

Tadalafil STELLA 10 mg film-coated tablet

Tadalafil STELLA 20 mg film-coated tablet

Tadalafil (10 mg, 20 mg)

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1. What Tadalafil STELLA is used for

Tadalafil STELLA contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Tadalafil STELLA is a treatment of erectile dysfunction in adult males. In order for tadalafil to be effective, sexual stimulation is required. Tadalafil is not indicated for use by women.

2. How Tadalafil STELLA works

Following sexual stimulation Tadalafil STELLA 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 STELLA will not help you if you do not have erectile dysfunction.

It is important to note that Tadalafil STELLA 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.

3. Before you use Tadalafil STELLA

- When you must not use it

Do not take the medicine if you:

- are allergic to tadalafil or any of the other ingredients of this medicine.
- 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 has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.

- have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".
- are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Tadalafil STELLA, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking this drug.

- Before you start to use it

Talk to your doctor before taking Tadalafil STELLA.

Be aware that 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.

Before taking the tablets, tell your doctor if you have:

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

It is not known if Tadalafil STELLA is effective in patients who have had:

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy).

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

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Tadalafil STELLA and contact your doctor immediately.

Tadalafil STELLA is not intended for use by women.

Children and adolescents

Tadalafil STELLA is not intended for use by children and adolescents under the age of 18.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any following medicines, including medicines obtained without a prescription.

Do not take Tadalafil STELLA if you are already taking nitrates.

Some medicines may be affected by Tadalafil STELLA or they may affect how well Tadalafil STELLA will work. Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- riociguat.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).

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- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

Tadalafil STELLA with drink and alcohol
Information on the effect of alcohol is in section **How to use Tadalafil STELLA**. Grapefruit juice may affect how well Tadalafil STELLA will work and should be taken with caution. Talk to your doctor for further information.

4. How to use Tadalafil STELLA

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

Tadalafil STELLA tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

- How much to use

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 STELLA tablets are for oral use.

- When to use it

You may take a Tadalafil STELLA tablet at least 30 minutes before sexual activity.

Tadalafil STELLA may still be effective up to 36 hours after taking the tablet.

It is important to note that Tadalafil STELLA 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.

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Tadalafil STELLA, avoid excessive drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

- How long to use it

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. While you are using Tadalafil STELLA

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists, and pharmacists treating you that you are taking Tadalafil STELLA.

- Things you must not do

Tadalafil STELLA with alcohol

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Tadalafil STELLA, avoid excessive drinking, since this may increase the risk of dizziness when standing up.

Talk to your doctor for further information.

- Things to be careful of

Driving and using machines

Some men taking tadalafil have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

Tadalafil STELLA contains lactose

If you have an intolerance to some sugars, contact your doctor before taking this medicine.

Fertility

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

6. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- priapism, a prolonged and possibly painful erection after taking Tadalafil STELLA (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (frequency rare).

Other side effects have been reported:

Common

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, and indigestion.

Uncommon

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding

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heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired.

Rare

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking tadalafil. Most of these men had known heart problems before taking this medicine.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects have been reported in men taking tadalafil. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

The side effect dizziness has been reported more frequently in men over 75 years of age taking tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking tadalafil.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or 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)].

7. Storage and Disposal of Tadalafil STELLA

- Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date.

Do not store above 30°C.

Keep medicine out of reach of children.

- Disposal

Medicines should not be disposed of using wastewater or household waste.

Ask your pharmacist how to dispose of medicines which are no longer required. These measures will help to protect the environment.

8. Product description

- What it looks like

Tadalafil STELLA 10 mg

Yellow, oblong film-coated tablets, biconvex, engraved with logo “” on one side and scored on the other side.

Dimension: About 5.6 mm x 11.6 mm.

Thickness: About 3.4 mm.

The tablet can be divided into equal doses.

Tadalafil STELLA 20 mg

Yellow, almond-shaped, film - coated tablet, biconvex, engraved with “T20” on one side and plain on the other side.

Dimension: About 7.8 mm x 12.6 mm.

Thickness: About 4.80 mm.

- Ingredients

- Active ingredient:

Tadalafil STELLA 10 mg

Each film coated tablet contains 10 mg of tadalafil.

Tadalafil STELLA 20 mg

Each film coated tablet contains 20 mg of tadalafil.

- Inactive ingredient(s):

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, hydroxypropyl cellulose, magnesium stearate, hypromellose, macrogol 6000, talc, titanium dioxide, yellow ferric oxide.

- MAL number:

Tadalafil STELLA 10 mg:

MAL18126002AZ

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MAL18126001AZ

9. Manufacturer:

STELLAPHARM J.V. CO., LTD. - BRANCH 1

(A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam-Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

10. Product Registration Holder

STADPHARM SDN. BHD.

E-9-01, Oasis Square, Ara Damansara

No: 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia

11. Date of revision:

04/07/2024

12. Serial Number

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