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EPAR summary for the public

Viagra

sildenafil

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

What is Viagra?

Viagra is a medicine that contains the active substance sildenafil. It is available as tablets (25, 50 or 100 mg) and as orodispersible tablets (50 mg). Orodispersible tablets are tablets that dissolve in the mouth.

What is Viagra used for?

Viagra 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 Viagra to be effective, sexual stimulation is required.

The medicine can only be obtained with a prescription.

How is Viagra used?

The recommended dose of Viagra is 50 mg taken as needed about one hour before sexual activity. If Viagra is taken with food, the onset of activity may be delayed compared with taking it without food. The orodispersible tablets should be placed on the tongue and left to disintegrate before swallowing.

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 kidney problems should start treatment with the 25 mg dose. The maximum recommended dosing frequency is once a day.



How does Viagra work?

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

How has Viagra been studied?

Viagra has been studied in four main studies including 1,690 men aged 19 to 87 years, where it was compared with placebo (a dummy treatment) for between 12 and 26 weeks. Two of these studies used fixed doses (patients allocated to 25, 50 or 100 mg) and two studies were flexible (patients started on 25 mg and could be moved to 50 or 100 mg depending on their response). In addition, there were studies in patients with spinal cord injury and with diabetes. The main measure of effectiveness was based on the ability of the men to get and maintain an erection. This was recorded in a special questionnaire completed at home using a scoring system on a five-point scale, where a score of 5 represents the best result.

What benefit has Viagra shown during the studies?

Viagra was significantly more effective than placebo in all studies. In the questionnaire, scores for the question on how often the patient was able to achieve intercourse went from about 2 without treatment to 3 or 4 with Viagra 50 mg. In the fixed-dose studies, the proportions of patients reporting that treatment improved their erections were 62% (25 mg), 74% (50 mg) and 82% (100 mg), compared with 25% on placebo.

What is the risk associated with Viagra?

The most common side effects with Viagra are headache, flushing, dyspepsia (indigestion), visual disorders, including visual colour distortion and blurred vision, nasal congestion (blocked nose), dizziness, nausea and hot flushes. For the full list of all side effects reported with Viagra, see the package leaflet.

Viagra must not be used where sexual activity is inadvisable (e.g. men with severe heart disease such as unstable angina or severe heart failure). It must also not be taken by patients who have ever had loss of vision because of a problem with blood flow to the nerve in the eye (non-arteritic anterior ischemic optic neuropathy or NAION). Viagra must not be taken with nitrates (medicines used to treat angina) or medicines of the class 'guanylate cyclase stimulators' such as riociguat (used to treat pulmonary hypertension [high blood pressure in the lungs]). Because Viagra has not been studied in patients with severe liver disease, hypotension (low blood pressure), recent stroke or myocardial infarction (heart attack), or a hereditary eye disease, such as retinitis pigmentosa, these patients must not use it. For the full list of restrictions, see the package leaflet.

Why has Viagra been approved?

The CHMP decided that Viagra's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Viagra

The European Commission granted a marketing authorisation valid throughout the European Union for Viagra on 14 September 1998.

The full EPAR for Viagra can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Viagra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.