Package leaflet: Information for the patient

Spedra 50 mg tablets
Spedra 100 mg tablets
Spedra 200 mg tablets

avanafil

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 or pharmacist.
- 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 Spedra is and what it is used for

Spedra contains the active substance avanafil. It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. Spedra is a treatment for adult men suffering from erectile dysfunction (also known as impotence). This is when you cannot get, or keep a hard, erect penis suitable for sexual activity.

Spedra works by helping the blood vessels in your penis to relax. This increases the blood flow into your penis, helping it stay hard and erect when you get sexually excited. Spedra does not cure your condition.

It is important to note that Spedra only works if you are sexually stimulated. You and your partner will still need to use foreplay to get ready for sex – just as you would if you were not taking a medicine to help you.

Spedra will not help you if you do not have erectile dysfunction. Spedra is not for women.

2. What you need to know before you take Spedra

Do not take Spedra:

- If you are allergic to avanafil or any of the other ingredients of this medicine (listed in section 6)
- If you are taking “nitrate” medicines for chest pain (angina), such as amyl nitrite or glyceryl trinitrate. Spedra can increase the effects of these medicines and severely lower your blood pressure
- If you are taking medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir

- If you are taking medicines for fungal infections such as ketoconazole, itraconazole or voriconazole or certain antibiotics for bacterial infections, such as clarithromycin or telithromycin
- If you have a serious cardiac problem
- If you have had a stroke or heart attack in the last 6 months
- If you have low blood pressure or high blood pressure not controlled by medicines
- If you have chest pain (angina) or you get chest pain during sexual intercourse
- If you have a serious liver or kidney problem
- If you have loss of vision in one eye due to not enough blood getting to your eye (non-arteritic ischemic optic neuropathy [NAION])
- If certain serious eye problems run in your family (such as retinitis pigmentosa).
- If you are taking riociguat. This medicine is used to treat 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 have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Do not take Spedra if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Spedra.

Warnings and precautions

Talk to your doctor or pharmacist before taking Spedra:
- If you have heart trouble. It may be risky for you to have sexual intercourse
- If you suffer from priapism, that is a persistent erection lasting 4 hours or more. This can happen in men with conditions like sickle cell disease, multiple myeloma or leukaemia.
- If you have a physical condition that affects the shape of your penis (such as angulation, Peyronie's disease or cavernosal fibrosis)
- If you have any bleeding disorder or active peptic ulceration.

If any of the above apply to you talk to your doctor or pharmacist before taking Spedra. Check with your doctor or pharmacist if you are not sure.

<u>Problems with your sight or hearing</u>
Some men taking medicines like Spedra have had problems with their sight and hearing – see "Serious side effects" in section 4 for more details. It is not known if these problems are related directly to Spedra, other diseases that you may have or a combination of factors.

Children and adolescents

Spedra should not be taken by children and adolescents under 18 years of age.

Other medicines and Spedra

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Spedra can affect the way some other medicines work. Also some other medicines can affect the way Spedra works.

In particular, tell your doctor and do not take Spedra if you are taking "nitrate" medicines for chest pain (angina) such as amyl nitrite or glyceryl trinitrate. Spedra has been shown to increase the effects of these medicines and severely lower your blood pressure. Also do not take Spedra if you are taking medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir or if you are taking medicines for fungal infections such as ketoconazole, itraconazole or voriconazole or certain antibiotics for bacterial infections, such as clarithromycin or telithromycin (see beginning of section 2 under 'Do not take Spedra').

Tell your doctor or pharmacist if you are taking any of the following medicines:
- so called "alpha-blockers" – for prostate problems or for lowering your high blood pressure
- medicines for an irregular heartbeat ("arrhythmia") such as quinidine, procainamide, amiodarone or sotalol
- antibiotics for infections such as erythromycin
- phenobarbital or primidone – for epilepsy
- carbamazepine – for epilepsy, to stabilise your mood or for certain types of pain
- other medicines that may reduce 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 apply to you talk to your doctor or pharmacist before taking Spedra. Check with your doctor or pharmacist if you are not sure.

Spedra with drink and alcohol

Grapefruit juice can increase exposure to the medicine and should be avoided within 24 hours prior to taking Spedra.
Drinking alcohol at the same time as taking Spedra may increase your heart rate and lower your blood pressure. You may feel dizzy (especially when standing), have a headache or feel your heart beating in your chest (palpitations). Drinking alcohol may also decrease your ability to get an erection.

Fertility

There was no effect on sperm movement or structure after single 200 mg oral doses of avanafil in healthy volunteers.

The repeated oral administration of avanafil 100 mg over a period of 26 weeks to healthy volunteers and adult males with mild erectile dysfunction was not associated with any untoward effects on sperm concentration, count, motility, or morphology.

Driving and using machines

Spedra can make you feel dizzy or affect your vision. If this happens, do not drive, cycle, use tools or machines.

3. How to take Spedra

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is a 100 mg tablet, as needed. You should not take Spedra more than once a day. You could have been given the dose of one 200 mg tablet if your doctor has decided that the 100 mg dose was too weak for you, or the dose of one 50 mg tablet if your doctor has decided that the 100 mg tablet was too strong for you. Dose adjustments can also be required if Spedra is used together with certain other medicines. If you are taking a medicine such as erythromycin, amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir or verapamil ('moderate CYP3A4 inhibitors') the recommended dose of Spedra is a 100 mg tablet, with an interval of at least 2 days between doses.

You should take Spedra about 30 minutes (50 mg) or approximately 15 to 30 minutes (100 mg and 200 mg) before you have sexual intercourse. Remember that Spedra will only help you to get an erection if you are sexually stimulated.

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

If you take more Spedra than you should

If you take too much Spedra, you should tell your doctor straight away. You may get more side effects than usual and they may be worse.

If you have any further questions on the use of Spedra, ask 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 taking Spedra and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- an erection that will not go away ("priapism"). If you get an erection that lasts more than 4 hours, this must be treated as soon as possible or lasting damage can happen to your penis (including not being able 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 ringing in your ears).

Stop taking Spedra and see a doctor straight away, if you notice any of the serious side effects above.

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 flush
- feeling out of breath when you exert yourself
- heartbeat changes seen on a heart tracing (ECG)
- increased heart beat
- feeling your heartbeat in your chest (palpitations)
- indigestion, feeling or being sick to your stomach
- blurry vision
- raised liver enzymes

Rare (may affect up to 1 in 1,000 people)

- influenza
- influenza-like illness
- stuffy or runny nose
- hayfever
- congestion in the nose, sinuses or upper part of the airway bringing air into the lungs
- gout

- trouble sleeping (insomnia)
- premature ejaculation
- feeling strange
- feeling unable to keep still
- chest pain
- serious chest pain
- fast heart beat
- high blood pressure
- dry mouth
- stomach ache or heartburn
- pain or discomfort in the lower abdomen
- diarrhoea
- rash
- pain in the lower back or side of lower chest
- muscle aches or pains
- muscle spasms
- frequent urination
- penile disorder
- spontaneous erection without sexual stimulation
- itching in the genital area
- feeling weak or tired all the time
- swelling in the feet or ankles
- increased blood pressure
- pink or red urine, blood in the urine
- abnormal extra sound from the heart
- an abnormal blood test result for a prostate test called 'PSA'
- an abnormal blood test result for bilirubin, a chemical produced from the normal breakdown of red blood cells
- an abnormal blood test result for creatinine, a chemical excreted in the urine, and a measure of kidney function
- weight gain
- fever
- nosebleed

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance Website: www.hpra.ie.

5. How to store Spedra

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 blister and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

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 Spedra contains

- The active substance is avanafil. Each tablet contains 50 mg, 100 mg or 200 mg of avanafil.
- The other ingredients are mannitol, fumaric acid, hydroxypropylcellulose, hydroxypropylcellulose low substituted, calcium carbonate, magnesium stearate and ferric oxide yellow (E172).

What Spedra looks like and contents of the pack

Spedra is a pale yellow oval tablet, marked "50", "100" or "200" on one side.
50 mg tablets: The tablets are provided in perforated unit dose blister packs containing 4x1, 8x1, or 12x1 tablets.
100 mg tablets: The tablets are provided in perforated unit dose blister packs containing 2x1, 4x1, 8x1, or 12x1 tablets.
200 mg tablets: The tablets are provided in perforated unit dose blister packs containing 2x1, 4x1, 8x1, or 12x1 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder:
MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A., 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg.

Manufacturer:
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.