

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 (typical signs are dizziness, fainting, blurred vision, nausea and tiredness), 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.
- Additional side effects reported from post-marketing experience: Unstable angina (a heart condition) and sudden death have been reported rarely. 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 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 at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sildenafil orodispersible film

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.

Store in the original package, in order to protect from moisture. This medicinal product 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 Sildenafil orodispersible film contains

The active substance is sildenafil (as citrate). Each orodispersible film contains 50 mg, sildenafil (as citrate).

The other ingredients are maltodextrin, glycerol, polysorbate 20, propylene glycol monocaprylate, polyvinyl acetate dispersion 30%, lemon and grapefruit flavours (lemon essential oil, citral, linalool, grapefruit essential oil, orange essential oil, nootkaton, butylated hydroxyanisol E320, ascorbic acid E300, maltodextrin, arabic gum (E414), sucralose, titanium dioxide (E171), indigotine (E132).

What Sildenafil orodispersible film looks like and contents of the pack

Sildenafil orodispersible films 50mg are square, flexible, light blue film strips (30 mm x 30 mm). The orodispersible films are provided in packs containing 2, 4 or 8 sachets. Each sachet contains one orodispersible film. Not all pack sizes may be marketed.

Marketing Authorisation Holder

IBSA Farmaceutici Italia S.r.l.,
Via Martiri di Cefalonia 2,
26900 Lodi, Italy

Distributed by

The Boots Company PLC,
Nottingham, NG2 3AA

Manufacturer

Altergon Italia S.r.l.,
Zona Industriale, 83040
Morra de Sanctis (AV), Italy

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Package leaflet: Information for the user



Sildenafil 50mg Orodispersible Film

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

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you have taken Sildenafil orodispersible film as directed and were not able to get or keep an erection firm enough for sex.

What is in this leaflet

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

1. What Sildenafil orodispersible film is and what it is used for

The name of your medicine is Sildenafil 50mg orodispersible film. Sildenafil orodispersible film 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 and causing an erection. Sildenafil orodispersible film will only help you to get an erection if you are sexually stimulated. Sildenafil orodispersible film 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 orodispersible film Do not take Sildenafil orodispersible film if you:

- do not have an erection problem
- take any nitrate medicine for chest pain or heart failure (see "Other medicines and Sildenafil orodispersible film")
- take amyl nitrite, so called "poppers" as recreational drugs
- take riociguat (or other guanylate cyclase stimulators) for high blood pressure in the lungs (see "Other medicines and Sildenafil orodispersible film")
- take ritonavir for the treatment of HIV (see "Other medicines and Sildenafil orodispersible film")
- have been advised by your doctor to avoid sexual activity because of a problem with your heart or blood vessels (see "Warnings and precautions")
- have a severe heart problem such as recent heart attack or stroke (within the last 6 months), unstable angina (chest pain) or severe cardiac failure (reduced pumping capacity of the heart)
- have a severe liver problem
- have low blood pressure (below 90/50 mmHg) which can cause symptoms such as tiredness, dizziness, light-headedness, feeling sick, clammy skin, depression, loss of consciousness, or blurry vision
- have ever had severe vision loss because of nerve damage in the eyes, such as nonarteritic anterior ischaemic optic neuropathy (NAION); or have a rare inherited eye disease, such as retinitis pigmentosa (see "Warnings and precautions")
- have a deformed penis
- are a woman
- are under 18 years of age
- are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

You should schedule a health check-up with your doctor as soon as possible within the first 6 months of starting to use Sildenafil orodispersible film to ensure that your erection problems are not caused by any serious health condition.

Erectile dysfunction may be an early sign of:

- cardiovascular disease
- diabetes
- high blood pressure
- high cholesterol

Tell your doctor about your problems if you have not already done so.

Talk to your doctor before taking Sildenafil orodispersible film if you:

- get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex.
- have a problem with a valve in your heart (valvular heart disease)
- have a disease in which the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy).

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- have an irregular heartbeat (arrhythmia).
- you have had surgery to improve blood flow to your heart, or you have high blood pressure which is now adequately treated.
- have high blood pressure that is not controlled.
- have ever had an erection that lasted more than 4 hours (priapism). Some conditions can increase the probability of having a persistent erection, such as sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow). Use of impotence medicines may increase the risk of priapism. Long lasting erection may cause damage to the tissue in the penis and permanent loss of ability to have an erection.
- currently have a stomach ulcer, or bleeding problems (such as haemophilia).
- have previously been diagnosed with mild to moderate liver disease, or severe kidney problems. Sildenafil orodispersible film may not be suitable for you, you should consult your doctor before taking Sildenafil orodispersible film.
- experience sudden decrease or loss of vision, stop taking Sildenafil orodispersible film and contact your doctor immediately. Cases of visual effects have been reported when using Sildenafil orodispersible film.

Children and adolescents

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

Other medicines and Sildenafil orodispersible film

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Sildenafil orodispersible film or they may affect how Sildenafil orodispersible film works and this may result in side effects.

Do not take Sildenafil orodispersible film if you take:

- Nitrate medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) for chest pain (angina pectoris) or heart failure or "poppers" as recreational drugs (nitric oxide donors (such as amyl nitrite), nicorandil or sodium nitropruside). This is because these substances could lead to a dangerous fall in blood pressure if taken together with Sildenafil orodispersible film.
- Riociguat (or other medicines of a group called guanylate cyclase stimulators). Riociguat is used to treat high blood pressure in the lungs and can lead to a dangerous fall in blood pressure if taken together with Sildenafil orodispersible film.
- A medicine to treat HIV-infections called Ritonavir. Do not take Sildenafil orodispersible film if you are taking ritonavir since this combination can lead to a dangerous fall in blood pressure.

Talk to your pharmacist or doctor before using Sildenafil orodispersible film if you are taking:

- Medicines to treat fungal infections and antibiotics: Medicines to treat fungal infections called itraconazole or ketoconazole and an antibiotic called erythromycin increase the concentration of Sildenafil orodispersible film in the body and may result in side effects. You should contact your doctor before taking Sildenafil orodispersible film if you are using these medicines.
- Heartburn treatment medicine called cimetidine as this increases the concentration of Sildenafil in the body and may result in side effects. You should contact your doctor before taking Sildenafil orodispersible film.
- Other treatments for erectile dysfunction as the safety and efficacy of combinations of Sildenafil orodispersible film with other treatments for erectile dysfunction have not been studied and this combination is therefore not recommended.
- Alpha-blockers used to treat high blood pressure or urinary problems due to enlarged prostate (such as alfuzosin, doxazosin or tamsulosin) may lead to dizziness, lightheadedness, nausea, fainting, lack of concentration, or blurred vision due to low blood pressure (symptomatic hypotension).
- Medicines containing sacubitril/valsartan, used to treat heart failure. You should contact your doctor or pharmacist before taking Sildenafil orodispersible film.

In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken Sildenafil orodispersible film and when you did.

Sildenafil orodispersible film with food, drink and alcohol

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

Do not take Sildenafil orodispersible film with grapefruit or grapefruit juice, because this can affect how the medicine works.

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 orodispersible film.

Pregnancy, breast-feeding and fertility

Sildenafil orodispersible film should not be used by women.

Driving and using machines

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

3. How to take Sildenafil orodispersible film

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take one 50 mg film, as needed, approximately 1 hour before sexual activity.

Do not take Sildenafil orodispersible film more than once a day.

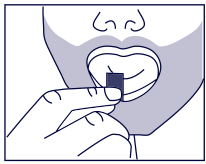
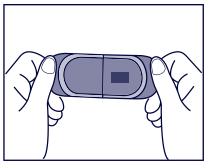
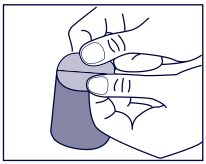
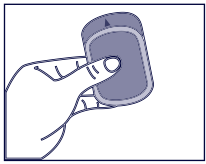
Sildenafil orodispersible films are for oral use and are taken without water. If desired you may also take Sildenafil orodispersible film with water.

The amount of time this medicine takes to work varies from person to person, but it normally takes between 30 to 60 minutes. You may take it up to 4 hours before sexual activity.

Instructions for use

Important: Do not handle the orodispersible film with wet hands!

- a) Take a sachet, locate the arrow mark on the top of the sachet and hold it with this side facing up. The sachet is not sealed here.
- b) Gently peel both parts of the sachet. Now you can hold each between your thumb and your index finger using one hand for each part.
- c) Carefully tear both parts of the sachet into opposite directions until they are separated. The orodispersible film is now visible and placed on one of the separated sachet parts.
- d) Take the orodispersible film with dry fingers out of the sachet and put it in your mouth directly on your tongue. It will dissolve rapidly, so that it can be easily swallowed.



Sildenafil orodispersible film will only help you to get an erection if you are sexually stimulated. You and your partner should engage in foreplay just as you would if you were not taking a medicine for erectile dysfunction. The amount of time Sildenafil orodispersible film takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Sildenafil orodispersible film takes longer to work if you take it with a heavy meal.

Relax and be patient if Sildenafil orodispersible film does not help you the first time. You can try again later but remember you can only take 1 film a day. For most men, Sildenafil orodispersible film will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take a couple of attempts before you achieve the desired effect. Talk to your doctor if you have tried Sildenafil orodispersible film, and are still not able to get and keep an erection. If you feel the effect of Sildenafil orodispersible film is too strong, talk to your pharmacist or doctor.

If you take more Sildenafil orodispersible film than you should

Contact your pharmacist or doctor immediately if you take more orodispersible films than you should. Taking more than the recommended dose may result in side effects and/or more severe side effects.

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.

The side effects reported in association with the use of Sildenafil orodispersible film are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildenafil orodispersible film 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 such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) - this occurs **rarely**. Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes and 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 or visual disturbance, stuffy nose and dizziness.