

Package leaflet: Information for the patient

Sildenafil Ajanta Pharma 50 mg film-coated tablets
Sildenafil Ajanta Pharma 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 or pharmacist. This includes any possible side effects not listed in this leaflet. . See section 4.

What is in this leaflet:

1. What Sildenafil Ajanta Pharma is and what it is used for
2. What you need to know before you take Sildenafil Ajanta Pharma
3. How to take Sildenafil Ajanta Pharma
4. Possible side effects
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1. What Sildenafil Ajanta Pharma is and what it is used for

Sildenafil Ajanta Pharma 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. Sildenafil Ajanta Pharma will only help you to get an erection if you are sexually stimulated.

Sildenafil Ajanta Pharma 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 Ajanta Pharma

Do not take Sildenafil Ajanta Pharma

- 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 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 Ajanta Pharma

- 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 Ajanta Pharma and contact your doctor immediately.

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

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

You should not take Sildenafil Ajanta Pharma 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 Ajanta Pharma should not be given to individuals under the age of 18.

Other medicines and Sildenafil Ajanta Pharma:

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

- Sildenafil Ajanta Pharma 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 Ajanta Pharma and when you did. Do not take Sildenafil Ajanta Pharma with other medicines unless your doctor tells you that you can.

- You should not take Sildenafil Ajanta Pharma 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 Ajanta Pharma 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 medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg).
- 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 Ajanta Pharma with alpha-blockers. This is most likely to happen within 4 hours after taking Sildenafil Ajanta Pharma. 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 Sildenafil Ajanta Pharma. Your doctor may start you on a lower dose (25 mg).

Sildenafil Ajanta Pharma with food and drink and alcohol

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

Pregnancy, breast-feeding and fertility

Sildenafil Ajanta Pharma is not indicated for use by women.

Driving and using machines

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

3. HOW TO TAKE SILDENAFIL AJANTA PHARMA

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 Ajanta Pharma more than once a day.

You should take Sildenafil Ajanta Pharma 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 Sildenafil Ajanta Pharma is too strong or too weak, talk to your doctor or pharmacist.

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

If Sildenafil Ajanta Pharma 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 Ajanta Pharma 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 Ajanta Pharma are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildenafil Ajanta Pharma and seek medical help immediately:

- An allergic reaction (this occurs **rarely**)
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 (**frequency unknown**)
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 (**frequency unknown**)
- Serious skin reactions (**frequency unknown**)
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits (**frequency unknown**)

Other side effects

Very common: headache.

Common (may affect up to 1 in 10 people): facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness.

Uncommon (may affect 1 in 100 people): 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, watery eyes, pounding heartbeat, rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, penile bleeding, presence of blood in semen and/or urine, chest pain and feeling tired.

Rare (may affect up to 1 in 1,000 people): high blood pressure, low blood pressure, fainting, stroke, heart attack, nosebleed and sudden decrease or loss of hearing.

Not known (frequency cannot be estimated from the available data):

Additional side effects reported from post-marketing experience include: Unstable angina (a heart condition), sudden death, temporary decreased blood flow to parts of the brain. 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, 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.

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5. HOW TO STORE SILDENAFIL AJANTA PHARMA

Keep out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package, in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the blister & 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 to protect the environment.

6. Contents of the pack and other information

What Sildenafil Ajanta Pharma contains

- The active substance is sildenafil. Each film-coated tablet contains 50 mg or 100 mg of sildenafil (as the citrate salt).
- The other ingredients are:
 - Tablet core: Sodium Starch Glycolate, Povidone, Microcrystalline Cellulose, Talc, Magnesium Stearate.
 - Film coat: Hypromellose.
Titanium Dioxide (E171), Instacoat Sol IC-S-3788 Green
[Instacoat Sol IC-S-3788 Green comprises of Hypromellose, Polyethylene Glycol, Talc, Lake Brilliant Blue (E133), Lake Quinoline Yellow (E104) and Titanium Dioxide (E171)]

What Sildenafil Ajanta Pharma looks like and contents of the pack

Sildenafil Ajanta Pharma film-coated tablets are green, with an oval shape. They are marked “ap” on one side and “50” or “100” on the other side.

The tablets are provided in blister packs containing 4 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder of Sildenafil Ajanta Pharma is
Ajanta Pharma UK Limited, 2 Cabot House, Compass Point Business Park, St. Ives,
Cambridgeshire, PE27 5JL, UK.

The manufacturer of Sildenafil Ajanta Pharma is
APC Pharmaceuticals & Chemicals (Europe) Ltd, 9th Floor, C P House, 97- 107 Uxbridge Road,
Ealing, London W5 5TL, United Kingdom

Sildenafil Ajanta Pharma 50 mg: PA1747/001/001
Sildenafil Ajanta Pharma 100 mg: PA1747/001/002

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

Ajanta Pharma UK Limited
Tel: 0044 1480465755

This leaflet was last approved in