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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



PACKAGE LEAFLET: INFORMATION FOR THE USER

Levitra 5 mg film-coated tablets Vardenafil

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Levitra is and what it is used for
2. Before you take Levitra
3. How to take Levitra
4. Possible side effects
5. How to store Levitra
6. Further information

1. WHAT LEVITRA IS AND WHAT IT IS USED FOR

Levitra belongs to a group of medicines which are used to treat difficulties in getting or keeping an erection (erectile dysfunction).

About erection difficulties

At least one in ten men has trouble getting or keeping an erection at some time. There may be physical or psychological causes, or a mixture of both. Whatever the cause is, due to muscle and blood vessel changes not enough blood stays in the penis to make it hard and keep it hard.

How Levitra works

Levitra will only work when you are sexually stimulated. It reduces the action of the natural chemical in your body which makes erections go away. LEVITRA allows an erection to last long enough for you to satisfactorily complete sexual activity.

2. BEFORE YOU TAKE LEVITRA

Do not take Levitra

- If you are allergic (hypersensitive) to vardenafil or any of the other ingredients of Levitra. See the ingredients in section 6. Signs of an allergic reaction include a rash, itching, swollen face or lips and shortness of breath.
- If you are taking medicines containing nitrates, such as glycerol trinitrate for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Levitra could seriously affect your blood pressure.
- If you are taking ritonavir or indinavir, medicines for HIV.
- If you are over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines
- If you have a severe heart or liver problem
- If you are having kidney dialysis
- If you have recently had a stroke or heart attack
- If you have or have had low blood pressure
- If your family has a history of degenerative eye diseases (such as *retinitis pigmentosa*)
- If you have ever had a condition involving loss of vision due to damage to the optic nerve from insufficient blood supply known as non-arteritic ischemic optic neuropathy (NAION)

Take special care with Levitra

- If you have heart trouble. It may be risky for you to have sex
- If you suffer from irregular heart beat (cardiac arrhythmia) or inherited heart diseases affecting your electrocardiogram
- If you have a physical condition affecting the shape of the penis. This includes conditions called *angulation*, *Peyronie's disease* and *cavernosal fibrosis*
- If you have an illness that can cause erections which won't go away (*priapism*). These include *sickle cell disease*, *multiple myeloma* and *leukaemia*
- If you have stomach ulcers (also called *gastric* or *peptic* ulcers)
- If you have a bleeding disorder (such as *haemophilia*)
- If you are using any other treatments for erection difficulties
- If you experience sudden decrease or loss of vision, stop taking Levitra and contact your doctor immediately.

Levitra is for men of 18 years and over

It is not intended for use by women, children or men under 18.

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Levitra will usually be fine with most medicines. But some may cause problems, especially these:

- Nitrates, medicines for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Levitra could seriously affect your blood pressure. *Talk to a doctor without taking Levitra*
- Medicine for the treatment of arrhythmias, such as quinidine, procainamide, amiodarone or sotalol
- Ritonavir or indinavir, medicines for HIV. *Talk to a doctor without taking Levitra*
- Ketoconazole or itraconazole, anti-fungal medicines
- Erythromycin or clarithromycin, macrolide antibiotics
- Alpha-blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate (as benign prostatic hyperplasia)

Taking Levitra with food and drink

- You can take Levitra with or without food – but preferably not after a heavy or high-fat meal as this may delay the effect.
- Don't drink grapefruit juice when you use Levitra. It can interfere with the usual effect of the medicine.
- Alcoholic drink can make erection difficulties worse.

Pregnancy and breast-feeding

Levitra is not for use by women.

Driving and using machines

Levitra might make some people feel dizzy or affect their vision. If you feel dizzy, or if your vision is affected after taking Levitra don't drive or operate any tools or machines.

3. HOW TO TAKE LEVITRA

Always take Levitra exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 10 mg.

Take a Levitra tablet about 25 to 60 minutes before sexual activity. With sexual stimulation you may achieve an erection anywhere from 25 minutes up to four to five hours after taking Levitra.

- Swallow one tablet with a glass of water
- Don't use Levitra more than once a day.

Tell the doctor if you think Levitra is too strong or too weak. He or she may suggest a different dose, depending on how well it works for you.

If you take more Levitra than you should

Men who take too much Levitra may experience more side effects or may get severe back pain. If you take more Levitra than you should, tell your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Levitra can cause side effects, although not everybody gets them. Most of the effects are mild or moderate. The chance of having a side effect is described by the following categories:

Very common (*affects more than 1 user in 10*)

- Headache

- Flushing

Common (*affects 1 to 10 users in 100*)

- Indigestion
- Feeling sick (*nausea*)
- Dizziness
- Blocked or runny nose

Uncommon (*affects 1 to 10 users in 1,000*)

- Sensitivity of the skin to sunlight
- High or low blood pressure
- Back or muscle pain
- Effects on vision
- Bloodshot or watery eyes
- Rash
- Sleepiness
- Effect in results of blood tests to check liver function
- Increase in blood of a muscle enzyme (creatine phosphokinase)
- Breathlessness
- Fast heart beat or pounding heart
- Nose bleeds
- Facial swelling

Rare (*affects 1 to 10 users in 10,000*)

- Fainting
- Muscle stiffness
- Increase pressure in the eye (glaucoma)
- Prolonged or painful erections
- Allergic reaction
- Effects on the heart (such as angina)
- Anxiety
- Swelling inside the throat
- Temporary loss of memory (such as transient global amnesia)
- Seizure

Partial, sudden, temporary or permanent decrease or loss of vision in one or both eyes has been experienced by patients.

Sudden decrease or loss of hearing has been reported.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE LEVITRA

Keep out of the reach and sight of children.

Do not use Levitra after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Levitra contains

- The active substance is vardenafil. Each tablet contains 5 mg of vardenafil (as hydrochloride trihydrate).
- The other ingredients of the tablets are:
Tablet core: crospovidone, magnesium stearate, microcrystalline cellulose, colloidal anhydrous silica.
Film coat: macrogol 400, hypromellose, titanium dioxide (E171), ferric oxide yellow (E172), ferric oxide red (E172).

What Levitra looks like and contents of the pack

Levitra 5 mg film-coated tablets are orange with the BAYER cross on one side and the strength (5) on the other side. The tablets are provided in blister packs containing 2, 4, 8 or 12 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Bayer Schering Pharma AG, 13342 Berlin, Germany.

Manufacturer: Bayer Schering Pharma AG, 51368 Leverkusen, Germany.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved in June 2009

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu>.