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EPAR summary for the public

Sildenafil Actavis

sildenafil

This is a summary of the European public assessment report (EPAR) for Sildenafil Actavis. 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 Actavis.

What is Sildenafil Actavis?

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

Sildenafil Actavis is a 'generic medicine'. This means that Sildenafil Actavis 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 Actavis used for?

Sildenafil Actavis 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 Actavis to be effective, sexual stimulation is required.

The medicine can only be obtained with a prescription.

How is Sildenafil Actavis used?

The recommended dose of Sildenafil Actavis is 50 mg taken as needed about one hour before sexual activity. If Sildenafil Actavis is taken with food, the onset of activity may be delayed compared with taking Sildenafil Actavis 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

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

How does Sildenafil Actavis work?

The active ingredient in Sildenafil Actavis, 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 Actavis restores erectile function. Sexual stimulation is still needed to produce an erection.

How has Sildenafil Actavis been studied?

Because Sildenafil Actavis is a generic medicine, studies in people 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 Actavis?

Because Sildenafil Actavis 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 Actavis been approved?

The CHMP concluded that, in accordance with EU requirements, Sildenafil Actavis 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 Actavis be given marketing authorisation.

Other information about Sildenafil Actavis

The European Commission granted a marketing authorisation valid throughout the European Union for Sildenafil Actavis on 10 December 2009.

The full EPAR for Sildenafil Actavis 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 Actavis, 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 08-2014.