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EPAR summary for the public

Sildenafil Teva

sildenafil

This is a summary of the European public assessment report (EPAR) for Sildenafil Teva. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Sildenafil Teva.

What is Sildenafil Teva?

Sildenafil Teva is a medicine that contains the active substance sildenafil. It is available as tablets (25, 50 and 100 mg).

Sildenafil Teva is a 'generic medicine'. This means that Sildenafil Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Viagra. For more information on generic medicines, see the question-and-answer document here.

What is Sildenafil Teva used for?

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

The medicine can only be obtained with a prescription.

How is Sildenafil Teva used?

The recommended dose of Sildenafil Teva is 50 mg taken as needed about one hour before sexual activity. If Sildenafil Teva is taken with food, the onset of activity may be delayed compared with taking Sildenafil Teva without food. The dose may be increased to a maximum of 100 mg or decreased to 25 mg depending on the effectiveness and side effects. Patients with liver problems or severe

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kidney problems should start treatment with the 25 mg dose. The maximum recommended dosing frequency is one tablet per day.

How does Sildenafil Teva work?

The active ingredient in Sildenafil Teva, sildenafil, 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. This allows blood to flow into the corpora, producing the erection. By blocking the breakdown of cGMP, Sildenafil Teva restores erectile function. Sexual stimulation is still needed to produce an erection.

How has Sildenafil Teva been studied?

Because Sildenafil Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Viagra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Sildenafil Teva?

Because Sildenafil Teva 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 has Sildenafil Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Sildenafil Teva has been shown to have comparable quality and to be bioequivalent to Viagra. Therefore, the CHMP's view was that, as for Viagra, the benefit outweighs the identified risk. The Committee recommended that Sildenafil Teva be given marketing authorisation.

Other information about Sildenafil Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Sildenafil Teva on 30 November 2009.

The full EPAR for Sildenafil Teva 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 Sildenafil Teva, 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 10-2012.