

Package leaflet: Information for the patient

Tadalafil Krka 5 mg film-coated tablets tadalafil

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. See section 4.

What is in this leaflet

1. What Tadalafil Krka is and what it is used for
2. What you need to know before you take Tadalafil Krka
3. How to take Tadalafil Krka
4. Possible side effects
5. How to store Tadalafil Krka
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1. What Tadalafil Krka is and what it is used for

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

Tadalafil Krka 5 mg is used to treat adult men with:

- **erectile dysfunction.** This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.
Following sexual stimulation Tadalafil Krka 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 will not help you if you do not have erectile dysfunction. It is important to note that Tadalafil Krka for the treatment of erectile dysfunction 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.
- urinary symptoms associated with a common condition called **benign prostatic hyperplasia.** This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. Tadalafil improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Tadalafil has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

2. What you need to know before you take Tadalafil Krka

Do not take Tadalafil Krka

- if you are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- 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 has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.

- if you have serious heart disease or recently had a heart attack within the last 3 months.
- if you have recently had a stroke within the last 6 months.
- if you have low blood pressure or uncontrolled high blood pressure.
- if you have ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- if you 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 Krka, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tadalafil Krka.

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

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with Tadalafil Krka for benign prostatic hyperplasia. Tadalafil Krka does not treat prostate cancer.

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

- sickle cell anemia (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 Krka 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 Krka 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 Krka and contact your doctor immediately.

Tadalafil Krka 5 mg is not intended for use by women.

Children and adolescents

Tadalafil Krka is not indicated for use by children and adolescents under the age of 18.

Other medicines and Tadalafil Krka

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

Do NOT take Tadalafil Krka if you are already taking nitrates.

Some medicines may be affected by Tadalafil Krka or they may affect how well Tadalafil Krka 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 (to treat some forms of pulmonary hypertension).
- a 5-alpha reductase inhibitor (to treat benign prostatic hyperplasia).
- protease inhibitors for the treatment of AIDS or HIV infection (e.g. ritonavir).
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin (to treat bacterial infections).
- medicines such as ketoconazole or itraconazole (to treat fungal infections)
- other treatments for erectile dysfunction .

Tadalafil Krka with drink and alcohol

Information on the effect of alcohol is in section 3.

Grapefruit juice may affect how well Tadalafil Krka will work and should be taken with caution.

Talk to your doctor for further information.

Fertility

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

Driving and using machines

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

Tadalafil Krka contains lactose and sodium

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

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

3. How to take Tadalafil Krka

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

Tadalafil Krka 5 mg tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

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 Krka, avoid excessive drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

For the treatment of erectile dysfunction

The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day. Your doctor may adjust the dose to 2.5 mg based on your response to Tadalafil Krka. This will be given as one 2.5 mg tablet. Alternatively, the 2.5 mg dose can be obtained by dividing the 5 mg tablet into equal halves.

Do not take Tadalafil Krka more than once a day.

When taken once a day Tadalafil Krka allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of Tadalafil Krka may be useful to men who anticipate having sexual activity two or more times per week.

It is important to note that Tadalafil Krka 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.

For the treatment benign prostatic hyperplasia

The **dose** is one 5 mg tablet taken once a day at approximately the same time of the day.

If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet taken once a day.

Do not take Tadalafil Krka more than once a day.

If you take more Tadalafil Krka than you should

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

If you forget to take Tadalafil Krka

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 Krka more than once a day.

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. 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 Krka (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 (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- dizziness, stomach ache, reflux, feeling sick, being sick (vomiting), blurred vision, eye pain, difficulty 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 and feeling tired.

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

- 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), increased sweating, bleeding from the penis and presence of blood in semen.

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 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.

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 HPRC Pharmacovigilance.

Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tadalafil Krka

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 packaging after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Tadalafil Krka contains

- The active substance is tadalafil. Each film-coated tablet contains 5 mg tadalafil.
- The other ingredients are: hypromellose phtalate, mannitol, croscarmellose sodium, sodium laurilsulfate, magnesium stearate (E470b) in the tablet core and lactose monohydrate, hypromellose, talc (E553b), titanium dioxide (E171), yellow iron oxide (E172) and triacetin (E1518) in the film coating.
- See section 2 “Tadalafil Krka contains lactose and sodium”.

What Tadalafil Krka looks like and contents of the pack

Tadalafil Krka 5 mg film-coated tablets (tablets) are: light yellow, biconvex, oval, film-coated tablets, scored on one side and with sign 5 on the other side. The tablet can be divided into equal doses. Tablet dimensions: approximately 9 mm long and 6 mm wide.

Tadalafil Krka is available in boxes containing 2, 4, 8, 12, 14, 28, 56 and 84 film-coated tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Slovenia, Austria, Belgium, Denmark, Spain, Finland, France,	Tadalafil Krka
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Ireland, Iceland, Italy, Norway, Portugal, Sweden, United Kingdom	
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This leaflet was last revised in