Summary Public Assessment Report

Generics

Tadalafil Sandoz 2.5 mg, 5 mg, 10 mg and 20 mg, film-coated tablets

(tadalafil)

NL/H/3612/001-004/DC

Date: 24 May 2017

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Active substance: tadalafil

This is a summary of the public assessment report (PAR) for Tadalafil Sandoz 2.5 mg, 5 mg, 10 mg and 20 mg, film-coated tablets. It explains how this medicine 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 Sandoz.

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

What is Tadalafil Sandoz and what is it used for?
Tadalafil Sandoz is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Cialis.

This medicine 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 Sandoz to be effective in this condition, sexual stimulation is required.

Tadalafil Sandoz can also be prescribed to treat pulmonary arterial hypertension in adults. This is a rare blood vessel disorder of the lung in which the pressure in the pulmonary artery (the vessel that leads blood from the heart to the lungs) rises above normal levels.

This medicine 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.

How does this medicine work?
The active substance of Tadalafil Sandoz, 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, this medicine restores erectile function. However, sexual stimulation is still needed. By blocking the phosphodiesterase enzyme and preventing the breakdown of cGMP, tadalafil 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 is this medicine used?
The pharmaceutical form of Tadalafil Sandoz is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription.

For treating erectile dysfunction, the recommended dose 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 Sandoz is not recommended.

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.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Tadalafil Sandoz 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 this medicine?
Because Tadalafil Sandoz 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 all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Cialis, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Sandoz, 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 this medicine
In the Netherlands, the marketing authorisation for Tadalafil Sandoz 2.5 mg, 5 mg, 10 mg and 20 mg, film-coated tablets was granted 15 February 2017.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Tadalafil Sandoz, read the package leaflet (https://mri.cts-mrp.eu/Human/Product/Details/49014) or contact your doctor or pharmacist.

This summary was last updated in May 2017.