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EPAR summary for the public

Sildenafil ratiopahrm

sildenafil

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

What is sildenafil?

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

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

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

The medicine can only be obtained with a prescription.

How is sildenafil used?

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

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liver function or severely reduced kidney function should start treatment with the 25-mg dose. The maximum recommended dosing frequency is one tablet per day.

How does sildenafil work?

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

How has sildenafil been studied?

Because Sildenafil ratiopharm 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?

Because Sildenafil ratiopharm is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has sildenafil been approved?

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

Other information about sildenafil

The European Commission granted a marketing authorisation valid throughout the European Union for Sildenafil ratiopharm on 23 December 2009.

The full EPAR for Sildenafil ratiopharm 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, 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.

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