

## Sildenafil Actavis 25 mg, 50 mg and 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, 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 Actavis is and what it is used for
2. What you need to know before you take Sildenafil Actavis
3. How to take Sildenafil Actavis
4. Possible side effects
5. How to store Sildenafil Actavis
6. Contents of the pack and other information

#### 1. What Sildenafil Actavis is and what it is used for

Sildenafil Actavis contains the active substance sildenafil which 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 Actavis will only help you to get an erection if you are sexually stimulated. Sildenafil Actavis is a treatment for 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 Actavis

##### Do not take Sildenafil Actavis

- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall 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 medicines known as nitric oxide donors such as amyl nitrite (“poppers”), as the combination may also lead to a dangerous fall 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 Sildenafil Actavis 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

Talk to your doctor, pharmacist or nurse before taking Sildenafil Actavis

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have a deformity of your penis or Peyronie’s Disease.
- If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Sildenafil Actavis and contact your doctor immediately.

You should not use Sildenafil Actavis with any other oral or local treatments for erectile dysfunction.

You should not use Sildenafil Actavis with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take Sildenafil Actavis if you do not have erectile dysfunction.

You should not take Sildenafil Actavis if you are a woman.

##### *Special considerations for patients with kidney or liver problems*

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

##### Children and adolescents

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

##### Other medicines and Sildenafil Actavis

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

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

You should not take Sildenafil Actavis if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall 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 Actavis if you are using any of the medicines known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a dangerous fall 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 Actavis.

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 with alpha-blockers. This is most likely to happen within 4 hours after taking Sildenafil Actavis. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil Actavis. Your doctor may start you on a lower dose (25 mg) of Sildenafil Actavis.

##### Sildenafil Actavis with food and drink and alcohol

Sildenafil Actavis can be taken with or without food. However, you may find that Sildenafil Actavis 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 Actavis.

##### Pregnancy, breast-feeding and fertility

Sildenafil Actavis is not indicated for use by women.

##### Driving and using machines

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

##### Sildenafil Actavis contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking Sildenafil Actavis.

#### 3. How to take Sildenafil Actavis

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 starting dose is 50 mg.

***You should not take Sildenafil Actavis more than once a day.***

You should take Sildenafil Actavis about one hour before sexual activity. Swallow the tablet whole with a glass of water.

If you feel that the effect of Sildenafil Actavis is too strong or too weak, talk to your doctor or pharmacist.

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

If Sildenafil Actavis does 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 Actavis 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, pharmacist or nurse.

#### 4. Possible side effects

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

**If you experience any of the following serious side effects stop taking Sildenafil Actavis 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**

**Other side effects:**

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

**Common** (may affect up to 1 in 10 people): nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

**Uncommon** (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, watery eyes, 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 (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

**Rare** (may affect up to 1 in 1,000 people): fainting, stroke, heart attack, irregular heartbeat, 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 and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, most, but not all, 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 sildenafil.

#### Reporting of side effects

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

#### Ireland

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

#### United Kingdom

Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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

#### 5. How to store Sildenafil Actavis

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.

Store below 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 Sildenafil Actavis contains

- The active substance is sildenafil. Each tablet contains 25 mg, 50 mg or 100 mg of sildenafil (as citrate).
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone K29-32, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol 6000, indigo carmine aluminium lake (E132).

##### What Sildenafil Actavis looks like and contents of the pack

Film-coated tablet

Sildenafil Actavis 25 mg film-coated tablets are blue elliptical, biconvex, 10.0 x 5.0 mm and marked "SL25" on one side. Sildenafil Actavis 50 mg film-coated tablets are blue elliptical, biconvex, 13.0 x 6.5 mm and marked "SL50" on one side. Sildenafil Actavis 100 mg film-coated tablets are blue elliptical, biconvex, 17.0 x 8.5 mm and marked "SL100" on one side.

The tablets are provided in blister packs containing 1, 2, 4, 8, 12 or 24 tablets.

Some pack sizes may not be marketed in your country.

##### Marketing Authorisation Holder and Manufacturer

*Marketing Authorisation Holder*  
Actavis Group PTC ehf.  
Reykjavíkurvegi 76-78  
IS-220 Hafnarfjörður  
Iceland

*Manufacturer*  
Actavis Ltd.  
BLB 016 Bulebel Industrial Estate  
Zejtun ZTN 3000  
Malta

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### Ireland

Actavis Ireland Limited  
Tel: + 353 (0)21 4619040

#### United Kingdom

Actavis UK Limited  
Tel: + 441271385257

**This leaflet was last revised in June 2016**

##### Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu/>.

## **Package Leaflet: Information for the user**

Tadalafil 10 mg film-coated tablets  
Tadalafil

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

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

#### **1. What Tadalafil is and what it is used for**

Tadalafil contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Tadalafil is used to treat adult men with:

**Erectile dysfunction.** This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation Tadalafil works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. Tadalafil will not help you if you do not have erectile dysfunction. It is important to note that Tadalafil does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

#### **2. What you need to know before you take Tadalafil**

##### **Do not take Tadalafil if you:**

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines ("nitrates") used in the treatment of angina pectoris ("chest pain"). Tadalafil has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have serious heart disease or recently had a heart attack within the last 90 days.
- have recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".

- 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 tadalafil, 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 Tadalafil.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor.

Before taking the tablets, tell your doctor if you have:

- sickle cell anaemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis or unwanted or persistent erections lasting more than 4 hours
- a serious liver problem.
- a severe kidney problem.

It is not known if Tadalafil is effective in patients who have had:

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking Tadalafil and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Tadalafil and contact your doctor immediately.

**Tadalafil should not be used as treatment of erectile dysfunction by women because these are health problems specific to men.**

### **Children and adolescents**

Tadalafil is not intended for use by children and adolescents under the age of 18.

### **Other medicines and Tadalafil**

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

Do not take Tadalafil if you are already taking nitrates.

Some medicines may be affected by Tadalafil or they may affect how well Tadalafil will work. Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- riociguat.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.

- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin , clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

#### **Tadalafil with drink and alcohol**

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well Tadalafil will work and should be taken with caution. Talk to your doctor for further information.

#### **Pregnancy, breastfeeding and Fertility**

##### **Pregnancy**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not take tadalafil when pregnant, unless it is strictly necessary and you have discussed this with your doctor.

##### **Breastfeeding**

Do not breastfeed while taking these tablets as it is not known if the medicine passes into human breast milk. Ask your doctor or pharmacist for advice before taking any medicine while pregnant or breastfeeding.

##### **Fertility**

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

##### **Driving and using machines**

Some men taking tadalafil in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

##### **Tadalafil contains lactose:**

If you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take Tadalafil**

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

Swallow the tablet whole with some water. The tablets can be taken with or without food.

##### **To treat erectile dysfunction**

**The recommended starting dose** is one 10 mg tablet before sexual activity. If the effect of this dose is too weak your doctor may increase the dose to 20 mg. Tadalafil tablets are for oral use.

You may take a Tadalafil tablet at least 30 minutes before sexual activity. Tadalafil may still be effective up to 36 hours after taking the tablet.

Do not take Tadalafil more than once a day. Tadalafil 10 mg and 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

It is important to note that Tadalafil does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction. Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Tadalafil, avoid excessive

drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

**If you take more Tadalafil than you should**

If you or anyone else takes more tablets than they should, tell your doctor or go to a hospital immediately, taking the medicine or pack with you. You may experience side effects described in section 4.

**If you forget to take Tadalafil**

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take Tadalafil more than once a day.

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. These effects are normally mild to moderate in nature.

**If you experience any of the following side effects stop using the medicine and seek medical help immediately:**

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- priapism, a prolonged and possibly painful erection after taking Tadalafil (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (frequency rare).

Other side effects have been reported:

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

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, and indigestion.

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

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired..

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

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking Tadalafil. Most of these men had known heart problems before taking this medicine.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

**Some additional rare side effects** have been reported in men taking Tadalafil that were not seen in clinical trials. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

The side effects dizziness have been reported more frequently in men over 75 years of age taking Tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking Tadalafil.

### **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 Yellow Card Scheme Website:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

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

## **5. How to store Tadalafil**

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 blister or carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature 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 Tadalafil contains**

- The **active substance** is tadalafil.  
Each film-coated tablet contains 10 mg tadalafil.
- The **other ingredients** are:  
**Tablet core:**  
Lactose monohydrate, Croscarmellose sodium, Hypromellose, cellulose microcrystalline, Sorbitan stearate and Magnesium stearate  
**Film-coating:**  
Lactose monohydrate, Hypromellose, Titanium dioxide (E171), Triacetin, Talc and Iron oxide yellow (E172).

### **What Tadalafil look like and contents of the pack**

Light yellow, capsule shaped, approximately 11 mm in length and 5.5 mm in width, biconvex, bevelled edged, film coated tablet, debossed with "T 10" on one side and plain on other side.

Tadalafil is available in PVC/PE/PVdC clear Aluminium blister.

Pack size: 4, 14, 28, 30 tablets

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

**Manufacturer**

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

Wessling Hungary Kft  
Főti út 56., Budapest 1047,  
Hungary

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

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

Country	Invented Name
United Kingdom	Tadalafil 2.5/5/10/20 mg Film-coated Tablets
Austria	Tadalafil Accord 5/10/20 mg Filmtabletten
Bulgaria	Tadalafil Акорд 2.5/5/10/20 мг филмирани таблетки
Cyprus	Tadalafil Accord 5/20 mg Film-coated Tablets
Czech	Tadalafil Accord 5/20 mg potahované tablety
Germany	Tadalafil Accord 5/20 mg Filmtabletten
Denmark	Tadalafil Accord
Estonia	Tadalafil Accord
Finland	Tadalafil Accord 2.5/5/10/20 mg tabletti kalvopäällysteinen/ filmdragerad tablet
Italy	Tadalafil Accord
Ireland	Tadalafil 5/10/20 mg Film-coated Tablets
Lithuania	Tadalafil Accord 5/10/20 mg plėvele dengtos tabletės
Latvia	Tadalafil Accord 20 mg apvalkotās tabletes
Netherlands	Tadalafil Accord 5/10/20 mg, filmomhulde tabletten
Norway	Tadalafil Accord
Poland	Tadalafil Accord
Sweden	Tadalafil Accord 2.5/5/10/20 mg filmdragerad tablet
Slovakia	Tadalafil Accord 2,5 mg/ 5 mg/ 10 mg/ 20 mg filmom obalené tablety
France	TADALAFIL ACCORD 2,5 mg,/ 5 mg,/ 10 mg,/ 20 mg, comprimé pelliculé

**This leaflet was revised in 06/2017.**



## **Package Leaflet: Information for the user**

**Vardenafil 5 mg tablets**

**Vardenafil 10 mg tablets**

**Vardenafil 20 mg tablets**

vardenafil

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- 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**

Vardenafil 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 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 Vardenafil**

##### **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.
- 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 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 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.

### **Take special care with Vardenafil**

- 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 ).
- If you experience sudden decrease or loss of vision, 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**

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 could seriously affect your blood pressure. Talk to a doctor without taking Vardenafil.
- 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 Vardenafil.
- 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 tablets combined with any other treatment for erectile dysfunction.

### **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 and breast-feeding**

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.

### **Vardenafil contains aspartame (E951)**

Vardenafil contains aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria. If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism) talk to your doctor before you start to take this medicine.

### 3. How to take Vardenafil

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 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** 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.

### 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 Vardenafil 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
- 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

**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*)

### **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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). 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 after “EXP”. The expiry date refers to the last day of that month.

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 contains**

- The active substance is vardenafil.  
Vardenafil is available in three strengths, containing either 5 mg, 10 mg or 20 mg of vardenafil (as hydrochloride).
- The other ingredients of the tablets are:  
Cellulose microcrystalline  
Crospovidone  
Silica colloidal anhydrous  
Aspartame (E951)  
Titanium dioxide (E171)  
Iron oxide red (E172)  
Iron oxide yellow (E172)  
Magnesium Stearate

#### **What Vardenafil looks like and contents of the pack**

Vardenafil 5 mg is presented as 6 mm orange, round, biconvex tablets marked “5” on one side.

Vardenafil 10 mg is presented as 7 mm orange, round, biconvex tablets marked “10” on one side.

Vardenafil 20 mg is presented as 9 mm orange, round, biconvex tablets marked “20” on one side.

The tablets are provided in 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 :

Rivopharm UK Ltd.

30<sup>th</sup> Floor, 40 Bank Street, Canary Wharf

E14 5NR, London  
United Kingdom

Manufacturer:

Rivopharm UK Ltd.  
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United Kingdom

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