Package leaflet: information for the patient

Spedra, 50 mg tablets

avanafil

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Spedra and what is it used for?

Spedra contains the active substance avanafil. It belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE5 inhibitors). Spedra is a treatment for adult men with erectile dysfunction (also known as impotence). This is the case when a man cannot achieve or maintain an erection sufficient for sexual activity.

Spedra helps to relax the blood vessels in your penis. This allows more blood to flow into your penis and keeps it hard and erect when you become sexually aroused. Spedra does not cure the condition.

Spedra only works with sexual stimulation. You and your partner still need foreplay as preparation for intercourse – just as you would if you were not using medication to help you.

Spedra does not work if you do not have erectile dysfunction. Spedra is not intended for women.

2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You are using nitrate medicines for chest pain (angina), such as amyl nitrite or glyceryl trinitrate. Spedra can enhance the effect of these medicines and severely lower your blood pressure.
You are using medicines for the treatment of HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir, or atazanavir.
You are using medicines for the treatment of fungal infections such as ketoconazole, itraconazole, or voriconazole, or certain antibiotics for the treatment of bacterial infections, such as clarithromycin or telithromycin.
You have severe heart problems.
You have had a stroke or heart attack in the past six months.
You have low blood pressure or high blood pressure that is not controlled by medication.
You have chest pain (angina) or experience chest pain during intercourse.
You have severe liver or kidney problems.
You have ever had vision loss in one eye due to insufficient blood supply to your eye (non-arteritic anterior ischemic optic neuropathy [NAION]).
Certain serious eye problems (such as retinitis pigmentosa) run in your family.
If you are using riociguat. This medicine is used for the treatment of pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs due to blood clots). It has been shown that PDE5 inhibitors enhance the blood pressure-lowering effect of this medicine. If you are taking riociguat or are unsure, consult your doctor.

Do not use Spedra if any of the above apply to you. If you are not sure, consult your doctor or pharmacist before using Spedra.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before taking this medicine if:
you have heart problems. Sexual intercourse may be risky for you;
you suffer from priapism, an erection lasting four hours or longer. This can occur in men with conditions such as sickle cell disease, multiple myeloma, or leukemia;
you have a physical condition that affects the shape of your penis (such as angulation, Peyronie's disease, or cavernous fibrosis);
you have a bleeding disorder or an active ulcer in the gastrointestinal tract (peptic ulcer).

If any of the above apply to you, consult your doctor or pharmacist before using Spedra. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Problems with your vision or hearing
In some men using medicines like Spedra, problems with vision and hearing have occurred – see “Serious side effects” in section 4 for more details. It is not known whether these problems are directly related to Spedra, other diseases you may have, or a combination of factors.

If you experience sudden reduction or loss of vision or if your vision becomes distorted or worsens while using Spedra, stop taking Spedra and contact your doctor immediately.

Children and adolescents under 18 years
Spedra should not be used in children and adolescents under 18 years.

Are you using any other medicines?
Are you using any other medicines besides Spedra, have you done so recently, or is there a possibility that you will use other medicines soon? Then tell your doctor or pharmacist. This is because Spedra can affect the action of certain other medicines. Also, some other medicines can affect the action of Spedra.

Contact your doctor and do not use Spedra if you are using nitrate medicines for chest pain (angina pectoris), such as amyl nitrite or glyceryl trinitrate. Spedra has been shown to enhance the effect of these medicines and can severely lower your blood pressure. Also, do not use Spedra if you are using medicines for the treatment of HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir, or atazanavir, or if you are using medicines for the treatment of fungal infections, such as ketoconazole, itraconazole, or voriconazole, or certain antibiotics for the treatment of bacterial infections, such as clarithromycin or telithromycin (see the beginning of section 2, under 'When should you not use this medicine?').

It is important to inform the doctor or pharmacist if you are taking any of the following medicines:

so-called "alpha-blockers" – for prostate problems or for lowering high blood pressure;
medicines for an irregular heartbeat (arrhythmia) such as quinidine, procainamide, amiodarone, or sotalol;
antibiotics for the treatment of infections, such as erythromycin;
phenobarbital or primidone – for the treatment of epilepsy;
carbamazepine – for the treatment of epilepsy, mood swings, or certain types of pain;
other medicines that can counteract 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 points apply to you, consult your doctor or pharmacist before using Spedra. Unsure about the correct use? Contact your doctor or pharmacist.

What should you be aware of with drinking and alcohol?
Grapefruit juice can increase the exposure to the medicine. It is advised not to consume grapefruit juice in the 24 hours before taking Spedra.

If you consume alcohol while using Spedra, your heart rate may increase and your blood pressure may drop. You may experience dizziness (especially when standing), headache, or a noticeable heartbeat (palpitations). Drinking alcohol can also reduce your ability to get an erection.

Fertility
In healthy volunteers, no effect on sperm motility or structure was observed after a single oral dose of 200 mg avanafil.

Repeated daily oral administration of 100 mg avanafil over a period of 26 weeks to healthy volunteers and adult men with mild erectile dysfunction was not associated with adverse effects on the concentration, count, motility, or morphology of sperm.

Driving and using machines
Spedra can cause dizziness or affect your vision. If this happens, do not drive vehicles or use tools or machines.

3. How do you take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. Unsure about the correct use? Contact your doctor or pharmacist.

The recommended dose is one 100 mg tablet as needed. Do not use Spedra more than once a day. You may have been given a dose of 200 mg if your doctor decided that a dose of 100 mg was too weak for you, or you may have been given a dose of 50 mg if your doctor decided that a dose of 100 mg was too strong for you. Dose adjustments may also be necessary if Spedra is used in combination with certain other medicines. If you are using a medicine such as erythromycin, amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir, or verapamil (moderate CYP3A4 inhibitors), the recommended dose of Spedra is one 100 mg tablet, to be taken at intervals of at least two days.

Take Spedra approximately 30 minutes before sexual intercourse. Remember that Spedra only helps you get an erection with sexual stimulation.

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

Have you taken too much of this medicine?

If you have used too much Spedra, contact your doctor immediately. You may experience more side effects than usual, and they may be more severe.

Do you have any other questions about the use of Spedra? Then contact 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 using Spedra and contact your doctor immediately if you notice any of the following serious side effects – you may need urgent medical treatment:

- an erection that persists (priapism); if you get an erection that lasts more than four hours, it should be treated as soon as possible to prevent permanent damage to your penis (such as being unable 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 a ringing in your ears).

Stop using Spedra and contact your doctor immediately if you notice any of the above serious side effects.

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 flashes
- shortness of breath when exerting yourself
- heart rate changes shown on an electrocardiogram (ECG)
- accelerated heart rate
- palpitations
- digestive problems, nausea or vomiting
- blurred vision
- elevated liver enzyme levels

Rare (may occur in up to 1 in 1000 people)
- influenza
- influenza-like illness
- stuffy or runny nose
- hay fever
- nasal, sinus, or upper airway congestion that carries air to the lungs
- gout
- sleep problems (insomnia)
- premature ejaculation
- a strange feeling
- inability to sit still
- chest pain
- severe chest pain
- rapid heartbeat
- high blood pressure
- low blood pressure
- dry mouth
- stomach pain or heartburn
- pain or discomfort in the lower abdomen
- diarrhea
- rash
- pain in the lower back or side of the chest
- stabbing or muscle pain

muscle cramps
frequent urination
penile disorder
spontaneous erection without sexual stimulation
itching in the genital area
persistent feeling of weakness or fatigue
swollen feet or ankles
increased blood pressure
pink or red urine, blood in the urine
abnormal extra heart murmur
an abnormal result of a blood test for the prostate, called 'PSA'
an abnormal result of a blood test for bilirubin, a chemical produced during the normal breakdown of red blood cells
an abnormal result of a blood test for creatinine, a chemical excreted in the urine and a measure of kidney function
weight gain
fever
nosebleed

Reporting side effects
If you experience any side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You will find it on the label and the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. Proper disposal of medications ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?
The active substance in this medicine is avanafil. Each tablet contains 50 mg of avanafil.
The other substances in this medicine are mannitol, fumaric acid, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, calcium carbonate, magnesium stearate, and yellow iron oxide (E172).

What does Spedra look like and what is in a package?

Spedra is a light yellow oval tablet, marked with "50" on one side. The tablets are supplied in perforated unit-dose blister packs of 4x1, 8x1, or 12x1 tablets.

Not all pack sizes may be marketed in your country.
Marketing authorization holder:
MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.,
1, Avenue de la Gare
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Manufacturer:
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More information about this medicine is available on the website of the European Medicines Agency (http://www.ema.europa.eu).