

Summary Public Assessment Report

Tadalafil Germed (tadalafil)

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(tadalafil)

Film-coated tablet 5mg, 10mg and 20 mg

This is a summary of the public assessment report (PAR) for Tadalafil Germed. It explains how Tadalafil Germed 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 Tadalafil Germed.

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

What is Tadalafil Germed and what is it used for?

Tadalafil Germed is a 'generic medicine'. This means that Tadalafil Germed is similar to a 'reference medicine' already authorised in the European Union (EU) called Cialis.

Tadalafil Germed 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 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 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.

How does Tadalafil Germed work?

Tadalafil Germed contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. They give a smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection.

Tadalafil has no effect in the treatment of erectile dysfunction in the absence of sexual stimulation.

How is Tadalafil Germed used?

The pharmaceutical form of Tadalafil Germed 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 Tadalafil Germed have been shown in studies?

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

What are the possible side effects of Tadalafil Germed?

Because Tadalafil Germed 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 Tadalafil Germed approved?

It was concluded that, in accordance with EU requirements, Tadalafil Germed has been shown to have comparable quality and to be bioequivalent to the reference medicine Cialis. Therefore, the Medical Products Agency in Sweden decided that, as for Cialis, 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 Tadalafil Germed?

A risk management plan has been developed to ensure that Tadalafil Germed 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 Tadalafil Germed, 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 Tadalafil Germed

The marketing authorisation for Tadalafil Germed was granted on 2017-07-07 in Sweden.

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

This summary was last updated in 2017-09.