LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fillata
(tadalafil)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Fillata
(tadalafil)

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

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

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

What is Fillata and what is it used for?

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

Fillata 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 Fillata work?

Fillata 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 Fillata used?

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

Because Fillata 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 Fillata?

Because Fillata 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 Fillata approved?

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

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

The marketing authorisation for Fillata was granted on 2017-07-13 in Sweden.

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

This summary was last updated in 2017-09.