LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vixantus
(tadalafil)

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Summary Public Assessment Report

Vixantus
(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 Vixantus. It explains how Vixantus 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 Vixantus.

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

What is Vixantus and what is it used for?

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

How does Vixantus work?

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

How is Vixantus used?

The pharmaceutical form of Vixantus 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 Vixantus have been shown in studies?

Because Vixantus 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 Vixantus?

Because Vixantus 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 Vixantus approved?

It was concluded that, in accordance with EU requirements, Vixantus 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 Vixantus?

A risk management plan has been developed to ensure that Vixantus 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 Vixantus, 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 Vixantus

The marketing authorisation for Vixantus was granted on 2017-02-17 in Sweden.

The full PAR for Vixantus can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Vixantus, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2017-02.