

## PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking LEVITRA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LEVITRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**SCHEDULING STATUS:**

**S4**

**NAME OF THE MEDICINAL PRODUCT:**

**LEVITRA 5  
LEVITRA 10  
LEVITRA 20  
LEVITRA ODT 10**

Tablets

### 1. WHAT LEVITRA CONTAINS:

- The active substance for LEVITRA film-coated tablets is vardenafil monohydrochloride trihydrate equivalent to 5 mg, 10 mg or 20 mg vardenafil.
- The other ingredients are crospovidone, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide (anhydrous), macrogol 400, hypromellose, titanium dioxide, ferric oxide yellow, ferric oxide red.
- The active substance for LEVITRA ODT 10 is vardenafil monohydrochloride trihydrate equivalent to 10 mg vardenafil.
- The other ingredients are aspartame, flavour peppermint, magnesium stearate, crospovidone, mannitol, silica colloidal hydrated and sorbitol.

### 2. WHAT LEVITRA IS USED FOR:

LEVITRA is prescribed for the treatment of erectile dysfunction in men. This is a condition where men have difficulties in achieving a penile erection hard enough for successful penetrative sex.

### 3. BEFORE YOU USE LEVITRA:

Your doctor should consider your cardiovascular status, since there is a degree of heart risk associated with sexual activity.

LEVITRA should not be used in men for whom sexual activity is not recommendable because of their underlying cardiovascular status. If sexual activity is not recommended for you due to some underlying heart condition, do not take LEVITRA.

#### **Elderly (above 65 years):**

Dosage adjustments are not required in elderly patients.

#### **Children:**

LEVITRA should not be given to children.

#### **Hepatic impairment:**

Patients with mild liver impairment can take any recommended dose of LEVITRA, dose adjustment is not necessary. Patients suffering from moderate liver impairment will require a starting dose of 5 mg, which may subsequently be increased to 10 mg by their doctor.

Patients suffering from moderate liver impairment should not take LEVITRA ODT 10. Patients suffering from severe liver impairment are not advised to use LEVITRA.

### **Renal impairment:**

Patients suffering with only moderate kidney impairment can take any of the recommended dosages of LEVITRA.

The pharmacokinetics of vardenafil has not been studied in patients requiring dialysis of the kidneys.

### **3.1 Do not take LEVITRA:**

- If you are hypersensitive (allergic) to vardenafil or any of the other ingredients of LEVITRA (see "What LEVITRA contains").
- If you are concomitantly treated with nitrates or nitric oxide donors.
- If you are suffering from end-stage kidney disease requiring dialysis.
- If you are a woman or a child.
- If you are suffering from sickle cell anaemia, multiple myeloma or leukaemia.
- If you have anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease).
- If you are suffering from hypotension or low blood pressure (resting systolic blood pressure of < 90 mmHg).
- If you are suffering from uncontrolled hypertension or high blood pressure (> 170/110 mmHg).
- If you have a recent history of stroke, life-threatening irregular heart rhythm or heart attack (within last 6 months).
- If you are suffering from uncontrolled cardiac (heart) failure.
- If you suffer from unstable angina (chest pains as a result of lack of oxygen supply to the heart muscles).
- If there is a known hereditary (family related) degenerative eye disorders such as progressive degeneration of the retina.
- If you suffer from bleeding disorders.
- If you suffer from active peptic ulcers.
- If you suffer from severe impairment of liver function.
- If you are currently taking the HIV protease inhibitors indinavir and ritonavir.

In addition to the above, do not take LEVITRA ODT 10 if:

- You suffer from moderate liver impairment.
- You have phenylketonuria.
- You have hereditary problems of fructose intolerance.

If you are not at all sure, please consult your doctor.

### **3.2 Take special care with LEVITRA:**

Some loss of vision or blindness that is irreversible has been reported with some medication similar to LEVITRA. Should this occur, please consult your doctor immediately.

There have been reports of prolonged erections greater than 4 hours and priapism (painful erections greater than 6 hours in duration) for this class of medicines. In the event that your erection persists longer than 4 hours, you should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

Patients taking Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic medications or those with congenital QT prolongation, should avoid using LEVITRA.

The concomitant use of LEVITRA with alpha-blockers (for hypertension) may lead to symptomatic hypotension in some patients. If you are on alpha-blockers treatment such as doxazosin, prazosin, phentolamine, etc, consult your doctor.

A sudden decrease or loss of hearing in one or both ears, with or without ringing in the ears and dizziness has been reported. You should contact your doctor as soon as you become aware of the hearing loss.

### **3.3 Taking LEVITRA with food and drink:**

LEVITRA can be taken with or without food.

### **3.4 Pregnancy and breastfeeding:**

LEVITRA is not indicated for use by women.

### **3.5 Driving and using machinery:**

Exercise caution when driving, as dizziness and abnormal vision or eye disorder were reported in clinical trials with LEVITRA.

Exercise caution when operating hazardous machinery or performing hazardous tasks.

### **3.6 Taking other medicines with LEVITRA:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LEVITRA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

The safety and efficacy of combinations of LEVITRA with other treatments for erectile dysfunction have not been studied, therefore, do not take LEVITRA in combinations with other erectile dysfunction medicines, unless if it is directed by your doctor.

Medicines for treatment of fungal infections such as ketoconazole, itraconazole, and medicines for HIV treatment such as indinavir and ritonavir can increase the effects of LEVITRA.

Your doctor may reduce your dose if you are taking medicines for infections such as ketoconazole, itraconazole, erythromycin and clarithromycin.

Do not take LEVITRA when using HIV protease inhibitors like indinavir or ritonavir.

If you are taking alpha-blockers treatment, discuss with your doctor before taking LEVITRA ODT 10 (see "Take special care with LEVITRA").

## **4. HOW TO TAKE LEVITRA:**

Always take LEVITRA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take LEVITRA by mouth.

LEVITRA ODT 10 is placed on the tongue and dissolves in the mouth in the presence of saliva. It should be taken immediately after release from the blister. It should be taken by itself without food or liquid in the mouth.

The recommended daily dose range is 5 mg, or 10 mg, or 20 mg per day. The recommended starting dose of LEVITRA is 10 mg. Based on efficacy and tolerability; your dose may be increased to 20 mg or decreased to 5 mg. The maximum recommended dose is 20 mg once daily.

Take LEVITRA as needed (approximately one hour) before sexual activity.

However, you can take LEVITRA anytime from 25 minutes to at least up to 4 to 5 hours before sexual activity.

Do not take more than one (1) tablet of LEVITRA per day.

LEVITRA will not give you an instant erection; you will require sexual stimulation, either visual or physical, for an erection to occur after taking LEVITRA.

LEVITRA offers no protection against sexually transmitted diseases.

If you have the impression that the effect of LEVITRA is too strong or too weak, talk to your doctor or pharmacist.

#### **4.1 If you take more LEVITRA than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

You may experience severe back pain if you have taken an overdose of LEVITRA.

In cases of overdose, your doctor or paramedics will take standard supportive measures as dictated by your clinical status.

#### **5. POSSIBLE SIDE EFFECTS:**

LEVITRA can have side effects. Please refer to the following possible side effects which you may experience during treatment with LEVITRA:

If you experience sudden loss of vision while taking LEVITRA, you should stop treatment immediately and consult your doctor.

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

- headache

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

- dizziness
- flushing (vasodilation)
- blocked or runny nose
- indigestion (dyspepsia)

##### **Uncommon (affects 1 to 10 users in 1000):**

- swelling of the skin and mucous tissue including swollen face, lips or throat
- sleep disorder
- "pins and needles" and unpleasant sensation (paresthesia and dyesthesia), sleepiness
- visual disturbances, redness of eyes or watery eyes (ocular hyperemia), sensitivity to light, color distortion, eye pain and discomfort
- tinnitus, vertigo
- palpitation, rapid heart rate (tachycardia)
- breathlessness (dyspnea), stuffy nose (sinus congestion)
- nausea, stomach and abdominal pain, dry mouth, diarrhoea, acid reflux, gastritis, vomiting
- increase in protein enzymes (transaminases)
- inflammatory skin redness (erythema), rash
- back pain, increase in the enzyme creatine phosphokinase, increased muscle tone and cramping, muscle pain (myalgia)
- increase in erection
- feeling unwell

##### **Rare (affects 1 to 10 users in 10 000):**

- conjunctivitis
- allergic reaction
- fainting (syncope) loss of memory (amnesia), seizure
- increase in eye pressure (glaucoma)
- effects on the heart such as angina pectoris, heart attack (myocardial infarction), abnormal rapid heart rhythm that originates in the ventricles (ventricular tachyarrhythmias)
- low blood pressure
- prolonged and painful erection (priapism)

- chest pain

**Unknown frequencies:**

- partial, sudden, temporary, or permanent loss in vision in one or both eyes
- sudden decrease or loss of hearing

Not all side effects reported for LEVITRA are included in this leaflet. Should your general health worsen while taking LEVITRA, please consult your doctor, pharmacist or other health-care professional for advice.

**6. STORING AND DISPOSING OF LEVITRA:**

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Store LEVITRA below 25 °C (room temperature), in a dry place.

Store in the manufacturer's original container.

Do not use after the expiry date stated on the blister or carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**7. PRESENTATION OF LEVITRA:**

LEVITRA tablets: They come in polypropylene (clear/opaque)/Alu or Alu/Alu blister packs of 2, 4 or 12 tablets.

LEVITRA ODT 10: They come in Alu/Alu blisters packs of 1, 2 or 4 orodispersible tablets.

**8. IDENTIFICATION OF LEVITRA:**

LEVITRA 5: Orange (light-orange to grey-orange) film-coated round tablet. One side is embossed "BAYER" and the other "5".

LEVITRA 10: Orange (light-orange to grey-orange) film-coated round tablet. One side is embossed "BAYER" and the other "10".

LEVITRA 20: Orange (light-orange to grey-orange) film-coated round tablet. One side is embossed "BAYER" and the other "20".

LEVITRA ODT 10: White uncoated tablet, round, biconvex without tablet markings.

**9. REGISTRATION NUMBERS:**

LEVITRA 5 36/7.1.5/0515

LEVITRA 10 36/7.1.5/0516

LEVITRA 20 36/7.1.5/0517

LEVITRA ODT 10 44/7.1.5/1049

**10. NAME AND ADDRESS OF REGISTRATION HOLDER:**

Bayer (Pty) Ltd  
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27 Wrench Road  
ISANDO  
1609

**11. DATE OF PUBLICATION OF THIS LEAFLET:**

26 October 2012