

Package Leaflet: Information for the user

Devarin ODT 10 mg orodispersible tablets Vardenafil

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Devarin ODT is and what it is used for
2. What you need to know before you take Devarin ODT
3. How to take Devarin ODT
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1. What Devarin ODT is and what it is used for

Devarin ODT contains vardenafil, a member of a class of medicines called phosphodiesterase type 5 inhibitors. They are used for the treatment of erectile dysfunction in adult men, a condition which implies difficulties in getting or keeping an erection.

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.

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

2. What you need to know before you take Devarin ODT

Do not take Devarin ODT

- If you are allergic to vardenafil or any of the other ingredients of this medicine (listed 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 vardenafil orodispersible could seriously affect your blood pressure.
- If you are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- 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 ischaemic optic neuropathy (NAION).
- If you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e. high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e. high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as vardenafil have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Devarin ODT.

Take special care with vardenafil orodispersible tablets

- 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, including vardenafil film-coated tablets (see section Other medicines and Devarin ODT).
- If you experience sudden decrease or loss of vision, stop taking Devarin ODT and contact your doctor immediately.

Children and adolescents

Vardenafil orodispersible is not intended for use by children or adolescents under 18.

Other medicines and Devarin ODT

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

Some medicines may cause problems, especially these:

- Nitrates, medicines for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with vardenafil orodispersible tablets could seriously affect your blood pressure. Talk to a doctor without taking Devarin ODT.
- 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 Devarin ODT.
- 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*).
- Riociguat.

Do not use vardenafil orodispersible tablets combined with any other treatment for erectile dysfunction, including vardenafil film-coated tablets.

Devarin ODT with food, drink and alcohol

- You can take Devarin ODT with or without food but do not take this medicine with any liquid.

- Don't drink grapefruit juice when you use Devarin ODT. It can interfere with the usual effect of the medicine.
- Alcoholic drink can make erection difficulties worse.

Pregnancy and breast-feeding

Vardenafil orodispersible is not for use by women.

Driving and using machines

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

Devarin ODT contains Aspartame and lactose monohydrate.

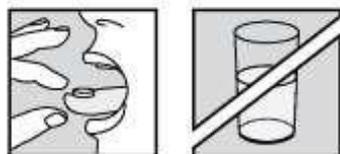
- Aspartame is a source of phenylalanine, and may be harmful for people with a disorder called phenylketonuria.
- Lactose monohydrate: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Devarin ODT

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is 10 mg.

Take a Devarin ODT 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 Devarin ODT.

- Do not remove the orodispersible tablet from the blister until you are going to take it. With dry hands press gently to release the tablet on your hand. Do not crush the tablet.
- Place the entire orodispersible tablet in the mouth, on the tongue, where it will dissolve in seconds, then swallow with saliva. The orodispersible tablet must be taken without any liquid.



Do not take Devarin ODT orodispersible tablets with any other forms of vardenafil.

Do not take Devarin ODT more than once a day.

Tell your doctor if you think Devarin ODT is too strong or too weak. He or she may suggest a switch to an alternative vardenafil formulation with a different dose, depending on how well it works for you.

If you take more Devarin ODT than you should

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the effects are mild or moderate.

Partial, sudden, temporary or permanent decrease or loss of vision in one or both eyes has been experienced by patients. Stop taking Devarin ODT and contact your doctor immediately. Sudden decrease or loss of hearing has been reported.

The chance of having a side effect is described by the following categories:

Very common:

may affect more than 1 in 10 users

- Headache

Common:

may affect up to 1 in 10 users

- Dizziness
- Flushing
- Blocked or runny nose
- Indigestion

Uncommon:

may affect up to 1 in 100 users

- Swelling of skin and mucous tissue including swollen face, lips or throat
- Sleep disorder
- Numbness and impaired perception of touch
- Sleepiness
- Effects on vision, redness of the eye, effects on colour vision, eye pain and discomfort, light sensitivity
- Ringing in the ears, vertigo
- Fast heart beat or pounding heart
- Breathlessness
- Stuffy nose
- Acid reflux, gastritis, abdominal pain, diarrhoea, vomiting; feeling sick (*nausea*), dry mouth
- Raised levels of liver enzymes in your blood
- Rash, reddened skin
- Back or muscle pain, increase in blood of a muscle enzyme (*creatine phosphokinase*), muscle stiffness
- Prolonged erections
- Malaise

Rare:

may affect up to 1 in 1,000 users

- Inflammation of the eyes (*conjunctivitis*)
- Allergic reaction
- Anxiety
- Fainting
- Amnesia
- Seizure
- Increased pressure in the eye (*glaucoma*), lacrimation increased
- Effects on the heart (such as heart attack, altered heart beat or *angina*)
- High or low blood pressure
- Nose bleed
- Effect on results of blood tests to check liver function

- Sensitivity of the skin to sun light
- Painful erections
- Chest pain

Very rare or not known:

may affect less than 1 in 10,000 users or frequency cannot be estimated from the available data

- Blood in the urine (*Haematuria*)
- Penile bleeding (*Penile Haemorrhage*)
- Presence of blood in the semen (*Haemospermia*)

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Devarin ODT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Devarin ODT contains

- The active substance is vardenafil.

Each orodispersible tablet contains: vardenafil 10 mg (vardenafil HCl trihydrate 11.85 mg).

The other ingredients of the tablets are:

Lactose monohydrate, calcium silicate, hydroxypropyl cellulose, crospovidone, aspartame, mint flavour, aniseed flavour, colloidal silicon dioxide and magnesium stearate.

What Devarin ODT looks like and contents of the pack

Devarin ODT 10 mg are biconvex, cylindrical, white to off white, non-scored with the code “VB” on one side.

Devarin ODT is supplied in packages containing 4 tablets.

Marketing Authorisation Holder and Manufacturer

LABORATORIOS CINFA, S.A.
OlazChipi,10. Polígono Industrial Areta,
31620 Huarte-Pamplona (Navarra) – Spain

This leaflet was last revised in 09/2018.

To Report any side effect(s):

The National Pharmacovigilance & Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**