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## EPAR summary for the public

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# Tadalafil Lilly

tadalafil

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

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

## What is Tadalafil Lilly and what is it used for?

Tadalafil Lilly is a medicine used to treat men with erectile dysfunction (sometimes called impotence).

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

Tadalafil Lilly contains the active substance tadalafil and is the same as Cialis, which is already authorised in the European Union (EU). The company that makes Cialis has agreed that its scientific data can be used for Tadalafil Lilly ('informed consent').

## How is Tadalafil Lilly used?

Tadalafil Lilly is available as tablets (2.5, 5, 10 and 20 mg) to be taken by mouth. For erectile dysfunction, the usual dose is 10 mg at least 30 minutes before sexual activity. The dose may be increased to 20 mg if the 10 mg dose is not effective. Men who intend to use Tadalafil Lilly frequently (twice a week or more) can take a lower dose (5 or 2.5 mg) once a day, based on the doctor's judgement. The medicine should be taken around the same time every day and the need for the once-a-day dosing should be assessed regularly.

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

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

## How does Tadalafil Lilly work?

The active substance of Tadalafil Lilly, 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, Tadalafil Lilly restores erectile function during sexual stimulation and 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.

## What benefits of Tadalafil Lilly have been shown in studies?

Tadalafil Lilly has been shown to improve the ability to get and maintain an erection in nine main studies involving over 2,000 men with erectile dysfunction. All the studies compared Tadalafil Lilly with placebo (a dummy treatment) and measured improvements using questionnaires completed before and after treatment.

Six of the studies included 1,328 patients who took the medicine before sexual activity. Results for one of the questionnaires, in which men rated their condition on a scale of 0 (indicating severe erectile dysfunction) to 30 (no erectile dysfunction), showed that patients improved from about 15 before treatment, to 23 and 25 after treatment with Tadalafil Lilly 10 and 20 mg, respectively. The other three studies included 853 patients taking Tadalafil Lilly once a day at doses of 2.5 or 5 mg. Results also reported improved erections with Tadalafil Lilly compared with those taking placebo.

Tadalafil Lilly has also been shown to improve the symptoms of benign prostatic hyperplasia as measured using the international prostate symptom score (IPSS), which ranges from 0 (no symptoms) to 35 (severe symptoms). In four main studies involving 1,500 patients, some of whom also had erectile dysfunction, patients taking Tadalafil Lilly at a dose of 5 mg had greater reductions in IPSS (4.8 to 6.3 points) after 12 weeks than those taking placebo (2.2 to 4.4 points).

## What are the risks associated with Tadalafil Lilly?

The most common side effects with Tadalafil Lilly are headache, indigestion, back pain and muscle pain, which are more common at higher doses. For the full list of all side effects with Tadalafil Lilly, see the package leaflet.

Tadalafil Lilly must not be used in men with certain cardiovascular (heart and blood vessel) conditions or when sexual activity is inadvisable. It must also not be taken by patients who have ever had loss of vision in one eye because of a problem with blood flow to the nerve in the eye (non-arteritic anterior ischemic optic neuropathy, NAION). Tadalafil Lilly 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). For the full list of restrictions, see the package leaflet.

## Why is Tadalafil Lilly approved?

As shown in studies, Tadalafil Lilly is effective at improving the ability to get and maintain erections and at relieving the symptoms of benign prostatic hyperplasia. The side effects seen with the medicine are considered manageable. The Agency's Committee for Medicinal Products for Human Use (CHMP)

therefore concluded that Tadalafil Lilly'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 Tadalafil Lilly?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tadalafil Lilly have been included in the summary of product characteristics and the package leaflet.

### **Other information about Tadalafil Lilly**

The European Commission granted a marketing authorisation valid throughout the European Union for Tadalafil Lilly on 22 March 2017

The full EPAR for Tadalafil Lilly 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%20medicines/European%20public%20assessment%20reports). For more information about treatment with Tadalafil Lilly, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2017.