

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 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 Vardenafil Accord is and what it is used for
2. What you need to know before you take Vardenafil Accord
3. How to take Vardenafil Accord
4. Possible side effects
5. How to store Vardenafil Accord
6. Contents of the pack and other information

1. What Vardenafil Accord is and what it is used for

Vardenafil Accord 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.

Vardenafil Accord 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 Accord allows an erection to last long enough for you to satisfactorily complete sexual activity.

2. What you need to know before you take Vardenafil Accord

Do not take Vardenafil Accord

- 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 Accord 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 ischemic 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 Accord 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 Accord.

Take special care with Vardenafil Accord

- 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 orodispersible tablets (see section: Other medicines and Vardenafil Accord).
- If you experience sudden decrease or loss of vision, stop taking Vardenafil Accord and contact your doctor immediately.

Children and adolescents

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

Other medicines and Vardenafil Accord

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 Accord 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.
- 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 Accord film-coated tablets combined with any other treatment for erectile dysfunction, including vardenafil orodispersible tablets.

Vardenafil Accord with food, drink and alcohol

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

- Alcoholic drink can make erection difficulties worse.

Pregnancy and breast-feeding

This medicine is not for use by women.

Driving and using machines

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

3. How to take Vardenafil Accord

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 Vardenafil Accord 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 Accord.

- Swallow one tablet with a glass of water

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

Do not take Vardenafil Accord more than once a day.

Tell your doctor if you think Vardenafil Accord 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 Accord than you should

Men who take too much Vardenafil Accord may experience more side effects or may get severe back pain. If you take more Vardenafil Accord 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 this medicine 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 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
- 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

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 (*Haematospermia*)
- Sudden death; Bleeding in the brain

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 via

HPRRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Vardenafil Accord

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.

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 Accord contains

- The active substance 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 ingredients of the tablets are:
 - Tablet core: crospovidone (type B), magnesium stearate, cellulose microcrystalline and silica colloidal anhydrous.
 - Film-coat: macrogol 400, hypromellose (E464), titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172).

What Vardenafil Accord looks like and contents of the pack

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

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

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

The tablets are provided in PVC/PVdC -Aluminium blister packs containing 2, 4, 8, 12 or 20 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

United Kingdom

Accord Healthcare Limited
Sage house, 319 Pinner Road,
North Harrow,
Middlesex HA1 4HF,
United Kingdom

Ireland

Accord Healthcare Ireland Limited,
Euro House,

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Little Island,
Cork T45 K857,
Ireland

Manufacturer

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3526 KV Utrecht,
The Netherlands

Laboratori Fundació DAU
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Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola, PLA 3000
Malta

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

Member States	Invented Names
Austria	Vardenafil Accord 5 mg/10 mg/20 mg Filmtabletten
Denmark	Vardenafil Accord 5 mg/10 mg/20 mg
Finland	Vardenafil Accord 5 mg/10 mg/20 mg kalvopäällysteiset tabletit
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
Netherland	Vardenafil Accord 5 mg/10 mg/20 mg filmomhulde tabletten
Poland	Vardenafil Accord
Sweden	Vardenafil Accord 5 mg/10 mg/20 mg filmdragerad tabletter
United Kingdom	Vardenafil Accord 5 mg/10 mg/20 mg film-coated tablets
Spain	Vardenafil Accord 5 mg/10 mg/20 mg comprimidos recubiertos con película
France	VARDENAFIL ACCORD 5 mg/ 10 mg/ 20 mg, comprimé pelliculé

This leaflet was last revised in 05/2021.