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EPAR summary for the public

Vivanza vardenafil

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

What is Vivanza?

Vivanza is a medicine that contains the active substance vardenafil. It is available as film-coated tablets (5, 10 and 20 mg) and as orodispersible tablets (10 mg). Orodispersible tablets are tablets that dissolve in the mouth.

What is Vivanza used for?

Vivanza 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 Vivanza to be effective, sexual stimulation is required.

The medicine can only be obtained with a prescription.

How is Vivanza used?

The recommended dose of Vivanza is 10 mg, taken by mouth with or without food, about 25 to 60 minutes before sexual activity; patients should not take more than one dose a day. The orodispersible tablets must be taken without liquid. If Vivanza is taken with a high fat meal, the onset of activity may be delayed. The dose may be increased to a maximum of 20 mg or decreased to 5 mg depending on the effectiveness and side effects. Patients with liver problems or severe kidney problems should start treatment on the 5 mg dose.

The dose may need to be adjusted in patients taking other medicines that block enzymes that break down Vivanza. For full details, see the package leaflet.



How does Vivanza work?

The active ingredient of Vivanza, vardenafil, 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, Vivanza restores erectile function. Sexual stimulation is still needed to produce an erection.

How has Vivanza been studied?

Vivanza film-coated tablets have been compared with placebo (a dummy treatment) in four main studies including 2,431 men aged 20 to 83 years. One study was carried out in diabetic men and another in men who had had their prostate gland removed. Two additional main studies compared orodispersible tablets with placebo in 701 men aged 21 to 84 years.

The main measure of effectiveness was the ability to get and maintain an erection. This was recorded in two questionnaires completed at home.

What benefit has Vivanza shown during the studies?

Vivanza was significantly more effective than placebo for all measures in all studies.

What is the risk associated with Vivanza?

The most common side effect with Vivanza (seen in more than 1 patient in 10) is headache. For the full list of all side effects reported with Vivanza, see the package leaflet.

Vivanza must not be used in people who are hypersensitive (allergic) to vardenafil or any of the other ingredients. It must not be used when sexual activity is inadvisable, such as in men with severe heart disease. 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). Vivanza must not be taken with nitrates (medicines used to treat angina).

Because Vivanza has not been studied in the following groups of patients, they must not use the medicine:

- patients with severe liver disease or end-stage kidney disease requiring dialysis;
- patients who have hypotension (low blood pressure);
- patients who have had a stroke or a heart attack within the last six months;
- patients with unstable angina or hereditary eye problems known as 'retinal degenerative disorders'.

Vivanza must not be taken with some medicines, such as ketoconazole and itraconazole (to treat fungal infections) in men over 75 years, or medicines called 'HIV protease inhibitors' such as ritonavir or indinavir (to treat HIV infection).

In addition, Vivanza must not be taken with medicines known as guanylate cyclase stimulators, including riociguat (used to treat pulmonary hypertension [high blood pressure in the lungs]).

Why has Vivanza been approved?

The CHMP decided that Vivanza'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 Vivanza?

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

Other information about Vivanza

The European Commission granted a marketing authorisation valid throughout the European Union for Vivanza on 4 March 2003.

The full EPAR for Vivanza can be found on the Agency's website: [ema.europa.eu/Find_medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports). For more information about treatment with Vivanza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.