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EPAR summary for the public

Cialis

tadalafil

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

What is Cialis?

Cialis is a medicine containing the active substance tadalafil. It is available as tablets (2.5, 5, 10 and 20 mg).

What is Cialis used for?

Cialis is used to treat men with erectile dysfunction (sometimes called impotence) when they cannot get, or keep, a hard penis (erection) sufficient for satisfactory sexual activity. For Cialis to be effective in this condition, sexual stimulation is required.

Cialis can also be used in men to treat the signs and symptoms of benign prostatic hyperplasia (enlarged prostate gland that is not cancerous), which involve problems with the flow of urine.

The medicine can only be obtained with a prescription.

How is Cialis used?

For treating erectile dysfunction, the recommended dose of Cialis is 10 mg taken 'on demand' at least 30 minutes before sexual activity. The dose may be increased to 20 mg for men who do not respond to the 10 mg dose. The maximum recommended dosing frequency is once per day, but continuous daily use of 10 or 20 mg Cialis is not recommended. Cialis can be used at a lower dose once a day in men who intend to use it frequently (twice a week or more), based on the doctor's judgement. The dose is 5 mg once a day, but can be lowered to 2.5 mg once a day depending on how well it is tolerated. The



medicine should be taken around the same time every day and the appropriateness of the once-a-day dosing should be re-assessed regularly.

For treating men with benign prostatic hyperplasia, or men with both benign prostatic hyperplasia and erectile dysfunction, the recommended dose is 5 mg once a day.

Patients with severe liver problems or kidney problems should not take more than 10 mg in one dose. Once-a-day dosing is not recommended in patients with severe kidney problems, and should only be prescribed to patients with liver problems after a careful evaluation of the benefits and risks of taking the medicine.

How does Cialis work?

The active substance of Cialis, tadalafil, 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, Cialis restores erectile function. However, sexual stimulation is still needed. By blocking the phosphodiesterase enzyme and preventing the breakdown of cGMP, Cialis also improves the blood flow to, and relaxes the muscles of, the prostate and bladder. This may reduce the problems with the flow of urine which are symptoms of benign prostatic hyperplasia.

How has Cialis been studied?

Cialis, when taken 'on demand' before sexual activity, has been studied in six main studies including 1,328 patients with erectile dysfunction. One of these studies contained only diabetic men. Once-a-day dosing of Cialis was studied in three further studies lasting 12 to 24 weeks and involving a total of 853 patients. In all studies, the effects of Cialis were compared with those of placebo (a dummy treatment), and the main measure of effectiveness was the ability to get and maintain an erection. This was recorded in two questionnaires completed at home.

Cialis has also been studied in patients with benign prostatic hyperplasia. Four main studies comparing Cialis with placebo were carried out in 1,500 patients with the condition, including some who also had erectile dysfunction. The main measure of effectiveness was the improvement in symptoms after 12 weeks.

What benefit has Cialis shown during the studies?

Cialis was significantly more effective than placebo in all studies in erectile dysfunction. For one of the questionnaires, where the maximum score is 30, patients who recorded scores of about 15 before treatment, recorded scores of 22.6 or 25 after receiving Cialis 10 mg or 20 mg, respectively. Overall, in the studies of general populations, 81% of patients reported that Cialis 'on demand' improved their erections as compared to 35% of those taking placebo. Patients taking Cialis once a day at doses of 2.5 or 5 mg also reported improved erections compared with those taking placebo.

Cialis given at a dose of 5 mg was also more effective than placebo in all the studies in patients with benign prostatic hyperplasia, with the results showing a significant improvement in symptoms after 12 weeks compared with placebo.

What is the risk associated with Cialis?

The most common side effects with Cialis are headache, dyspepsia (indigestion), back pain and myalgia (muscle pain), which are more common at higher doses. For the full list of all side effects reported with Cialis, see the package leaflet.

Cialis must not be used where sexual activity is inadvisable (e.g. in men with 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, NAION). Cialis must not be taken with nitrates (a type of medicine used for angina) or medicines of the class 'guanylate cyclase stimulators' such as riociguat (a medicine for high blood pressure in the vessels supplying the lungs, known as pulmonary hypertension). A doctor should consider the potential risks of sexual activity in men who have cardiovascular disease. Because Cialis has not been studied in patients who have had a heart attack within the last three months or a stroke within the last six months, or those who have high blood pressure or heart disorders (irregular heart beat), these men should not use the medicine. For the full list of restrictions, see the package leaflet.

Why has Cialis been approved?

The CHMP decided that Cialis'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 Cialis?

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

Other information about Cialis

The European Commission granted a marketing authorisation valid throughout the European Union for Cialis on 12 November 2002.

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

This summary was last updated in 07-2015.