

Package leaflet: Information for the user

Tadalafil STADA 10 mg, filmomhulde tabletten

tadalafil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- If you have taken <Product name> as directed (see section 3) and were not able to get or keep an erection hard enough for satisfactory sex, you should talk to your pharmacist or doctor.

What is in this leaflet

1. What <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> is a treatment for adult men who have erection problems (erectile dysfunction). This is when a man cannot get or keep an erection hard enough for satisfactory sexual activity.

<Product name> contain the active substance tadalafil. It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

It works by relaxing the blood vessels in your penis, allowing blood flow into your penis.

It is important to know that you will not get an erection just by taking <Product name>. This medicine works with your body's natural function to get an erection only when you are sexually stimulated.

2. What you need to know before you take <Product name>

DO NOT take <Product name> if you:

- do not have an erection problem, as this medicine will not provide any benefit to you
- are allergic to tadalafil or any of the other ingredients in this medicine (listed in section 6)
- take any **medicines called nitrates or nitric oxide donors** (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate for the relief of chest pain or heart failure, or nicorandil, molsidomine or sodium nitroprusside), as the combination may lead to a dangerous fall in blood pressure
- take amyl nitrite also known as "poppers" as recreational drugs, as the combination may lead to a dangerous fall in blood pressure

- have been advised by your doctor to avoid sexual activity because of a problem with your heart or blood vessels, such as recent heart attack (within the last 90 days) or stroke (within the last 6 months), unstable angina or severe cardiac failure
- have low blood pressure or uncontrolled high blood pressure
- have ever had loss of vision because of non-arthritic anterior ischaemic optic neuropathy (NAION), a condition described as “stroke of the eye”
- take riociguat or other medicines belonging to a group called guanylate cyclase stimulators. These medicines are 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)
- have a deformed penis (such as angulation, cavernosal fibrosis or Peyronie’s disease)
- are a woman
- are under 18 years of age.

Warnings and precautions

Talk to your pharmacist or doctor before taking <Product name>.

Sexual activity can put extra strain on your heart. If you have a heart problem or think you might have a heart problem, you should tell your pharmacist or doctor.

It is important to have a check-up with your doctor as soon as possible within the first 6 months of using <Product name> to ensure that your erection problems are not caused by another serious health condition.

Even if you feel healthy, your erection problems may be linked to other serious health conditions. Erectile dysfunction may be an early sign of:

- heart and blood vessel problems
- diabetes
- high blood pressure
- depression

You should discuss your symptoms and these conditions with your doctor if you have not already done so.

Cardiovascular risk factors

Before taking <Product name>, in order to ensure this medicine is suitable for you and that you are fit enough to have sex, tell your doctor if you:

- get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex
- have or have ever had any heart disease or heart surgery e.g. valvular heart disease (damaged or diseased heart valve), cardiomyopathy (disease of the heart muscle), arrhythmia (irregular heart beat)
- have high blood pressure that is not controlled
- have an abnormal or impaired left lower heart chamber
- have a restriction of the blood flow from the heart e.g. aortic stenosis
- have Multiple System Atrophy (a rare condition causing severe loss of control of blood pressure due to shrinkage of muscle or nerve tissue)

Other risk factors

Talk to your doctor before taking <Product name> if you:

- have ever had an erection that lasted more than 4 hours (called priapism) or have any condition which can cause priapism which includes sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow).
- take any other medicines listed in this leaflet. Please refer to section 2 ‘Other medicines and <Product name>’
- have any deformation of your penis

- have a serious liver problem
- have a severe kidney problem

Speak to your doctor if you have:

- undergone pelvic surgery or removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy) as it is not known if <Product name> will be effective for you
- known hereditary degenerative retinal disorders such as retinitis pigmentosa (a genetic disorder that causes loss of vision) as it is unknown whether tadalafil is safe for you to use
- If you experience sudden decrease or loss of vision or your vision is distorted, dimmed while you are taking <Product name>, stop taking <Product name> 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 <Product name> and contact your doctor immediately.

Children and adolescents

<Product name> is not intended for use by children and adolescents under the age of 18.

Other medicines and <Product name>

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines.

Do not take <Product name> if you take:

- **NITRATE medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) or nitric oxide donors (such as amyl nitrite (“poppers”), nicorandil, molsidomine or sodium nitroprusside).** These are often used for the relief of chest pain (angina pectoris), or heart failure. Using <Product name> with any of these medicines may lead to a dangerous fall in blood pressure.
- Riociguat (or other medicines of a group called guanylate cyclase stimulators), 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 due to blood clots).

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

- an alpha blocker such as alfuzosin, doxazosin or tamsulosin, which are **medicines used to treat urinary problems due to an enlarged prostate (benign prostatic hyperplasia) or occasionally high blood pressure**
- **other medicines to treat high blood pressure.**
- finasteride (a 5-alpha reductase inhibitor **to treat benign prostatic hyperplasia**)
- itraconazole or ketoconazole (**medicines to treat fungal infections**)
- rifampicin, erythromycin or clarithromycin (**antibiotics**)
- ritonavir or saquinavir (protease inhibitors for treatment of AIDS or HIV infection)
- phenobarbital, phenytoin and carbamazepine (**anticonvulsant medicines**)
- other treatments for erectile dysfunction
- theophylline (**to treat asthma**)
- cimetidine (**used to treat heartburn and stomach ulcers**)

<Product name> with drink and alcohol

Grapefruit juice may affect how well <Product name> will work and must be avoided. Drinking excessive alcohol can temporarily reduce your ability to get an erection. To get the

maximum benefit from your medicine, you are advised not to drink large amounts of alcohol before sexual activity. Talk to your pharmacist or doctor for further information.

Recreational drugs

Do not take amyl nitrite (also known as “poppers”) as recreational drugs, as the combination may lead to a dangerous fall in blood pressure.

Avoid the use of <Product name> with other recreational drugs (including but not limited to nitrous oxide, GHB/GBL, methamphetamines, MDMA/ecstasy, ketamine, flunitrazepam, cannabis, opioids, cocaine, etc.), as it may lead to side effects such as dizziness, decrease of blood pressure, stroke or heart attack, seizures, priapism, and coma.

Pregnancy, breast-feeding and fertility

This medicine should not be used by women.

Driving and using machines

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

<Product name> contains lactose

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

<Product name> contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take <Product name>

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

take one tablet as needed, at least 30 minutes before sexual activity
swallow the tablet whole with water
do not take more than 1 tablet a day

You can get an erection, when sexually stimulated, in 30 minutes and for up to 36 hours after taking one <Product name> tablet.

The tablets can be taken with or without food.

This medicine is intended for use prior to anticipated sexual activity. It is not recommended for continuous daily use. Talk to your doctor if you feel you need to take this medicine every day.

You will not get an erection just by taking <Product name>. This medicine will only help you get an erection if you are sexually aroused. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Remember to relax and be patient. There is no rush. If you are not successful the first time, try to have sex again, but remember you can only take one tablet a day. For most men, <Product name> will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take several attempts before you are able to achieve an erection. If you feel the effect of <Product name> is too strong or too weak, talk to your pharmacist or doctor.

Talk to your pharmacist or doctor if you have taken <Product name> as directed and are still not able to get and keep an erection.

If you take more <Product name> than you should

Contact your doctor. You may experience side effects described in section 4.

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

4. Possible 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:

- an allergic reactions: this occurs uncommonly. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat, rashes
- chest pains: this occurs uncommonly. If this occurs before, during or after intercourse, get in a semi-sitting position and try to relax. **DO NOT use nitrates to treat chest pain. Seek immediate medical help**
- persistent and sometimes painful erection lasting longer than 4 hours: this occurs rarely
- a sudden loss of vision (frequency rare), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known)
- Stevens-Johnson syndrome (SJS) which is a rare, serious disorder of the skin causing flu-like symptoms and a painful rash that spreads and blisters

Other side effects have been reported

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

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

Rare (may affect up to 1 in 1 000 people)

- fainting
- seizures
- temporary 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
- 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 that were not seen in clinical trials. 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
- sudden cardiac death
- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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

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

This medicinal product does not require any special storage conditions. Divided tablets should be disregarded after 4 weeks of storage.

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 <Product name> contains

- The **active** substance is tadalafil.
One film-coated tablet contains 10 mg tadalafil.
- The other ingredients are:
Tablet core
Lactose monohydrate
Croscarmellose sodium
Sodium laurilsulfate (E487)
Hydroxypropyl cellulose
Polysorbate 80
Cellulose, microcrystalline
Magnesium stearate

Coating

Hypromellose 2910
Lactose monohydrate
Titanium dioxide (E171)
Triacetin
Iron oxide yellow (E172)
Talc

What <Product name> looks like and contents of the pack

Yellow, round, biconvex, film-coated tablets with score line on one side, white at the cross section with 8.1 ± 0.2 mm diameter. The tablets can be divided into equal doses.

Available in blister packs containing 4x1, 8x1, 12x1, 16x1, 20x1, 24x1, 28x1, 30x1, 36x1, 48x1 and 60x1 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant Vergunninghouder:

STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Fabrikant:

STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

STADA Arzneimittel GmbH
Muthgasse 36/2
1190 Wenen
Oostenrijk

Clonmel Healthcare Ltd.,
Waterford Road
Clonmel, Co. Tipperary,
Ierland

In het register ingeschreven onder

Tadalafil STADA 10 mg, filmomhulde tabletten RVG 130421

Deze bijsluiter is voor het laatst goedgekeurd in november 2023