

Summary Public Assessment Report

Vardenafil Krka (vardenafil)

SE/H/1619/01-03/DC

Summary Public Assessment Report

Vardenafil Krka
(vardenafil)

Film coated tablet 5 mg 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Vardenafil Krka. It explains how Vardenafil Krka was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Vardenafil Krka.

For practical information about using Vardenafil Krka, patients should read the package leaflet or contact their doctor or pharmacist.

What is Vardenafil Krka and what is it used for?

Vardenafil Krka is a 'generic medicine'. This means that Vardenafil Krka is similar to a 'reference medicine' already authorised in the European Union (EU) called Levitra.

Vardenafil Krka are used for the treatment of erectile dysfunction in adult men, a condition which implies difficulties in getting or keeping an erection.

How does Vardenafil Krka work?

Vardenafil Krka contains vardenafil, a member of a class of medicines called phosphodiesterase type 5 inhibitors.

Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction. In the natural setting, i.e., with sexual stimulation, it restores impaired erectile function by increasing blood flow to the penis.

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.

How is Vardenafil Krka used?

The pharmaceutical form of Vardenafil Krka is film coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Vardenafil Krka have been shown in studies?

Because Vardenafil Krka is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Levitra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Vardenafil Krka?

Because Vardenafil Krka is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Vardenafil Krka approved?

It was concluded that, in accordance with EU requirements, Vardenafil Krka has been shown to have comparable quality and to be bioequivalent similar to the reference medicine Levitra. Therefore, the Medical Products Agency in Sweden decided that, as for Levitra, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Vardenafil Krka?

A risk management plan has been developed to ensure that Vardenafil Krka is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Vardenafil Krka, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Vardenafil Krka

The marketing authorisation for Vardenafil Krka was granted on 2017-03-30 in Sweden.

The full PAR for Vardenafil Krka can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Vardenafil Krka, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2017-03.