

Package leaflet: Information for the user

CIALIS 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.

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

1. What CIALIS is and what it is used for

CIALIS is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. CIALIS has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

CIALIS contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation CIALIS 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. CIALIS will not help you if you do not have erectile dysfunction.

It is important to note that CIALIS 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 CIALIS

Do not take CIALIS 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"). CIALIS 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.
- 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 CIALIS, 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 before taking CIALIS.

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.
- a serious liver problem.
- a severe kidney problem.

It is not known if CIALIS 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 CIALIS 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 CIALIS and contact your doctor immediately.

CIALIS is not intended for use by women.

Children and adolescents

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

Other medicines and CIALIS

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

Do not take CIALIS if you are already taking nitrates.

Some medicines may be affected by CIALIS or they may affect how well CIALIS 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.

CIALIS with drink and alcohol

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

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

CIALIS contains lactose:

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

3. How to take CIALIS

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

CIALIS tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

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. CIALIS tablets are for oral use.

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

Do not take CIALIS more than once a day. CIALIS 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 CIALIS 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 CIALIS, 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 CIALIS than you should

Contact your doctor. You may experience side effects described in section 4.

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 CIALIS (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 (seen in 1 to 10 in every 100 patients)

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

Uncommon (seen in 1 to 10 in every 1,000 patients)

- 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 (seen in 1 to 10 in every 10,000 patients)

- 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 CIALIS. 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 CIALIS 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 effect dizziness has been reported more frequently in men over 75 years of age taking CIALIS. Diarrhoea has been reported more frequently in men over 65 years of age taking CIALIS.

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 national reporting system

United Kingdom: Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or **Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. **Malta:** ADR Reporting, Website:

www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CIALIS

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

Store in the original package in order to protect from moisture. Do not store above 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 CIALIS contains

- The **active** substance is tadalafil. Each tablet contains 10 mg of tadalafil.
- The **other ingredients** are:
Tablet core: lactose monohydrate (see end of section 2), croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurilsulfate, magnesium stearate.
Film-coat: lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), iron oxide yellow (E172), talc.

What CIALIS looks like and contents of the pack

CIALIS 10 mg is a light yellow film-coated tablet in the shape of an almond and has "C 10" marked on one side.

CIALIS 10 mg is available in blister packs containing 4 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

Manufacturer: Lilly S.A., Avda. de la Industria 30, 28108 Alcobendas, Madrid, Spain.

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

United Kingdom

Eli Lilly and Company Limited
Tel: + 44-(0) 1256 315000

Ireland

Eli Lilly and Company (Ireland) Limited
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Malta

Charles de Giorgio Ltd.
Tel: + 356 25600 500

This leaflet was last revised in February 2017.

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

Package leaflet: Information for the patient

Spedra 50 mg tablets
Spedra 100 mg tablets
Spedra 200 mg tablets

avanafil

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

1. What Spedra is and what it is used for

Spedra contains the active substance avanafil. It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. Spedra is a treatment for adult men suffering from erectile dysfunction (also known as impotence). This is when you cannot get, or keep a hard, erect penis suitable for sexual activity.

Spedra works by helping the blood vessels in your penis to relax. This increases the blood flow into your penis, helping it stay hard and erect when you get sexually excited. Spedra does not cure your condition.

It is important to note that Spedra only works if you are sexually stimulated. You and your partner will still need to use foreplay to get ready for sex – just as you would if you were not taking a medicine to help you.

Spedra will not help you if you do not have erectile dysfunction. Spedra is not for women.

2. What you need to know before you take Spedra

Do not take Spedra:

- If you are allergic to avanafil or any of the other ingredients of this medicine (listed in section 6)
- If you are taking “nitrate” medicines for chest pain (angina), such as amyl nitrite or glyceryl trinitrate. Spedra can increase the effects of these medicines and severely lower your blood pressure
- If you are taking medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir

- If you are taking medicines for fungal infections such as ketoconazole, itraconazole or voriconazole or certain antibiotics for bacterial infections, such as clarithromycin or telithromycin
- If you have a serious cardiac problem
- If you have had a stroke or heart attack in the last 6 months
- If you have low blood pressure or high blood pressure not controlled by medicines
- If you have chest pain (angina) or you get chest pain during sexual intercourse
- If you have a serious liver or kidney problem
- If you have loss of vision in one eye due to not enough blood getting to your eye (non-arteritic ischemic optic neuropathy [NAION])
- If certain serious eye problems run in your family (such as retinitis pigmentosa).
- If you are taking riociguat. This medicine 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 have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Do not take Spedra if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Spedra.

Warnings and precautions

Talk to your doctor or pharmacist before taking Spedra:

- If you have heart trouble. It may be risky for you to have sexual intercourse
- If you suffer from priapism, that is a persistent erection lasting 4 hours or more. This can happen in men with conditions like sickle cell disease, multiple myeloma or leukaemia.
- If you have a physical condition that affects the shape of your penis (such as angulation, Peyronie's disease or cavernosal fibrosis)
- If you have any bleeding disorder or active peptic ulceration.

If any of the above apply to you talk to your doctor or pharmacist before taking Spedra. Check with your doctor or pharmacist if you are not sure.

Problems with your sight or hearing

Some men taking medicines like Spedra have had problems with their sight and hearing – see “Serious side effects” in section 4 for more details. It is not known if these problems are related directly to Spedra, other diseases that you may have or a combination of factors.

Children and adolescents

Spedra should not be taken by children and adolescents under 18 years of age.

Other medicines and Spedra

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Spedra can affect the way some other medicines work. Also some other medicines can affect the way Spedra works.

In particular, tell your doctor and do not take Spedra if you are taking “nitrate” medicines for chest pain (angina) such as amyl nitrite or glyceryl trinitrate. Spedra has been shown to increase the effects of these medicines and severely lower your blood pressure. Also do not take Spedra if you are taking medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir or if you are taking medicines for fungal infections such as ketoconazole, itraconazole or voriconazole or certain antibiotics for bacterial infections, such as clarithromycin or telithromycin (see beginning of section 2 under ‘Do not take Spedra’).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- so called “alpha-blockers” – for prostate problems or for lowering your high blood pressure
- medicines for an irregular heartbeat (“arrhythmia”) such as quinidine, procainamide, amiodarone or sotalol
- antibiotics for infections such as erythromycin
- phenobarbital or primidone – for epilepsy
- carbamazepine – for epilepsy, to stabilise your mood or for certain types of pain
- other medicines that may reduce the breakdown of Spedra in the body (‘moderate CYP3A4 inhibitors’) including amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir, and verapamil.
- riociguat

Do not use Spedra together with other treatments for erectile dysfunction such as sildenafil, tadalafil or vardenafil.

If any of the above apply to you talk to your doctor or pharmacist before taking Spedra. Check with your doctor or pharmacist if you are not sure.

Spedra with drink and alcohol

Grapefruit juice can increase exposure to the medicine and should be avoided within 24 hours prior to taking Spedra.

Drinking alcohol at the same time as taking Spedra may increase your heart rate and lower your blood pressure. You may feel dizzy (especially when standing), have a headache or feel your heart beating in your chest (palpitations). Drinking alcohol may also decrease your ability to get an erection.

Fertility

There was no effect on sperm movement or structure after single 200 mg oral doses of avanafil in healthy volunteers.

The repeated oral administration of avanafil 100 mg over a period of 26 weeks to healthy volunteers and adult males with mild erectile dysfunction was not associated with any untoward effects on sperm concentration, count, motility, or morphology.

Driving and using machines

Spedra can make you feel dizzy or affect your vision. If this happens, do not drive, cycle, use tools or machines.

3. How to take Spedra

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 a 100 mg tablet, as needed. You should not take Spedra more than once a day. You could have been given the dose of one 200 mg tablet if your doctor has decided that the 100 mg dose was too weak for you, or the dose of one 50 mg tablet if your doctor has decided that the 100 mg tablet was too strong for you. Dose adjustments can also be required if Spedra is used together with certain other medicines. If you are taking a medicine such as erythromycin, amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir or verapamil (‘moderate CYP3A4 inhibitors’) the recommended dose of Spedra is a 100 mg tablet, with an interval of at least 2 days between doses.

You should take Spedra about 30 minutes (50 mg) or approximately 15 to 30 minutes (100 mg and 200 mg) before you have sexual intercourse. Remember that Spedra will only help you to get an erection if you are sexually stimulated.

Spedra can be taken with or without food; if taken with food, it may take longer to work.

If you take more Spedra than you should

If you take too much Spedra, you should tell your doctor straight away. You may get more side effects than usual and they may be worse.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Stop taking Spedra and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- an erection that will not go away (“priapism”). If you get an erection that lasts more than 4 hours, this must be treated as soon as possible or lasting damage can happen to your penis (including not being able to get erections).
- blurred vision.
- sudden decrease or loss of vision in one or both eyes.
- sudden decrease or loss of hearing (sometimes you may also feel dizzy or have ringing in your ears).

Stop taking Spedra and see a doctor straight away, if you notice any of the serious side effects above.

Other side effects include:

Common (may affect up to 1 in 10 people)

- headache
- flushing
- nasal congestion

Uncommon (may affect up to 1 in 100 people)

- feeling dizzy
- feeling sleepy or very tired
- sinus congestion
- back pain
- hot flush
- feeling out of breath when you exert yourself
- heartbeat changes seen on a heart tracing (ECG)
- increased heart beat
- feeling your heartbeat in your chest (palpitations)
- indigestion, feeling or being sick to your stomach
- blurry vision
- raised liver enzymes

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

- influenza
- influenza-like illness
- stuffy or runny nose
- hayfever
- congestion in the nose, sinuses or upper part of the airway bringing air into the lungs
- gout

- trouble sleeping (insomnia)
- premature ejaculation
- feeling strange
- feeling unable to keep still
- chest pain
- serious chest pain
- fast heart beat
- high blood pressure
- dry mouth
- stomach ache or heartburn
- pain or discomfort in the lower abdomen
- diarrhoea
- rash
- pain in the lower back or side of lower chest
- muscle aches or pains
- muscle spasms
- frequent urination
- penile disorder
- spontaneous erection without sexual stimulation
- itching in the genital area
- feeling weak or tired all the time
- swelling in the feet or ankles
- increased blood pressure
- pink or red urine, blood in the urine
- abnormal extra sound from the heart
- an abnormal blood test result for a prostate test called 'PSA'
- an abnormal blood test result for bilirubin, a chemical produced from the normal breakdown of red blood cells
- an abnormal blood test result for creatinine, a chemical excreted in the urine, and a measure of kidney function
- weight gain
- fever
- nosebleed

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Spedra

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 and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

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 Spedra contains

- The active substance is avanafil. Each tablet contains 50 mg, 100 mg or 200 mg of avanafil.
- The other ingredients are mannitol, fumaric acid, hydroxypropylcellulose, hydroxypropylcellulose low substituted, calcium carbonate, magnesium stearate and ferric oxide yellow (E172).

What Spedra looks like and contents of the pack

Spedra is a pale yellow oval tablet, marked “50”, “100” or “200” on one side.

50 mg tablets: The tablets are provided in perforated unit dose blister packs containing 4x1, 8x1, or 12x1 tablets.

100 mg tablets: The tablets are provided in perforated unit dose blister packs containing 2x1, 4x1, 8x1, or 12x1 tablets.

200 mg tablets: The tablets are provided in perforated unit dose blister packs containing 2x1, 4x1, 8x1, or 12x1 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder:

MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A., 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg.

Manufacturer:

Menarini - Von Heyden GmbH
Leipziger Straße 7-13
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Germany.

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

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Slovenija

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Berlin-Chemie AG - obchodné zastúpenie v SR
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This leaflet was last revised in 04/2018.

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

VIAGRA®
25 mg, 50 mg or 100 mg film-coated tablets
Sildenafil

Package leaflet: Information for the patient

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

1. What VIAGRA is and what it is used for

VIAGRA contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) 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. VIAGRA will only help you to get an erection if you are sexually stimulated.

VIAGRA 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 VIAGRA

Do not take VIAGRA

- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
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- 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 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

Talk to your doctor, pharmacist or nurse before taking VIAGRA

- 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 VIAGRA and contact your doctor immediately.

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

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

You should not take VIAGRA if you do not have erectile dysfunction.

You should not take VIAGRA 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

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

Other medicines and VIAGRA

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

VIAGRA 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

VIAGRA and when you did. Do not take VIAGRA with other medicines unless your doctor tells you that you can.

You should not take VIAGRA 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 VIAGRA 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 VIAGRA.

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

VIAGRA with food and drink and alcohol

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

Pregnancy, breast-feeding and fertility

VIAGRA is not indicated for use by women.

Driving and using machines

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

VIAGRA 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 VIAGRA.

3. How to take VIAGRA

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 VIAGRA more than once a day.

Do not take VIAGRA film-coated tablets in combination with VIAGRA orodispersible tablets.

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

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

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

If VIAGRA 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 VIAGRA 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 VIAGRA are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking VIAGRA 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 VIAGRA.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Malta

www.medicinesauthority.gov.mt/adrportal

5. How to store VIAGRA

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

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
Store in the original package, in order to protect from moisture.

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 VIAGRA contains

- The active substance is sildenafil. Each tablet contains 25 mg, 50 mg or 100 mg of sildenafil (as the citrate salt).
- The other ingredients are:
 - Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate
 - Film coat: hypromellose, titanium dioxide (E171), lactose monohydrate, triacetin, indigo carmine aluminium lake (E132)

What VIAGRA looks like and contents of the pack

VIAGRA film-coated tablets are blue, with a rounded-diamond shape. They are marked “PFIZER” on one side and “VGR 25”, “VGR 50” or “VGR 100” on the other side. The tablets are provided in blister packs containing 2, 4, 8, 12 or 24 tablets. Some pack sizes may not be marketed in your country.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder of VIAGRA is Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

The manufacturer of VIAGRA is Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

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

Ireland

Pfizer Healthcare Ireland
Tel: 1800 633 363 (toll free)
Tel: +44 (0)1304 616161

Malta

V.J. Salomone Pharma Ltd.
Tel: + 356 21 22 01 74

United Kingdom

Pfizer Limited
Tel: +44 (0)1304 616161

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.