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EPAR summary for the public

Tadalafil Mylan

tadalafil

This is a summary of the European public assessment report (EPAR) for Tadalafil Mylan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tadalafil Mylan.

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

What is Tadalafil Mylan and what is it used for?

Tadalafil Mylan is used to treat men with erectile dysfunction (sometimes called impotence) when they cannot get, or keep, a hard penis (erection) sufficient for satisfactory sexual activity. For Tadalafil Mylan to be effective in this condition, sexual stimulation is required.

Tadalafil Mylan can also be used in men to treat the signs and symptoms of benign prostatic hyperplasia (enlarged prostate gland that is not cancerous), which involve problems with the flow of urine.

Tadalafil Mylan contains the active substance tadalafil. It is a 'generic medicine'. This means that Tadalafil Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Cialis. For more information on generic medicines, see the question-and-answer document here.

How is Tadalafil Mylan used?

For treating erectile dysfunction, the recommended dose of Tadalafil Mylan is 10 mg taken 'on demand' at least 30 minutes before sexual activity. The dose may be increased to 20 mg for men who do not respond to the 10 mg dose. The maximum recommended dosing frequency is once per day, but continuous daily use of 10 or 20 mg Tadalafil Mylan is not recommended. Tadalafil Mylan can be used at a lower dose once a day in men who intend to use it frequently (twice a week or more), based on

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the doctor's judgment. The dose is 5 mg once a day, but can be lowered to 2.5 mg once a day depending on how well it is tolerated. The medicine should be taken around the same time every day and the appropriateness of the once-a-day dosing should be re-assessed regularly.

For treating men with benign prostatic hyperplasia, or men with both benign prostatic hyperplasia and erectile dysfunction, the recommended dose is 5 mg once a day.

Patients with severely impaired liver or kidney function should not take more than 10 mg in one dose. Once-a-day dosing is not recommended in patients with severely impaired kidney function, and should only be prescribed to patients with impaired liver function after a careful evaluation of the benefits and risks of taking the medicine.

Tadalafil Mylan can only be obtained with a prescription.

How does Tadalafil Mylan work?

The active substance of Tadalafil Mylan, tadalafil, belongs to a group of medicines called 'phosphodiesterase type 5 (PDE5) inhibitors'. It works by blocking the phosphodiesterase enzyme, which normally breaks down a substance known as cyclic guanosine monophosphate (cGMP). During normal sexual stimulation, cGMP is produced in the penis, where it causes the muscle in the spongy tissue of the penis (the corpora cavernosa) to relax, allowing the flow of blood into the corpora, producing the erection. Men with erectile dysfunction do not have enough cGMP to produce or maintain an erection. By blocking the breakdown of cGMP, Tadalafil Mylan restores erectile function. However, sexual stimulation is still needed. By blocking the phosphodiesterase enzyme and preventing the breakdown of cGMP, Tadalafil Mylan also improves the blood flow to, and relaxes the muscles of, the prostate and bladder. This may reduce the problems with the flow of urine which are symptoms of benign prostatic hyperplasia.

How has Tadalafil Mylan been studied?

Because Tadalafil Mylan is a generic medicine, studies in people 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 benefits and risks of Tadalafil Mylan?

Because Tadalafil Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Tadalafil Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Tadalafil Mylan has been shown to have comparable quality and to be bioequivalent to Cialis. Therefore, the CHMP's view was that, as for Cialis, the benefit outweighs the identified risk. The Committee recommended that Tadalafil Mylan be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Tadalafil Mylan?

A risk management plan has been developed to ensure that Tadalafil Mylan 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 Mylan, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Tadalafil Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Tadalafil Mylan on 21 November 2014.

The full EPAR and risk management plan summary for Tadalafil Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tadalafil Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 11-2014.