 6000, Titanium dioxide, Lake brilliant blue, Simethicone emulsion 30%, Acetone

- *MAL number:*
MAL09122030AZ

Manufacturer

UNISON LABORATORIES CO., LTD.
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Product Registration Holder

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