LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tadalafil Actavis
(tadalafil)

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Summary Public Assessment Report

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(tadalafil)

Film-coated tablets, 2.5 mg, 5 mg, 10 mg and 20 mg

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

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

What is Tadalafil Actavis and what is it used for?

Tadalafil Actavis is a 'generic medicine'. This means that Tadalafil Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Cialis. Tadalafil Actavis is a treatment for adult men with erectile dysfunction.

How does Tadalafil Actavis work?

When a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil Actavis has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

How is Tadalafil Actavis used?

The pharmaceutical form of Tadalafil Actavis is film-coated tablet.

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 Actavis have been shown in studies?

Because Tadalafil Actavis 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 Actavis?

Because Tadalafil Actavis 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 Actavis approved?

It was concluded that, in accordance with EU requirements, Tadalafil Actavis has been shown to have comparable quality and to be bioequivalentto 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 Actavis?

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

The marketing authorisation for Tadalafil Actavis was granted on 2016-07-20 in Sweden.

The full PAR for Tadalafil Actavis can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Tadalafil Actavis, please read the package leaflet, 2.5 mg, package leaflet, 5 mg, package leaflet, 10 mg and package leaflet, 20 mg or contact your doctor or pharmacist.

This summary was last updated in 2016-07.