Package leaflet: Information for the patient

Vardenafil Krka 5 mg film-coated tablets
Vardenafil Krka 10 mg film-coated tablets
Vardenafil Krka 20 mg film-coated tablets

vardenafil

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

Vardenafil Krka contains vardenafil, a member of a class of medicines called phosphodiesterase type 5 inhibitors. They are used for the treatment of erectile dysfunction in adult men, a condition which implies difficulties in getting or keeping an erection.

At least one in ten men has trouble getting or keeping an erection at some time. There may be physical or psychological causes, or a mixture of both. Whatever the cause is, due to muscle and blood vessel changes not enough blood stays in the penis to make it hard and keep it hard.

Vardenafil Krka will only work when you are sexually stimulated. It reduces the action of the natural chemical in your body which makes erections go away. Vardenafil Krka allows an erection to last long enough for you to satisfactorily complete sexual activity.

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

Do not take Vardenafil Krka
- If you are allergic to vardenafil or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include a rash, itching, swollen face or lips and shortness of breath.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Vardenafil Krka.
- If you are taking medicines containing nitrates, such as glycerol trinitrate for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Krka could seriously affect your blood pressure.
- If you are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- If you are over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines.
- If you have a severe heart or liver problem.
- If you are having kidney dialysis.
- If you have recently had a stroke or heart attack.
- If you have or have had low blood pressure.
- If your family has a history of degenerative eye diseases (such as retinitis pigmentosa).
- If you have ever had a condition involving loss of vision due to damage to the optic nerve from insufficient blood supply known as non-arteritic ischemic optic neuropathy (NAION).
- 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 Vardenafil 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 Vardenafil Krka.

Take special care with Vardenafil Krka
- If you have heart trouble. It may be risky for you to have sex.
- If you suffer from irregular heart beat (cardiac arrythmia) or inherited heart diseases affecting your electrocardiogram.
- If you have a physical condition affecting the shape of the penis. This includes conditions called angulation, Peyronie's disease and cavernosal fibrosis.
- If you have an illness that can cause erections which won't go away (priapism). These include sickle cell disease, multiple myeloma and leukaemia.
- If you have stomach ulcers (also called gastric or peptic ulcers).
- If you have a bleeding disorder (such as haemophilia).
- If you are using any other treatments for erection difficulties (see section: Other medicines and Vardenafil Krka).
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, have been reported in association with vardenafil treatment. Stop using Vardenafil Krka and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- If you experience sudden decrease or loss of vision or your vision is distorted or dimmed while you are taking Vardenafil Krka, stop taking Vardenafil Krka and contact your doctor immediately.

Children and adolescents
Vardenafil Krka is not intended for use by children or adolescents under 18.

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

Some medicines may cause problems, especially these:
- Nitrates, medicines for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Krka could seriously affect your blood pressure. Talk to a doctor without taking Vardenafil Krka.
- Medicine for the treatment of arrythmias, such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines for HIV. Talk to a doctor without taking Vardenafil Krka.
- Ketoconazole or itraconazole, anti-fungal medicines.
- Erythromycin, or clarithromycin, macrolide antibiotics.
- Alpha-blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate (as benign prostatic hyperplasia).
- Riociguat.

Do not use Vardenafil Krka film-coated tablets combined with any other treatment for erectile dysfunction.

Vardenafil Krka with food, drink and alcohol
- You can take Vardenafil Krka with or without food – but preferably not after a heavy or high-fat meal as this may delay the effect.
- Don't drink grapefruit juice when you use Vardenafil Krka. It can interfere with the usual effect of the medicine.
- Alcoholic drink can make erection difficulties worse.

Pregnancy and breast-feeding
Vardenafil Krka is not for use by women.

Driving and using machines
Vardenafil Krka might make some people feel dizzy or affect their vision. If you feel dizzy, or if your vision is affected after taking Vardenafil Krka don't drive or operate any tools or machines.

3. How to take Vardenafil Krka

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

The recommended dose is 10 mg.

Take a Vardenafil Krka tablet about 25 to 60 minutes before sexual activity. With sexual stimulation you may achieve an erection anywhere from 25 minutes up to four to five hours after taking Vardenafil Krka.
- Swallow one tablet with a glass of water

Do not take Vardenafil Krka more than once a day.
Tell your doctor if you think Vardenafil Krka is too strong or too weak.

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Article name.: PL.VARDENAFIL KRKA FCT GB
Prepared by: D. Primc
Date: 25.02.2025

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If you take more Vardenafil Krka than you should
Men who take too much Vardenafil Krka may experience more side effects or may get severe back pain. If you take more Vardenafil Krka than you should, tell your doctor.

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. Most of the effects are mild or moderate.

Partial, sudden, temporary or permanent decrease or loss of vision, or distorted, dimmed, or blurred central vision in one or both eyes has been experienced by patients. Stop taking Vardenafil Krka and contact your doctor immediately.

Cases of sudden death, fast or altered heart beat, heart attack, chest pain, and trouble in cerebral circulation (including temporarily decreased blood flow to parts of the brain and bleeding in the brain) have been reported in men taking vardenafil. Most of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to vardenafil.

Sudden decrease or loss of hearing has been reported.

The chance of having a side effect is described by the following categories:
Very common (may affect more than 1 in 10 people)
- Headache

Common (may affect up to 1 in 10 people)
- Dizziness
- Flushing
- Blocked or runny nose
- Indigestion

Uncommon (may affect up to 1 in 100 people)
- Swelling of skin and mucous tissue including swollen face, lips or throat
- Sleep disorder
- Numbness and impaired perception of touch
- Sleepiness
- Effects on vision; redness of the eye, effects on colour vision, eye pain and discomfort, light sensitivity
- Ringing in the ears; vertigo
- Fast heart beat or pounding heart
- Breathlessness
- Stuffy nose
- Acid reflux, gastritis, abdominal pain, diarrhoea, vomiting; feeling sick (*nausea*), dry mouth
- Raised levels of liver enzymes in your blood
- Rash, reddened skin
- Back or muscle pain; increase in blood of a muscle enzyme (*creatine phosphokinase*), muscle stiffness
- Prolonged erections
- Malaise

Rare (may affect up to 1 in 1 000 people)
- Inflammation of the eyes (*conjunctivitis*)
- Allergic reaction
- Anxiety
- Fainting
- Amnesia
- Seizure
- Increased pressure in the eye (*glaucoma*), increased tearing of the eyes
- Effects on the heart (such as heart attack, altered heart beat or angina)
- High or low blood pressure
- Nose bleed
- Effect on results of blood tests to check liver function
- Sensitivity of the skin to sun light
- Painful erections
- Chest pain
- Temporarily decreased blood flow to parts of the brain

Very rare or not known (may affect less than 1 in 10 000 users or frequency cannot be estimated from the available data)
- Blood in the urine *(Haematuria)*
- Penile bleeding *(Penile Haemorrhage)*
- Presence of blood in the semen *(Haematospermia)*
- Sudden death
- Bleeding in the brain
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (*Stevens-Johnson syndrome, toxic epidermal necrolysis*)
- Distorted, dimmed, or blurred central vision or sudden decrease of vision

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 Yellow Card Scheme at website: yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vardenafil 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 Vardenafil Krka contains
- The active substance is vardenafil.
  Each film-coated tablet contains 5 mg, 10 mg or 20 mg vardenafil (as vardenafil hydrochloride trihydrate).
- The other ingredients (excipients) are microcrystalline cellulose, crospovidone (Type A), colloidal anhydrous silica, magnesium stearate (E470b) in the tablet core and hypromellose, macrogol 4000, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172) in the film coating.

What Vardenafil Krka looks like and contents of the pack
5 mg film-coated tablets: Film-coated tablets (tablets) are orange-brown, round, slightly biconvex, with bevelled edges, engraved with 5 on one side, 5.5 mm in diameter.
10 mg film-coated tablets: Film-coated tablets (tablets) are orange-brown, oval, slightly biconvex, scored on one side and engraved with 10 on the other side, dimensions 10.5 mm x 5.5 mm. The tablet can be divided into equal doses.
20 mg film-coated tablets: Film-coated tablets (tablets) are orange-brown, round, biconvex, with bevelled edges, scored on one side and engraved with 20 on the other side, 10 mm in diameter. The tablet can be divided into equal doses.

Vardenafil Krka is available in boxes containing:
- 2, 4, 8, 12 and 20 film-coated tablets in blisters,
- 2 x 1, 4 x 1, 8 x 1, 12 x 1 and 20 x 1 film-coated tablet in unit-dose 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 leaflet was last revised in 03/2025.

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