

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sildenafil Accord 25mg Film Coated Tablets Sildenafil Accord 50 mg Film Coated Tablets Sildenafil Accord 100 mg Film Coated Tablets sildenafil

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, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Sildenafil Tablet is and what it is used for

Sildenafil tablets belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. Sildenafil tablets will only help you to get an erection if you are sexually stimulated.

Sildenafil tablets are used to treat adult men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. What you need to know before you take Sildenafil Tablets

Do not take Sildenafil tablets

- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of Sildenafil tablets (see section 6).
- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”), as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- 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 Viagra have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.

- If you have certain rare inherited eye diseases (such as *retinitis pigmentosa*).
- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions

Tell your doctor, pharmacist or nurse before taking Sildenafil tablets

- If you suffer from sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells) and multiple myeloma (cancer of bone marrow).
- If you suffer from deformity of your penis or Peyronie’s Disease.
- If you suffer from heart problems. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- If you are suffering from stomach ulcer, or a bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Sildenafil tablets and contact your doctor immediately.
- You should not use Sildenafil tablets with any other oral or local treatments for erectile dysfunction.
- You should not use Sildenafil tablets with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.
- You should not take Sildenafil if you do not have erectile dysfunction
- You should not take Sildenafil if you are a women.

Special considerations for patients with kidney or liver problems

If you suffer from kidney or liver problems. Your doctor may decide on a lower dose for you.

Children and adolescents

Sildenafil tablets should not be given to individuals under the age of 18.

Other medicines and Sildenafil tablets:

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

Sildenafil tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any health care professional treating your condition that you have taken Sildenafil tablets and when you did. Do not take Sildenafil tablets with other medicines unless your doctor tells you that you can.

You should not take Sildenafil tablets if you are taking medicines called nitrates, as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines that are often used for the relief of angina pectoris (or “chest pain”).

You should not take Sildenafil tablets if you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a potentially dangerous decrease in your blood pressure.

Tell your doctor or pharmacist if you are already taking riociguat.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of Sildenafil tablets.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Sildenafil tablets with alpha-blockers. This is most likely to occur within 4 hours after taking Sildenafil tablets. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil tablets. Your doctor may start you on a lower dose (25 mg) of Sildenafil tablets.

Taking Sildenafil tablets with food and drink

Sildenafil tablets can be taken with or without food. However, you may find that Sildenafil tablets takes longer to start working if you take it with a heavy meal.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking Sildenafil tablets.

Pregnancy ,Breast feeding and fertility

Sildenafil tablets are not indicated for use by women.

Driving and using machines

Sildenafil tablets can cause dizziness and can affect vision. You should be aware of how you react to Sildenafil tablets before you drive or use machinery.

Important information about some of the ingredients of Sildenafil tablets

Sildenafil tablets contain lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars, then contact your doctor before taking Sildenafil tablets.

3. How to take Sildenafil Tablets

Always take Sildenafil tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is 50 mg.

You should not take Sildenafil tablets more than once a day.

You should take Sildenafil tablets about one hour before you plan to have sex Swallow the tablet whole with a glass of water.

If you have the impression that the effect of Sildenafil tablets is too strong or too weak, talk to your doctor or pharmacist.

Sildenafil tablets will only help you to get an erection if you are sexually stimulated. The amount of time Sildenafil tablets takes to work varies from person to person, but it normally takes between half an hour to one hour. You may find that Sildenafil tablets takes longer to work if you take it with a heavy meal.

If Sildenafil tablets do not help you to get an erection or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

If you take more Sildenafil tablets than you should

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

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

4. Possible side effects

Like all medicines, Sildenafil tablets can cause side effects although not everybody gets them. The side effects reported in association with the use of Sildenafil tablets are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildenafil Tablets and seek medical help immediately:

- An allergic reaction - this occurs **uncommonly** (may affect up to 1 in 100 people)
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pains - this occurs **uncommonly**
If this occurs during or after intercourse
 - Get in a semi-sitting position and try to relax.
 - **Do not use nitrates** to treat your chest pain.

Prolonged and sometimes painful erections - this occurs **rarely** (may affect up to 1 in 1,000 people). If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

- A sudden decrease or loss of vision - this occurs **rarely**
- **Serious skin reactions - this occurs rarely**
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- **Seizures or fits - this occurs rarely**

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

- headache

Common side effects (may affect up to 1 in 10 people)

- facial flushing
- Hot flush (symptoms include a sudden feeling of heat in your upper body)
- Nausea
- indigestion
- visual disturbances (includes colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision)
- stuffy nose
- dizziness

Uncommon side effects (may affect up to 1 in 100 people)

- vomiting
- skin rash
- eye irritation
- bloodshot eyes /red eyes

- eye pain
- seeing flashes of light
- visual brightness
- light sensitivity
- pounding heartbeat
- rapid heartbeat
- high blood pressure
- low blood pressure
- muscle pain, feeling sleepy
- reduced sense of touch
- vertigo
- ringing in the ears
- dry mouth
- blocked or stuffy sinuses
- inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose)
- upper abdominal pain
- gastro-oesophageal reflux disease
- feeling tired
- feeling hot
- pain in arms or legs
- nose bleed
- presence of blood in urine
- watery eyes

Rare side effects (may affect up to 1 in 1,000 people)

- heart attack
- irregular heartbeat
- fainting
- stroke
- temporary decreased blood flow to parts of the brain
- feeling of tightening of the throat
- numb mouth
- bleeding at the back of the eye
- double vision
- reduced sharpness of vision
- abnormal sensation in the eye
- swelling of the eye or eyelid
- small particles or spots in your vision
- seeing halos around lights
- dilation of the pupil of the eye
- discolouration of the white of the eye
- penile bleeding
- presence of blood in semen
- dry nose
- swelling of the inside of the nose
- feeling irritable
- sudden decrease or loss of hearing

Additional side effects reported from post-marketing experience include:

- unstable angina (a heart condition)
- sudden death

Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Sildenafil tablets.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie.

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

5. How to store Sildenafil Tablets

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

This medicinal product does not require any special storage conditions.

Do not use Sildenafil tablets after the expiry date which is stated on the carton label and blister foil after 'EXP'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sildenafil Tablet contains

The active substance is Sildenafil. Each tablet contains 25mg, 50mg or 100mg of sildenafil as sildenafil citrate

The Other ingredients are:

- Tablet core: cellulose microcrystalline, calcium hydrogen phosphate anhydrous, croscarmellose sodium, hypromellose 5cp (E464), magnesium stearate
- Film coat hypromellose 15cp (E464), titanium dioxide(E171), lactose monohydrate, triacetin, indigo carmine aluminium lake (E132) (*see section 2 for Important information about some of the ingredients Sildenafil Tablets*)

What Sildenafil Tablets look like and contents of the pack

Sildenafil Tablets 25 mg are Blue, almond shaped, biconvex, film coated, debossed with '25' on one side and plain on other side.

Sildenafil Tablets 50 mg are Blue, almond shaped, biconvex, film coated, debossed with '50' on one side and

plain on other side.

Sildenafil Tablets 100 mg are Blue, almond shaped, biconvex, film coated, debossed with '100' on one side and plain on other side.

Sildenafil Tablets are available in blister packs of:

25mg: 2, 4, 8 or 12 tablets.

50mg: 2, 4, 8, 12 or 24 tablets.

100mg: 2, 4, 8, 12 or 24 tablets.

(Not all pack sizes may be marketed).

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,

Euro House,

Euro Business Park,

Little Island,

Cork T45 K857,

Ireland

Manufacturer

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

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

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

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

Name of the Member State	Name of the medicinal product
Czech Republic	Sildenafil Accord 100mg potahované tablety
Denmark	Sildenafil Accord 25mg /50mg/100mg filmovertrukne tabletter
Estonia	Sildenafil Accord 50mg/100mg õhukese polümeerikattega tabletid
Finland	Sildenafil Accord 50mg/100mg kalvopäällysteiset tabletit
France	Sildenafil Accord 25mg /50mg/100mg comprimé pelliculé
Ireland	Sildenafil Accord 25mg /50mg/100mg Film coated Tablets
Italy	Sildenafil Accord 25mg /50mg/100mg compresse rivestite con film
Latvia	Sildenafil Accord 50mg/100mg apvalkotās tabletes
Lithuania	Sildenafil Accord 50mg/100mg plėvele dengtos tabletės
Sweden	Sildenafil Accord 25mg /50mg/100mg filmdragerade tabletter
The Netherlands	Sildenafil Accord 25mg /50mg/100mg filmomhulde tabletten
UK	Sildenafil Accord 25mg /50mg/100mg

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