

Tadalafil Tablets IP

Tadalafil - sx

Read all of this leaflet carefully
before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What **Tadalafil - sx** is and what it is used for
2. Before you take **Tadalafil - sx**
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Tadalafil - sx

1. WHAT Tadalafil - sx IS AND WHAT IT IS USED FOR

Tadalafil - sx comes as light yellow film-coated tablets. They are elliptical shaped & plain on both side. These tablets are available in blister packs containing 2 and 4 tablets.

Tadalafil - sx is a treatment for men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

Tadalafil - sx belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation **Tadalafil - sx** works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. **Tadalafil - sx** will not help you if you do not have erectile dysfunction.

It is important to note that **Tadalafil - sx** does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

2. BEFORE YOU TAKE Tadalafil - sx

Do not take Tadalafil - sx:

- if you are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines ('nitrates') used in the treatment of angina pectoris ('chest pain'). **Tadalafil - sx** has been shown to increase the effects of these drugs. If you are taking any form of nitrate or are unsure tell your doctor.
- if you have serious heart disease or have had a recent

heart attack.

- if you have had a recent stroke.
- if you have low blood pressure or uncontrolled high blood pressure.
- if you are (hypersensitive) allergic to **Tadalafil - sx** or any of the other ingredients of Tadalafil

Take special care with Tadalafil - sx:

Sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor.

The following are reasons why **Tadalafil - sx** may also not be suitable for you. If any of them apply to you, talk to your doctor before you take the medicine:

- You have sickle cell anaemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), leukaemia (cancer of the blood cells) or any deformation of your penis.
- You have a serious liver or kidney problem.

Taking other medicines:

As a general rule, always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because occasionally they might interact. This is particularly important if you are treated with nitrates as you should not take **Tadalafil - sx** if you are taking these medicines. Do not take **Tadalafil - sx** with other medicines if your doctor tells you that you may not.

You should not use **Tadalafil - sx** together with any other treatments for erectile dysfunction.

Tadalafil - sx is not intended for use by women or by children under the age of 18.

Driving and using machines:

As dizziness has been reported in men taking **Tadalafil - sx** in clinical studies, you should be aware of how you react to **Tadalafil - sx** before you drive or operate machinery.

Information for men intolerant of lactose, one of the ingredients of Tadalafil - sx :

Tadalafil - sx contains lactose and should not be taken by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

3. HOW TO TAKE Tadalafil - sx

Always take **Tadalafil - sx** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended starting dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak your doctor may increase the dose to 20 mg. **Tadalafil - sx** tablets are for oral use. Swallow the tablet whole with some water. You may take **Tadalafil - sx** with or without food.

You may take a **Tadalafil - sx** tablet at any point in time from 30 minutes to 12 hours before sexual activity. **Tadalafil - sx** may still be effective up to 24 hours after taking the tablet. It is important to note that **Tadalafil - sx** does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

You should NOT take **Tadalafil - sx** more than once a day. Daily use of **Tadalafil - sx** is strongly discouraged.

If you take more Tadalafil - sx than you should:

Tell your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Tadalafil - sx** can have side effects. These effects are normally mild to moderate in nature.

The most common undesirable effects are headache and indigestion. Less commonly reported side effects are back pain, muscle aches, nasal congestion, facial flushing and dizziness. Uncommon effects are swelling of the eyelids, eye pain and red eyes.

If you have any of these side effects and they are troublesome, severe, or do not go away, tell your doctor.

Allergic reactions (including skin rashes) could occur.

In rare instances it is possible that a prolonged and possibly painful erection may occur after taking **Tadalafil - sx**. If you have such an erection, which lasts continuously for more than 4 hours, you should contact a doctor immediately.

In case of chest pain occurring during or after sexual activity you should NOT use nitrates but you should seek immediate medical assistance.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Heart attack, stroke, and irregular heart beats have been reported rarely in men taking **Tadalafil - sx**. Most, but not all of these men had known heart problems before taking this medicine. It is not possible to determine whether these events were directly related to **Tadalafil - sx**.

Effects were seen in one animal species that might indicate impairment of fertility. Subsequent studies in man suggest that this effect is unlikely in humans.

5. WARNING

To be sold by retail on the prescription of a Urologist / Psychiatrist / Endocrinologist / Venerologists only

6. STORAGE CONDITION **Tadalafil - sx**

Keep out of the reach and sight of children.

Store in the original package.

Do not use after the expiry date stated on the carton and blister.

Store below 30°C. Store protected from moisture.

7. PRESENTATION

Each film coated tablet containing **Tadalafil - sx** 10 mg / 20 mg is available in blister packs of 2 and 4 tablets.

Manufactured in India by :

 **ajanta pharma limited**

Ajanta House, Charkop, Kandivli (W),
Mumbai 400 067. India.