EMA/43198/2016
EMEA/H/C/000475

**EPAR summary for the public**

# Levitra

vardenafil

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

## What is Levitra?

Levitra 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 Levitra used for?

Levitra is used to treat adult men (aged 18 years or over) with erectile dysfunction (sometimes called impotence), when they cannot get or keep a hard penis (erection) sufficient for satisfactory sexual activity. For Levitra to be effective, sexual stimulation is required.

The medicine can only be obtained with a prescription.

## How is Levitra used?

The recommended dose of Levitra is 10 mg, taken about 25 to 60 minutes before sexual activity. The orodispersible tablets must be taken without liquid. If Levitra film-coated tablets are taken with a high fat meal, the onset of activity may be delayed. The dose of the film-coated tablets may be increased to a maximum of 20 mg or decreased to 5 mg, depending on the effectiveness of treatment and any side effects.

A starting dose of 5 mg should be considered for patients with mild and moderate liver problems or severe kidney problems. The dose may need to be adjusted in patients taking other medicines that block enzymes that break down Levitra. For full details, see the package leaflet.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

The maximum recommended dosing frequency is one film-coated tablet or orodispersible tablet per day.

## How does Levitra work?

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

## How has Levitra been studied?

Levitra tablets were compared with placebo (a dummy treatment) in four main studies including a total of 2,431 men with erectile dysfunction aged 20 to 83 years. One of these studies 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

In all of the studies, the main measure of effectiveness was the ability to get and maintain an erection. This was recorded in two questionnaires completed at home. The studies lasted 12 weeks.

## What benefit has Levitra shown during the studies?

Levitra tablets and orodispersible tablets were significantly more effective than placebo for all measures in all of the studies.

## What is the risk associated with Levitra?

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

Levitra 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 used in 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). Levitra must not be taken with nitrates (medicines used to treat angina).

Because Levitra has not been studied in the following group 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 and hereditary eye problems known as ‘retinal degenerative disorders’.

Levitra must not be taken with ketoconazole and itraconazole (used to treat fungal infections) in men over 75 years of age, or with medicines called ‘HIV protease inhibitors’ such as ritonavir or indinavir (used to treat HIV infection).

In addition, Levitra 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 Levitra been approved?

The CHMP decided that Levitra'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 Levitra?

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

## Other information about Levitra:

The European Commission granted a marketing authorisation valid throughout the European Union for Levitra on 6 March 2003.

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

This summary was last updated in 01-2016.