

Patient Information Leaflet

Sildenafil 35mg/Tadalafil 10mg/L-Arginine 2.5mg Transmucosal Film

Please read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

- If you have further questions, ask your pharmacist or medical provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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.

What is in this leaflet?

1. What are Sildenafil 35mg/Tadalafil 10mg/L-Arginine 2.5mg Transmucosal Films, and what are they used for?
2. What you need to know before you take Sildenafil 35mg/Tadalafil 10mg/L-Arginine 2.5mg Transmucosal Films tablets
3. How to take Sildenafil 35mg/Tadalafil 10mg/L-Arginine 2.5mg Transmucosal Film tablets
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1. What are Sildenafil 35mg/Tadalafil 10mg/L-Arginine 2.5mg Transmucosal Films, and what are they used for?

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets contain the active substances sildenafil and tadalafil, which belong to a class of medicines called phosphodiesterase type 5 inhibitors. They are used for the treatment of erectile dysfunction in adult men, a common condition which implies difficulties in getting or keeping an erection. There may be physical or psychological causes for erectile dysfunction (ED) or a mixture of both. Whatever the reason is, not enough blood stays in the penis to make it hard and keep it hard.

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets will only work when you are sexually stimulated. They reduce the action of the natural chemical in your body that makes erections go away. Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets allow an erection to last long enough for you to satisfactorily complete sexual activity.

The MHRA has not approved this compounded prescription product.

2. What you need to know before you take Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Films

Do not take Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets.

- If you are allergic to sildenafil, tadalafil 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 take 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”). Sildenafil and Tadalafil have been shown to increase the effects of these medicines. If you are taking nitrates or are unsure, please speak to your GP or pharmacist.
- If you have severe heart disease or recently had a heart attack within the last 90 days.
- If you have recently had a stroke within the last six months.
- If you have low blood pressure or uncontrolled high blood pressure.
- 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 treats 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 and Tadalafil, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure, ask your doctor or pharmacist.

Warnings and precautions

Talk to your pharmacist or medical provider before taking Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets.

Take special care with Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets.

- If you have heart trouble. It may be risky for you to have sex.
- If you suffer from an irregular heartbeat (cardiac arrhythmia) or inherited heart disease affecting your electrocardiogram.
- If you have a physical condition affecting the shape of your 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 have serious liver or kidney problems.
- If you are using any other treatments for erection difficulties (see section Other medicines and sildenafil and tadalafil transmucosal film).

- If you experience a sudden decrease or loss of vision or loss of hearing, stop taking Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets and contact your doctor immediately.
- It is not known if tadalafil is effective in patients who have had pelvic surgery or removal of all or part of the prostate gland in which nerves of the prostate are cut.

Children and adolescents

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets are not intended for use by children or adolescents under 18.

Other medicines and Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Films

Do not use Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets combined with any other treatment for erectile dysfunction.

Please tell your doctor or pharmacist if you have recently used or might use any other medicines, including those 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 Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets could seriously affect your blood pressure.
- Medicine for treating arrhythmias, such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines for HIV.
- Ketoconazole or itraconazole, antifungal 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.

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets with food, drink and alcohol

- You can take Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets 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 Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets. It can interfere with the usual effect of the medicine.
- Alcoholic drinks can make erection difficulties worse.

Pregnancy and breast-feeding

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets are not for use by women.

Driving and using machines

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets might make some people feel dizzy or affect their vision. If you feel dizzy or your vision is affected after taking Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film, Transmucosal Film tablets, don't drive or operate any tools or machines.

3. How do you take Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Films?

Always take as directed by your healthcare provider. Check with your healthcare provider if you are not sure.

The sildenafil 35mg, tadalafil 10mg, L-arginine 2.mg transmucosal film should be taken half an hour before sexual intercourse. The effects should start from half an hour and last up to 36 hours.

The transmucosal buccal film delivers the drug through the buccal mucosa and straight into the bloodstream.

When we talk about buccal mucosa we are referring to the inside of the mouth. But unlike regular tablets and capsules, which you swallow, you attach the film to the inside of the mouth. As soon as it makes contact with the inside of the cheek, it sticks to it immediately and begins to dissolve. The following list of the steps involved in applying a film:

1. Before removing the film, wash your hands thoroughly and dry them to ensure that the film doesn't stick to your fingers.
2. Then carefully peel off the film and, with your fingertip, position it on the inside of the cheek.
3. You will feel that the film immediately sticks to the side of the mouth and starts to dissolve.
4. Try not to swallow any saliva while the film is dissolving. The whole purpose of buccal administration is to allow it to dissolve across the inner lining of the mouth into the bloodstream.
5. Only eat or drink something for up to an hour before and after applying the film.
6. The film should dissolve in less than two minutes and may leave a slight aftertaste, depending on your prescribed transmucosal film.
7. Remember to seal the plastic blister tray to prevent the film from being exposed to air, and either return it to the silver foil envelope or store it in a dark cupboard at room temperature.

To watch a video of how to apply the transmucosal buccal film, please click the following link or scan the QR code.

<https://www.youtube.com/watch?v=ySIOCEqzgvw>



You should not swallow the transmucosal film. This medicine should not be crushed or cut in half.

Do not take more than one dose (one Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets) within 24 hours.

Do not take Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets with any other form of Sildenafil, Tadalafil, Viagra or Cialis.

Do not take Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets more than once daily.

Tell your pharmacist or medical provider if you think that Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets are too strong or too weak. They may suggest a switch to an alternative Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film formulation with a different dose, depending on how well it works for you.

If you take more Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Films, then you should inform your doctor immediately.

Men who take too much Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets may experience more side effects or may get severe back pain.

4. Possible Side Effects

This medicine can cause side effects like all medicines, although not everybody gets them. These effects are generally 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 (frequency uncommon); priapism, a prolonged and possibly painful erection which lasts continuously for more than 4 hours after taking Sildenafil or Tadalafil (frequency rare); sudden loss of vision (frequency rare).

The following categories describe the chance of having a side effect:

Common symptoms (which may affect up to 1 in 10 people) include headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, nausea, indigestion, and visual disturbances.

Uncommon (may affect up to 1 in 100 people) symptoms include dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, 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, 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 Sildenafil and 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 in men taking Sildenafil and Tadalafil were not seen in clinical trials. These include migraine,

swelling of the face, a 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 of dizziness has been reported more frequently in men over 75 years of age taking Sildenafil and Tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking Sildenafil and Tadalafil.

Reporting of side effects

Talk to your pharmacist or medical provider if you get any side effects. This includes any possible side effects not listed in this leaflet. You may also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

5. How to store Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Films

Keep this medicine out of sight and reach of children. Store the film tablets at room temperature (between 18° and 25°C) in the pharmacy's packaging. This means the plastic mould is refolded after removing the film and placing the blister back into the silver foil bag. The effectiveness of the medicine may be affected by exposure to extremes of heat, cold, or humidity. Do not use this medicine after the expiration date stated on the prescription label. 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 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets contain

The active substances are sildenafil, tadalafil, and L-arginine. Each transmucosal film contains 35mg of sildenafil and 10mg of tadalafil. The other ingredients are:

- menthol crystals,
- sucralose,
- silica,
- purified water,
- chondrus crispis (carrageenan) extract
- EDTA
- glycein
- locust bean gum
- mannitol
- potassium sorbate
- pullulan
- sodium benzoate
- polysorbate 80
- xanthan gum

What do Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets look like in the contents of the blister pack?

Sildenafil 35mg/Tadalafil 10mg/Arginine 2.5mg transmucosal buccal film Transmucosal Film tablets are wafer-thin blue film tablets.

7. What does Sildenafil 35mg/Tadalafil 10mg/ L-Arginine 2.5mg Transmucosal Buccal Film look like, and what contents of the pack

This medicine is available in brilliant blue films. There are ten transmucosal films in each blister.

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7. Company Contact Details

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