

Package leaflet: information for the user

Vardenafil Accord 5 mg, film-coated tablets
Vardenafil Accord 10 mg, film-coated tablets
Vardenafil Accord 20 mg, film-coated tablets
vardenafil

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Vardenafil Accord and what is this medicine used for?

This medicine contains vardenafil, a medicine from the group of medicines called phosphodiesterase type 5 inhibitors. They are used for the treatment of erectile dysfunction in adult men, a condition that means it is difficult to get or maintain an erection.

At least one in ten men has problems getting or maintaining an erection at some point. There can be physical or psychological causes, or a combination of both. Whatever the cause, due to changes in muscles and blood vessels, there is not enough blood in the penis to make and keep it erect.

This medicine only works if you are sexually stimulated. It reduces the effect of a natural chemical in the body that makes the erection disappear. With this medicine, an erection can last long enough for satisfactory sexual intercourse.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet. Hypersensitivity reactions may include rash, itching, swollen face or lips, and shortness of breath.

- You have ever developed a severe skin rash or skin peeling, blistering and/or sores in the mouth after taking this medicine.
- You are taking medicines that contain nitrates, such as glyceryl trinitrate, for the treatment of a tight, pressing, painful feeling in the chest (angina pectoris), or medicines that release nitric oxide, such as amyl nitrite. Taking these medicines together with this medicine can significantly change your blood pressure.
- You are taking ritonavir or indinavir, medicines used to treat an infection with the human immunodeficiency virus (HIV).
- You are over 75 years old and you are taking ketoconazole or itraconazole, medicines for fungal infections.
- You have severe heart or liver problems.
- You are undergoing kidney dialysis.
- You have recently had a stroke or heart attack.
- You have or had low blood pressure.
- Your family has a history of a degenerative eye disease (such as retinitis pigmentosa).
- You have ever had a condition where vision loss occurred due to damage to the optic nerve from insufficient blood supply, known as non-arteritic anterior ischemic optic neuropathy (NAION).
- You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (increased blood pressure in the pulmonary arteries) and chronic thromboembolic pulmonary hypertension (increased blood pressure in the pulmonary veins due to blood clots). PDE5 inhibitors, such as this medicine, have been shown to enhance the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure, contact your doctor.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

Be extra careful with this medicine

- If you have heart problems. It may be dangerous for you to have sex.
- If you suffer from an irregular heartbeat (arrhythmias) or have a hereditary heart disease that affects the electrocardiogram (ECG).
- If you have a physical condition that affects the shape of the penis. These can be conditions such as penile deformation (angulation), Peyronie's disease (curvature of the penis when erect), or fibrosis of the corpus cavernosum (scarring of the erectile tissue of the penis).
- If you have a condition that can cause erections that do not go away (priapism). These include sickle cell anemia (a type of anemia), multiple myeloma, and leukemia (certain types of blood cancer).
- When you have a stomach ulcer (also known as a peptic ulcer).
- When you have a bleeding disorder (such as increased bleeding tendency (hemophilia)).
- If you are using other medications for erectile dysfunction, including vardenafil orodispersible tablets (see section: Are you using any other medications?).
- Severe skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in connection with the treatment with vardenafil. Stop using this medicine and seek immediate medical help if you notice any of the symptoms related to these severe skin reactions described in section 4.

- If you suddenly experience a reduction or loss of vision, or if your vision becomes distorted or darkened while using this medication, stop taking this medication and contact your doctor immediately.

Children and adolescents under 18 years

This medication is not intended for use by children and adolescents under 18.

Are you using any other medications?

Are you using any other medications besides Vardenafil Accord, have you recently done so, or are you planning to do so soon? If so, tell your doctor or pharmacist. This also applies to medications for which you do not need a prescription.

Some medications can cause problems, particularly:

- nitrates, medications for a tight, pressing, painful feeling in the chest (angina), or substances that release nitric oxide, such as amyl nitrite ('poppers'). Using these medications simultaneously with Vardenafil Accord can significantly change your blood pressure.
- medications for the treatment of arrhythmias such as quinidine, procainamide, amiodarone, and sotalol.
- ritonavir or indinavir, medications against HIV.
- ketoconazole or itraconazole, medications against fungal infections.
- erythromycin or clarithromycin, macrolide antibiotics (medications against certain bacterial infections).
- alpha-blockers, a type of medication used to treat high blood pressure or an enlarged prostate (such as benign prostatic hyperplasia).
- riociguat.

Do not use this medication together with another treatment for erectile dysfunction, including vardenafil orodispersible tablets.

What should you pay attention to with food, drink, and alcohol?

- You can take this medicine with or without food – but preferably not after a heavy or high-fat meal, as this may delay the onset of action.
- Do not drink grapefruit juice while using this medicine. This can affect the action of the medicine.
- Alcoholic beverages can worsen erectile dysfunction.

Pregnancy and breastfeeding

This medicine is not intended for use by women.

Driving and using machines

This medicine can cause dizziness or affect vision in some people. If you feel dizzy or have impaired vision after using this medicine, do not drive or use tools or machines.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist. The recommended dosage is 10 mg.

Take a Vardenafil Accord tablet about 25 to 60 minutes before sexual activity. Sexual stimulation can lead to an erection approximately 25 minutes to 4-5 hours after taking Vardenafil Accord.

- Swallow one tablet with a glass of water.

Do not use Vardenafil Accord film-coated tablets together with other forms of vardenafil.

Do not use Vardenafil Accord more than once a day.

Inform your doctor if you think this medicine is too strong or not strong enough. He or she may suggest switching to another formulation of this medicine with a different dosage, depending on how well it works for you.

Have you used too much of this medicine?

Men who take too much of this medicine may experience more side effects or severe back pain. If you take more of this medicine than prescribed, tell your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone experiences them. Most effects are mild to moderate.

Partial, sudden, temporary, or permanent reduction or loss of vision, or distorted, darkened, or blurred central vision in one or both eyes has been experienced by patients. If this occurs, stop using this medicine and contact your doctor immediately. Sudden reduction or loss of hearing has been reported.

Cases of sudden death, rapid or altered heart rhythm, heart attack, chest pain, and problems in blood circulation in the brain (including temporary reduction of blood supply to parts of the brain and brain hemorrhages) have been reported in men using vardenafil. Most of the men who experienced these side effects had pre-existing heart problems before taking this medicine. It is not possible to determine if these events were directly related to the use of vardenafil.

The likelihood of experiencing a side effect is described in the following categories:

Very common (occurs in more than 1 in 10 users):

- headache

Common (occurs in less than 1 in 10 users):

- dizziness
- flushing
- blocked nose or runny nose
- indigestion

Uncommon (occurs in less than 1 in 100 users):

- swelling of skin and mucous membranes, including swollen face, lips, or throat
- sleep disorder
- numbness and reduced sense of touch
- drowsiness
- effects on vision; red eyes, effects on color vision, eye pain and discomfort, sensitivity to light
- tinnitus, vertigo
- rapid heartbeat or pounding heart
- shortness of breath
- congested nose
- heartburn, gastritis, abdominal pain, diarrhea, vomiting, nausea, dry mouth
- increased levels of liver enzymes in the blood
- rash, redness of the skin
- back or muscle pain, increased amount of a muscle enzyme in the blood (creatin phosphokinase), stiff muscles
- persistent erections
- feeling unwell, feeling sick (malaise)

Rare (occur in less than 1 in 1000 users):

- inflammation of the conjunctiva causing itching, tearing, or redness (conjunctivitis)
- allergic reactions
- anxiety
- fainting
- memory loss
- seizures
- increased pressure in the eye (glaucoma), increased tearing
- effects on the heart (such as a heart attack, altered heart rate, or a tight, pressing, painful feeling in the chest (angina))
- high or low blood pressure
- nosebleed
- effect on the results of blood tests for checking liver function
- sensitivity of the skin to sunlight
- painful erections
- pain on the chest
- Temporary reduction of blood supply to parts of the brain

Very rarely or not known (occur in less than 1 in 10,000 users or the frequency cannot be determined with the available data):

- blood in the urine (hematuria)
- bleeding from the penis (penile bleeding)
- presence of blood in the semen (hematospermia)
- sudden death;
- bleeding in the brain;
- reddish, non-elevated, disc-shaped or round spots on the trunk, often with central blistering, skin peeling, sores in the mouth, throat, nose, on the genitals and eyes. These severe skin reactions may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- distorted, darkened or blurred central vision or sudden decreased vision

Reporting side effects

If you experience side effects, contact your doctor. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. If you dispose of medicines correctly, they are destroyed properly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is vardenafil.
- Vardenafil Accord 5 mg film-coated tablets: Each tablet contains 5 mg vardenafil (as hydrochloride trihydrate).
- Vardenafil Accord 10 mg film-coated tablets: Each tablet contains 10 mg vardenafil (as hydrochloride trihydrate).
- Vardenafil Accord 20 mg film-coated tablets: Each tablet contains 20 mg vardenafil (as hydrochloride trihydrate).
- The other substances in this medicine are:
- Tablet core: crospovidone (type B), magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide (anhydrous).
- Film coating: macrogol 400 (E1521), hypromellose (E464), titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

What does Vardenafil Accord look like and what is in a package?

Vardenafil Accord 5 mg film-coated tablets are beige, round, biconvex film-coated tablets approximately 5.5 mm in diameter with the inscription 'FA1' on one side and plain on the other side.

Vardenafil Accord 10 mg film-coated tablets are beige, round, biconvex film-coated tablets approximately 6.8 mm in diameter with the inscription 'FA2' on one side and plain on the other side.

Vardenafil Accord 20 mg film-coated tablets are beige, round, biconvex film-coated tablets approximately 8.9 mm in diameter with the inscription 'FA3' on one side and plain on the other side.

The tablets are supplied in blister packs of 2, 4, 8, 12, or 20 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Accord Healthcare B.V.

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Manufacturer

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Registered under:

Vardenafil Accord 5 mg film-coated tablets: RVG 118384

Vardenafil Accord 10 mg film-coated tablets: RVG 118385

Vardenafil Accord 20 mg film-coated tablets: RVG 118386

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Member State	Brand Name
Austria	Vardenafil Accord 5 mg/10 mg/20 mg Film Tablets
Denmark	Vardenafil Accord 5 mg/10 mg/20 mg
Finland	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
Ireland	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
Italy	Vardenafil Accord
Malta	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
Netherlands	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
Poland	Vardenafil Accord
Sweden	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
United Kingdom	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets (PL 20075/0475-0477)

Spain	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
France	VARDENAFIL ACCORD 5 mg/10 mg/20 mg, film-coated tablet

This leaflet was last approved in December 2025

Transtoyou