

Summary Public Assessment Report

Tadalafil Jubilant tadalafil

SE/H/2061/01-04/DC

Summary Public Assessment Report

Tadalafil Jubilant
tadalafil

Film-coated tablet, 2,5 mg, 5 mg, 10 mg, 20 mg

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

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

What is Tadalafil Jubilant and what is it used for?

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

Tadalafil Jubilant is used in the treatment of erectile dysfunction and in the treatment of signs and symptoms of benign prostatic hyperplasia in adult males.

How does Tadalafil Jubilant work?

Tadalafil Jubilant 2.5 mg, 5 mg, 10 mg and 20 mg

Tadalafil Jubilant tablets contains the active substance Tadalafil Jubilant which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation Tadalafil Jubilant 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 Jubilant will not help you if you do not have erectile dysfunction.

It is important to note that Tadalafil Jubilant does not work if there is no sexual stimulation. The patient and his partner will need to engage in foreplay, just as the patient would if the patient was not taking a medicine for erectile dysfunction.

Tadalafil Jubilant 2.5 mg, 5 mg, 10 mg and 20 mg tablets are treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil Jubilant has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

Tadalafil Jubilant 5 mg only

Tadalafil Jubilant 5 mg tablet is used to treat adult men with 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 Jubilant improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Tadalafil Jubilant has been shown to improve these urinary symptoms as early as 1- 2 weeks after starting treatment

How is Tadalafil Jubilant used?

The pharmaceutical form of Tadalafil Jubilant 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 in Sweden.

What benefits of Tadalafil Jubilant have been shown in studies?

Because Tadalafil Jubilant is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Cialis.

What are the possible side effects from Tadalafil Jubilant?

Because Tadalafil Jubilant is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Tadalafil Jubilant approved?

It was concluded that, in accordance with EU requirements, Tadalafil Jubilant has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Cialis. Therefore, the Swedish Medical Products Agency 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 Jubilant?

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

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

This summary was last updated in 2021-11.