

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vardenafil Zentiva 5 mg film-coated tablets Vardenafil Zentiva 10 mg film-coated tablets Vardenafil Zentiva 20 mg film-coated tablets

vardenafil

Read all of this leaflet carefully before you start taking 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 Vardenafil is and what it is used for
2. What you need to know before you take Vardenafil
3. How to take Vardenafil
4. Possible side effects
5. How to store Vardenafil
6. Contents of the pack and other information

1. What Vardenafil is and what it is used for

The name of your medicine is Vardenafil Zentiva 5 mg, 10 mg and 20 mg film-coated tablets (called Vardenafil throughout this leaflet). It 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 have 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.

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

2. What you need to know before you take

Do not take Vardenafil 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.
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Vardenafil.
- 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 could seriously affect your blood pressure.
- you are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- you are over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines.
- you have a severe heart or liver problem.
- you are having kidney dialysis.
- you have recently had a stroke or heart attack.
- you have or have had low blood pressure.
- your family has a history of degenerative eye diseases (such as retinitis pigmentosa).
- 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).
- 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 Vardenafil if you

- have heart trouble. It may be risky for you to have sex.

- suffer from irregular heart beat (cardiac arrhythmia) or inherited heart diseases affecting your electrocardiogram.
- have a physical condition affecting the shape of the penis. This includes conditions called angulation, Peyronie's disease and cavernosal fibrosis.
- have an illness that can cause erections which won't go away (priapism). These include sickle cell disease, multiple myeloma and leukaemia.
- have stomach ulcers (also called gastric or peptic ulcers).
- have a bleeding disorder (such as haemophilia).
- are using any other treatments for erection difficulties, including vardenafil-containing orodispersible tablets (see section "Other medicines and Vardenafil").

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, have been reported in association with vardenafil treatment. Stop using Vardenafil and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4. If you experience sudden decrease or loss of vision or your vision is distorted or dimmed while you are taking Vardenafil, stop taking Vardenafil and contact your doctor immediately.

Children and adolescents

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

Other medicines and Vardenafil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may cause problems, especially these:

- Nitrates, medicines for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil could seriously affect your blood pressure.
- Medicine for the treatment of arrhythmias, such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines for HIV.
- Ketoconazole or itraconazole, anti-fungal medicines.
- Erythromycin, or clarithromycin, macrolide antibiotics.
- α -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 film-coated tablets combined with any other treatment for erectile dysfunction, including vardenafil-containing orodispersible tablets.

Vardenafil with food, drink and alcohol

You can take Vardenafil 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 Vardenafil. It can interfere with the usual effect of the medicine.

Alcoholic drink can make erection difficulties worse.

Pregnancy, breast-feeding and fertility

Vardenafil 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 don't drive or operate any tools or machines.

3. How to take Vardenafil

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 10 mg.

Take a Vardenafil 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 Vardenafil.

Swallow one tablet with a glass of water.

Do not take Vardenafil film-coated tablets with any other forms of vardenafil.

Do not take Vardenafil more than once a day. Tell your doctor if you think Vardenafil 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 Vardenafil than you should

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

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

reading

10 mm

10 mm

reading

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, or distorted, dimmed, or blurred central vision in one or both eyes has been experienced by patients. Stop taking Vardenafil and contact your doctor immediately.

Sudden decrease or loss of hearing has been reported.

Cases of sudden death, fast or altered heart beat, heart attack, chest pain, and trouble in cerebral circulation (including temporarily decreased blood flow to parts of the brain and bleeding in the brain) have been reported in men taking Vardenafil. Most of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Vardenafil.

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

Very common (may affect more than 1 in 10 people):

- Headache

Common (may affect up to 1 in 10 people):

- Dizziness.
- Flushing.
- Blocked or runny nose.
- Indigestion.

Uncommon (may affect up to 1 in 100 people):

- Swelling of skin and mucous tissue including swollen face, lips or throat.
- Sleep disorders.
- 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 people):

- Inflammation of the eyes (conjunctivitis).
- Allergic reaction.
- Anxiety.
- Fainting
- Amnesia.
- Seizure
- Increase 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.
- Temporarily decreased blood flow to parts of the brain.

Not known (frequency cannot be estimated from the available data):

- Blood in the urine (haematuria).
- Penile bleeding (penile haemorrhage).
- Presence of blood in the semen (haemospermia).
- Sudden death.
- Bleeding in the brain.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Distorted, dimmed, or blurred central vision or sudden decrease of vision.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vardenafil

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 and on the blister after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Vardenafil 5 mg, 10 mg and 20 mg film-coated tablets contain:

The active substance is: vardenafil (as hydrochloride trihydrate) 5 mg, 10 mg or 20 mg.

The other ingredients are:

Tablet core: Cellulose, microcrystalline; Silica colloidal anhydrous; Crospovidone (type A); Stearic acid.

Tablet coating: Hypromellose; Macrogol 400; Titanium dioxide (E171); Iron oxide yellow (E172); Iron oxide red (E172).

What Vardenafil looks like and contents of the pack:

5 mg: Slightly yellow to slightly brown round tablets of size approx. 6 mm, embossed with "5" on one side.

10 mg: Yellow-orange round tablets of size approx. 6 mm, embossed with "10" on one side and with decorative line on the other side. The score line is only to facilitate for ease of swallowing and not to divide into equal doses.

20 mg: Orange round tablets of size approx. 8 mm, embossed with "20" on one side and with decorative line on the other side.

The score line is only to facilitate for ease of swallowing and not to divide into equal doses.

Blisters in packages of:

5 mg: 2, 4, 8, 12 and 24 film-coated tablets.

10 mg: 2, 4, 8, 12, 24, 48 and 60 film-coated tablets

20 mg: 2, 4, 8, 12, 24, 48 and 60 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

Manufacturer:

ZENTIVA, k.s., U kabelovny 130, Dolní Měcholupy, 102 37 Prague 10, 102 37, Czech Republic

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