

SPEDRA®

avanafil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SPEDRA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SPEDRA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SPEDRA is used for

SPEDRA is used to treat erectile dysfunction, more commonly known as impotence, in adult men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.

SPEDRA belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

SPEDRA contains the active ingredient avanafil which works by relaxing the blood vessels in your penis. This increases the blood flow into your penis, helping it stay hard and erect when you get sexually aroused. SPEDRA does not cure your condition.

It is important to note that SPEDRA only works if you are sexually

aroused. SPEDRA will not increase your sex drive.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

Before you take SPEDRA

When you must not take it

Do not take SPEDRA if you have an allergy to:

- any medicine containing avanafil
- any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- rash, itching or hives on the skin.

Do not take SPEDRA if you are taking nitrate medicines which include:

- glyceryl trinitrate (also called nitroglycerin)
- nicorandil
- sodium nitroprusside
- isosorbide mononitrate
- isosorbide dinitrate
- amyl nitrite (also known as poppers, amyl or rush).

SPEDRA has been shown to increase the effects of these

medicines and severely lower your blood pressure.

Do not take SPEDRA if you are taking:

- riociguat, a medicine used to treat high blood pressure in the lungs
- nefazodone, a medicine used to treat depression
- medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir
- medicines for fungal infections such as ketoconazole, itraconazole or voriconazole
- clarithromycin and telithromycin, antibiotics used for bacterial infections.

Because sexual activity may place a strain on your heart, your doctor will need to check whether you are fit enough to take SPEDRA.

Do not take SPEDRA if you have:

- unstable angina (chest pain)
- congestive heart failure
- hypotension (low blood pressure)
- uncontrolled hypertension (high blood pressure)
- ever had loss of vision in one eye due to not enough blood getting to your eyes (non-arteritic ischaemic optic neuropathy-NAION)
- certain serious eye problems that run in your family (such as retinitis pigmentosa)
- serious liver or kidney problems.

Do not take SPEDRA if you have a serious cardiac problem or you have or have had any of the

following conditions within the previous 6 months:

- myocardial infarction (heart attack)
- stroke
- cardiac ischaemia
- serious arrhythmia (irregular heart beat).

Do not give SPEDRA to children, adolescents under 18 years of age, or women.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any heart trouble or blood vessel problems
- a physical condition that affects the shape of your penis (such as angulation, Peyronie's disease or cavernosal fibrosis)
- if you suffer from priapism, which is a persistent erection lasting 4 hours or more. This can happen in men with conditions like sickle cell disease, multiple myeloma or leukaemia
- any bleeding disorder or active peptic ulceration
- kidney or liver problems
- sudden loss of eyesight in one or both eyes
- sudden decrease or loss of hearing
- spinal cord injury or other neurological disorders.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking SPEDRA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and SPEDRA may interfere with each other. These include:

- some antibiotics such as erythromycin and rifampicin
- medicines called alpha-blockers, used for prostate problems or for lowering your high blood pressure e.g. terazosin tamsulosin and prazosin. Concomitant use of SPEDRA with alpha-blockers may contribute to dizziness or fainting
- other antihypertensives e.g. enalapril, amlodipine
- some medicines used to treat seizures such as phenytoin, phenobarbitone and carbamazepine
- efavirenz, a medicine used to treat HIV
- high doses of alcohol
- other medicines that may reduce the breakdown of SPEDRA in the body such as amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir and verapamil
- bosentan, a medicine used to treat pulmonary arterial hypotension
- other treatments for erectile dysfunction.

Grapefruit juice should be avoided within 24 hours prior to taking SPEDRA.

These medicines may be affected by SPEDRA, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist will have a more complete list of medicines to be careful with or avoid while taking SPEDRA.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take SPEDRA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the correct dose for you depending on your condition and response.

The recommended dose is a 100 mg tablet, as needed.

Do not take more than one dose of SPEDRA in a 24-hour period.

How to take it

Swallow the tablet whole with water.

SPEDRA can be taken with or without food.

If SPEDRA is taken with food, there may be a delay in how fast the medicine works compared to taking it on an empty stomach.

When to take it

You should take SPEDRA as needed, approximately 15 to 30 minutes before anticipated sexual activity. Remember that SPEDRA will only help you to get an erection if you are sexually stimulated.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much SPEDRA. Do this even if

there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using SPEDRA

Things you must do

Tell any other doctors, dentists and pharmacists who treat you that you are taking SPEDRA.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking SPEDRA.

If you have emergency treatment for any suspected heart condition, tell the emergency staff that you are taking SPEDRA.

Things you must not do

Do not use the recreational drug amyl nitrate (also known as 'poppers', 'amyl' or 'rush') while you are taking SPEDRA.

If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately or contact your nearest emergency department. Make sure your doctor knows you are taking SPEDRA.

Do not take SPEDRA if you are taking certain medicines used to treat HIV infection.

Do not take more than one dose of SPEDRA per day.

If SPEDRA does not help you get an erection, or if your erection does not last long enough to complete sexual intercourse, tell your doctor.

Do not give your tablets to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

Substantial consumption of alcohol in combination with SPEDRA can increase the potential for symptoms

such as increase in heart rate, decrease in standing blood pressure, dizziness, and headache.

Be careful driving or operating machinery until you know how SPEDRA affects you.

Dizziness or faintness may be worse if you are also taking alpha-blockers.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SPEDRA.

SPEDRA helps most men with erectile dysfunction, but it may have unwanted side effects in some people. All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- flushing
- dizziness or light-headedness
- nasal or sinus congestion
- feeling sleepy or very tired
- back pain
- indigestion, feeling or being sick in the stomach.

These side effects are usually mild and short lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- allergic reactions such as rash, wheezing, swelling of the face, lips or tongue which may cause difficulty in breathing
- angina (chest pain)
- irregular heartbeats or palpitations
- an erection that will not go away or lasts more than 4 hours ("priapism")

- 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).
- nose bleeds (rare)

These are serious side effects. You may need urgent medical attention or hospitalisation. Other side effects not listed above may also occur in some people. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using SPEDRA

Storage

Keep your tablets in the blister until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SPEDRA 50 mg tablets are pale yellow oval tablets marked '50' on one side. They are available in blister packs of 1, 2, 4, 8 and 12 tablets. *

SPEDRA 100 mg tablets are pale yellow oval tablets marked '100' on one side. They are available in blister packs of 1, 2, 4, 8 and 12 tablets. *

SPEDRA 200 mg tablets are pale yellow oval tablets marked '200' on one side. They are available in blister packs of 1, 2, 4, 8 and 12 tablets. *

* Not all pack sizes are available.

Ingredients

SPEDRA contains 50 mg, 100 mg, or 200 mg of avanafil as the active ingredient:

It also contains:

- iron oxide yellow
- mannitol
- fumaric acid
- hypolose
- calcium carbonate
- magnesium stearate

SPEDRA does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Supplier

SPEDRA is supplied in Australia by:

A. Menarini Australia Pty Ltd
Level 8, 67 Albert Ave
Chatswood NSW 2067
Medical Information: 1800 644 542

® = Registered Trademark

Australian Registration Number(s)

50 mg tablets: AUST R 228474

100 mg tablets: AUST R 228475

200 mg tablets: AUST R 228476

This leaflet was prepared in December 2018.

For the most up to date version of this leaflet, please go to www.menarini.com.au/cmi

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