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EPAR summary for the public

Spedra

avanafil

This is a summary of the European public assessment report (EPAR) for Spedra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Spedra.

For practical information about using Spedra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Spedra and what is it used for?

Spedra is a medicine 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 Spedra to be effective, sexual stimulation is required.

Spedra contains the active substance avanafil.

How is Spedra used?

Spedra is available as tablets (50, 100 and 200 mg) and can only be obtained with a prescription. The recommended dose is 100 mg, taken approximately 15 to 30 minutes before sexual activity; patients should not take more than one dose a day. Spedra may be taken with or without food. If it is taken with food, it may take longer to work. The dose may be adjusted if necessary; lower doses may be needed in patients with liver problems or who are taking certain other medicines.

For further information, see the package leaflet.

How does Spedra work?

The active ingredient in Spedra, avanafil, 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

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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, Spedra enhances its effect on erectile function. Sexual stimulation is still needed to produce an erection.

What benefits of Spedra have been shown in studies?

Spedra has been studied in three main studies involving over 3,400 men with erectile dysfunction. The first study involved men from the general population, but because certain conditions associated with erectile dysfunction might affect response to treatment the second study looked mainly at men who had erectile dysfunction and diabetes, and the third was in men who had erectile dysfunction after surgery on the prostate gland. In these studies, which lasted for 12 weeks, different doses of Spedra taken approximately 30 minutes before sexual activity were compared with placebo (a dummy tablet). The main measures of effectiveness in all three studies were the percentage of erections that lasted long enough for successful intercourse, the percentage of successful vaginal penetrations, and the change in an assessment score for erectile function.

Spedra was more effective than placebo in all studies. The results of the first study showed that Spedra taken approximately 30 minutes before sexual activity at a dose of 100 or 200 mg increased the percentage of successful attempts at intercourse from about 13% before treatment to about 57%, whereas placebo only increased it to 27%. The medicine also produced about 20% more successful vaginal penetrations than placebo. The improvement in assessment score was about 5 to 7 points more than with placebo.

An additional study involving 440 adults with erectile dysfunction was also carried out, where Spedra was taken approximately 15 minutes before sexual activity. The percentage of successful attempts was about 28% with Spedra at a dose of 200 mg and about 25% with a dose of 100 mg, compared with 14% with placebo.

What are the risks associated with Spedra?

The most common side effects with Spedra (which may affect up to 1 in 10 people) are headache, flushing (reddening of the skin) and nasal congestion; back pain has also been reported and may affect up to 1 in 100 people. For the full list of all side effects reported with Spedra, see the package leaflet.

Doctors should consider the potential risks of sexual activity for the heart in men who have heart disease before prescribing Spedra. The medicine must not be used by patients with certain serious heart or circulatory problems, including those who have had a heart attack, stroke, or serious arrhythmia (irregularity of the heart rhythm) in the last six months and those who have unstable angina (a severe type of chest pain), angina during sexual intercourse, heart failure, or high or low blood pressure. It must also not be used by patients who have severely reduced liver or kidney function, or who have had loss of vision because of a problem with blood flow to the nerve in the eye (non-arteritic anterior ischaemic optic neuropathy, NAION) that can be triggered by this class of medicines.

Spedra must not be taken with certain other medicines including nitrates (a type of medicine used for angina) or medicines that strongly reduce the breakdown of Spedra in the body. For the full list of restrictions, see the package leaflet.

Why is Spedra approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that Spedra was more effective than placebo in allowing successful intercourse. However, the fact that it was not compared directly with other medicines in its class made it hard to evaluate its potential place in treating erectile dysfunction. Regarding its safety, side effects were similar to other medicines of its class. The Committee therefore considered that Spedra's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Spedra

The European Commission granted a marketing authorisation valid throughout the European Union for Spedra on 21 June 2013.

The full EPAR for Spedra 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 Spedra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2015.