

LEVITRA® 5 (La·vee·trah)

LEVITRA® 10 (La·vee·trah)

LEVITRA® 20 (La·vee·trah)

varденафил

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Levitra. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Levitra against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT LEVITRA IS USED FOR

This medicine is used to treat erectile dysfunction.

Erectile dysfunction, also known as impotence in adult males, is the inability to obtain and/or maintain a hard erect penis sufficient for sexual activity.

Levitra tablet contains the active ingredient **varденафил** which works by relaxing the blood vessels in the penis when you are sexually aroused. This allows blood to flow into the penis, allowing you to get an erection.

Levitra will only work if you are sexually aroused. It will not increase your sex drive.

Levitra is not addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE LEVITRA

When you must not take it

Do not take Levitra if you have an allergy to:

- any medicine containing vardenafil hydrochloride trihydrate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Levitra if you are taking nitrate medicines which include:

- glyceryl trinitrate (also called nitroglycerine)
- nicorandil
- sodium nitroprusside

- isosorbide mononitrate
- isosorbide dinitrate
- amyl nitrite (also known as ‘poppers’, ‘amyl’ or ‘rush’)

Do not take Levitra if you are taking:

- HIV protease inhibitors, medicines used to treat HIV infection. Examples of HIV protease inhibitors are cobicistat, indinavir or ritonavir.
- Riociguat, used to treat a disease called pulmonary arterial hypertension.

Because sexual activity may place a strain on your heart, your doctor will need to check whether you are fit enough to have sexual intercourse.

Do not take Levitra if you have:

- unstable angina (chest pain)
- hypotension (low blood pressure)
- uncontrolled hypertension (high blood pressure)
- uncontrolled arrhythmia (irregular heart beat)
- ever had a condition involving loss of vision due to damage to the optic nerve from insufficient blood supply known as non-arteritic anterior optic neuropathy (NAION)
- hereditary degenerative retinal disorders (such as retinitis pigmentosa)
- severe liver problems
- severe kidney problems requiring dialysis

- been diagnosed with a disease called pulmonary arterial hypertension

Do not take Levitra if you have, or have had, any of the following conditions within the previous 6 months:

- myocardial infarction (heart attack)
- stroke
- cardiac ischaemia
- serious arrhythmia (irregular heart beat)

Do not give Levitra to children, adolescents or women.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal. The EXPIRY date is marked on the strip of tablets as well as on the label of the carton. For example, 11 18 refers to the eleventh month of 2018.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any heart or blood vessel problems
- leukaemia (cancer of the blood cells)
- multiple myeloma (a cancer of the bone marrow)
- any disease or deformity of your penis
- low or high blood pressure
- sickle cell anaemia
- bleeding disorders
- active stomach ulcer
- liver problems

If you have not told your doctor or pharmacist about any of the

above, tell them before you start taking Levitra.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including those that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Levitra or vice versa. These medicines include:

- nitrates, medicines for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Levitra could seriously affect your blood pressure
- cobicistat, ritonavir or indinavir, medicines for HIV
- ketoconazole and itraconazole, used to treat fungal infections
- erythromycin, clarithromycin and gatifloxacin, which are antibiotics
- alpha-blockers, medicines used to treat an enlarged prostate or high blood pressure. Examples of alpha-blockers are terazosin, alfuzosin, tamsulosin and prazosin
- Riociguat, a type of medicine used to treat high blood pressure in the arteries carrying blood from your heart to your lungs
- other treatments for erectile dysfunction

Levitra might increase the amount of some medicines in your blood (sensitive P-gp substrates).

Dabigatran is an example for these medicines.

You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will be able to advise you.

Talk to your doctor if you are taking certain medicines for arrhythmia, including quinidine, procainamide, amiodarone and sotalol.

Levitra should not be used with these medicines.

Levitra tablets may be used together with an alpha-blocker if you are on stable alpha-blocker therapy. If your doctor recommends this, they will start your Levitra treatment with a lower dose.

Concomitant use of Levitra with alpha-blockers may contribute to dizziness or fainting.

Your doctor or pharmacist will also have a more complete list of medicines to be careful with or avoid while taking Levitra.

Ask your doctor or pharmacist, if you are not sure if you are taking any of these medicines.

HOW TO TAKE LEVITRA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Swallow the tablet whole with water. Levitra can be taken with or without food.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much and how often you should take Levitra. Follow the directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

The dose ranges from 5 mg to 20 mg. Your doctor will determine the correct dose for you depending on your condition, other medicines and response.

Do not take more than one dose of Levitra a day.

When to take it

Sexual stimulation is required for a natural response to treatment with Levitra.

Take your dose of Levitra 25 to 60 minutes before you wish to have sex.

Levitra may work as soon as 15 minutes and as long as 4-5 hours after taking it. The amount of time it takes to start working varies from person to person.

If you are also taking an alpha-blocker other than tamsulosin or alfuzosin, allow at least 6 hours between the time you take it and the time you take your Levitra tablet (see *Taking other medicines*). Tamsulosin can be taken at the same time as Levitra or separately as you prefer.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone in Australia 13 11 26, in New Zealand 0800 POISON or 0800 764 766), or go to the accident and emergency department at your nearest hospital, if you think you or anyone else may have taken too much Levitra. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING LEVITRA

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Levitra. If you are about to start taking any new medicines, especially nitrates or

some medicines to treat HIV, e.g. cobicistat, indinavir or ritonavir, tell your doctor or pharmacist that you are taking Levitra.

Stop taking Levitra and tell your doctor if you notice a sudden decrease or loss of hearing.

ringing of the ears and dizziness may also occur.

Stop taking Levitra and tell your doctor if you notice a sudden loss in vision.

Please also be aware that you may have to take treatments like Levitra a few times before you get the best response.

If you're still not getting a response, speak to your doctor.

Things you must not do

Do not use the recreational drug amyl nitrite (sometimes called 'poppers', 'amyl' or 'rush') while you are taking Levitra.

Do not take Levitra if you are taking HIV protease inhibitors, medicines used to treat HIV infection.

Do not take Levitra if you are taking Riociguat, used to treat pulmonary arterial hypertension.

If you get an angina attack whilst taking Levitra, do not take nitrate medicines to relieve the pain. Tell your doctor immediately or contact your nearest emergency department. Make sure that your doctor knows you are taking Levitra tablets.

Do not take more than one dose of Levitra a day. If Levitra does not help you get an erection, or if your erection does not last long enough to complete sexual intercourse, tell your doctor.

Do not give your Levitra tablets to anyone else, even if they have the same condition as you.

What to be careful of

Drinking alcohol can temporarily impair the ability to get an erection. To reduce impairment, do not drink large amounts of alcohol before sexual activity.

Be careful driving or operating machinery until you know how Levitra affects you.

Levitra tablets may cause dizziness or faintness in some people. The ability to drive and/or operate machinery may be impaired.

Dizziness or faintness may be worse if you are also taking alpha-blocker medicines.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Levitra.

Levitra helps most men with erectile dysfunction, but it may have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need to stop taking the tablets or have medical treatment if you get some of the serious side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

These are the common side effects of Levitra. They are usually mild and short-lived.

- headache
- dizziness or light-headedness
- flushing
- a stuffy or runny nose
- dyspepsia (heartburn)
- nausea

Very rarely, your erection may persist for longer than usual. If your erection continues for longer than four hours, or if you have a painful erection, you should seek medical attention.

In rare instances, men have lost eyesight some time after taking drugs to treat erectile dysfunction. It is not known at this time if Levitra causes this. If you experience sudden decrease or loss of vision – stop taking Levitra and seek immediate medical attention.

Sudden decrease in hearing or loss of hearing has been reported in men

taking medicines to treat erectile dysfunction. It is not known at this time if Levitra causes this. If you experience sudden decrease or loss of hearing – stop taking Levitra and seek immediate medical attention.

You should tell your doctor immediately, or be reviewed in the accident and emergency department at your nearest hospital if you have any of the following:

- angina (chest pain)
- myocardial infarction
- irregular heart beats or palpitations
- loss of consciousness
- allergic reactions such as rash, wheezing, swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing

These are serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

AFTER USING LEVITRA

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not leave the tablets in the car on hot days. Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep your tablets where children cannot reach them. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Levitra tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

PRODUCT DESCRIPTION

What it looks like

Levitra 5 tablets are orange film-coated round tablets marked with BAYER-cross on one side and “5” on the other side.

Levitra 10 tablets are orange film-coated round tablets marked with BAYER-cross on one side and “10” on the other side.

Levitra 20 tablets are orange film-coated round tablets marked with BAYER-cross on one side and “20” on the other side.

Not all pack sizes are marketed.

Ingredients

Active ingredients:

- Levitra 5 - 5 mg vardenafil per tablet
- Levitra 10 - 10 mg vardenafil per tablet
- Levitra 20 - 20 mg vardenafil per tablet

Inactive ingredients:

- Colloidal anhydrous silica
- Crospovidone
- Hypromellose
- Iron oxide red (CI 77491-E172)
- Iron oxide yellow (CI 77492-E172)
- Macrogol 400
- Magnesium stearate
- Microcrystalline cellulose

- Titanium dioxide (CI 77891-E171)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Made in Germany for:

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
North Shore
Auckland 0627

Australian Registration Numbers

Levitra 5 - AUST R 90498

Levitra 10 - AUST R 90499

Levitra 20 - AUST R 90500

Date of preparation

December 2019

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

® Registered trademark

© Bayer Australia Ltd

All rights reserved

