

Please orally soluble film 50mg (Sildenafil)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.

- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT Please orally soluble film IS AND WHAT IT IS USED FOR

Please orally soluble film 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. Please orally soluble film will only help you to get an erection if you are sexually stimulated. You should not take Please orally soluble film if you do not have erectile dysfunction. You should not take Please orally soluble film if you are a woman.

Please orally soluble film is a treatment for 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. BEFORE YOU TAKE Please orally soluble film

Do not take Please orally soluble film.

- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or "chest pain"). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of Please orally soluble film.
- 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).

Take special care with Please orally soluble film

- Tell your doctor
- 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 in that case 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 Please orally soluble film and contact your doctor immediately.

You should not use Please orally soluble film with any other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents

Please orally soluble film should not be given to individuals under the age of 18.

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.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription.

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

You should not take Please orally soluble film if you are taking medicines called nitrates, as the combination of these products may cause a potentially dangerous decrease in your blood pressure.

Always tell your doctor or pharmacist 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 Please orally soluble film if you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.

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

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

Taking Please orally soluble film with food and drink
Please orally soluble film can be taken with or without food. However, you may find that Please orally soluble film 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 Please orally soluble film.

Pregnancy and Breast feeding

Please orally soluble film is not indicated for use by women.

Driving and using machines

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

Important information about some of the ingredients of Please orally soluble film

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking Please orally soluble film.

3. HOW TO TAKE Please orally soluble film

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

You should not take Please orally soluble film more than once a day.

You should take Please orally soluble film about one hour before you plan to have sex. Take 1 film off the pouch, melting it in tongue without water (or with water).

If you have the impression that the effect of Please orally soluble film is too strong or too weak, talk to your doctor or pharmacist.

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

If Please orally soluble film 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 Please orally soluble film 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 films than your doctor tells you to.

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

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

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4. POSSIBLE SIDE EFFECTS

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

If you have chest pains during or after intercourse:

- Get in a semi-sitting position and try to relax.
- **Do not use nitrates** to treat your chest pain.
- Contact your doctor immediately.

All medicines including Please orally soluble film can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Please orally soluble film: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking Please orally soluble film. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking Please orally soluble film and contact your doctor immediately.

A very common side effect (likely to occur in more than 1 in 10 patients) is:

- **headache**

Common side effects (likely to occur in 1 to 10 patients in 100) include:

- facial flushing
- indigestion
- effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision)
- stuffy nose
- dizziness

Uncommon side effects (likely to occur in 1 to 10 patients in 1000) include:

- vomiting
- skin rash
- bleeding at the back of the eye
- eye irritation
- bloodshot eyes /red eyes
- eye pain
- double vision
- abnormal sensation in the eye
- irregular or rapid heartbeat
- muscle pain
- feeling sleepy
- reduced sense of touch
- vertigo
- ringing in the ears
- nausea
- dry mouth
- chest pain
- feeling tired

Rare side effects (likely to occur in 1 to 10 patients in 10000) include:

- high blood pressure
- low blood pressure
- fainting
- stroke
- nosebleed
- sudden decrease or loss of hearing

Additional side effects reported from post-marketing experience include:

- pounding heartbeat
- chest pain
- sudden death
- heart attack
- temporary decreased blood flow to parts of the brain

Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Please orally soluble film. Cases of convulsions or seizures and serious skin reactions characterized by rash, blisters, peeling skin and pain which require immediate medical attention have also been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor.

5. HOW TO STORE Please orally soluble film

Keep out of the reach and sight of children. Store in a airtight container at room temperature (1-30 °C). Do not use Please orally soluble film after the expiry date which is stated on the carton. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Please orally soluble film contains

- The active substance is sildenafil. Each film contains 50 mg of sildenafil (as free base).
- The other ingredients are:
 - Pullulan, Propylene Glycol Alginate, Xanthan Gum, Concentrated Glycerin, Sodium Chloride, Simethicone Emulsion (30%), Polysorbate 80, Mentha Oil, Kollicoat® IR Brilliant Blue, Kollicoat® IR Carmine, Saccharin Sodium, Sucralose, Purified Water

What Please orally soluble film looks like and contents of the pack

Please orally soluble film 50mg is a blue or light blue, rectangular film (37 × 27 × 0.1 mm)

The film is provided in Laminate sachet of PET/PE/Al/PE/LLDPE. The carton contains 4 films.

Marketing Authorisation Holder, Manufacturer and Packaging

Marketing authorization holder

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Packaging

[Packaged in] Kahál, Lebanon by Pharmadex S.A.L. under license from CTCBIO, S.Korea

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