

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking SPEDRA?

SPEDRA contains the active ingredient avanafil. SPEDRA is used to treat erectile dysfunction (when you cannot get or keep a hard erect penis suitable for sexual activity) in adult men. See Section [1. Why am I taking SPEDRA?](#) in the full CMI for more details.

2. What should I know before I take SPEDRA?

There are a number of circumstances in which a person should not take this medicine or may need to use caution. It is important to understand if these apply to you before taking SPEDRA. For more information, see Section [2. What should I know before I take SPEDRA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SPEDRA and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take SPEDRA?

Your doctor will decide the correct dose for you depending on your condition and response. SPEDRA will only help you to get an erection if you are sexually stimulated.

- The recommended dose is a 100 mg tablet, as needed, approximately 15 to 30 minutes before anticipated sexual activity. Do not take more than one dose of SPEDRA in a 24-hour period.
- Swallow the tablet whole with water. SPEDRA can be taken with or without food.

More instructions can be found in Section [4. How do I take SPEDRA?](#) in the full CMI.

5. What should I know while taking SPEDRA?

There are many important things to consider while you are taking SPEDRA. The most common and serious considerations are summarised below.

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit 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 should not do	<ul style="list-style-type: none">• Do not take nitrate medicines for chest pain (angina) including the recreational drug amyl nitrite.• Do not take certain oral medicines used to treat HIV, fungal or bacterial infections, or grapefruit juice• Do not give your tablets to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools as SPEDRA can make you feel dizzy or affect your vision. Dizziness or faintness may be worse if you are also taking alpha-blockers.
Drinking alcohol	<ul style="list-style-type: none">• Avoid substantial consumption of alcohol as this can increase the potential for symptoms such as increase in heart rate, decrease in standing blood pressure, dizziness and headache.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister until it is time to take them. Store in a cool dry place below 25°C and keep out of reach of children.

For more information, see Section [5. What should I know while taking SPEDRA?](#) in the full CMI.

6. Are there any side effects?

Common but usually mild potential side effects include headache; flushing; dizziness or light-headedness; symptoms related to cold and influenza; back pain; indigestion, nausea, constipation, diarrhoea; rash; and joint pain. Serious potential side effects requiring medical attention include an allergic reaction; chest pain, irregular heartbeats or palpitations; an erection that will not go away or lasts more than 4 hours; changes to vision; and changes to hearing (possibly with dizziness or ringing in ears). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SPEDRA®

Active ingredient(s): *avanafil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SPEDRA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SPEDRA.**

Where to find information in this leaflet:

- [1. Why am I taking SPEDRA?](#)
- [2. What should I know before I take SPEDRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take SPEDRA?](#)
- [5. What should I know while taking SPEDRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking SPEDRA?

SPEDRA contains the active ingredient avanafil.

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

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 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.

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

2. What should I know before I take SPEDRA?

Warnings

Do not take SPEDRA if:

- you are allergic to avanafil, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

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:

- chest pain (unstable angina) or you get chest pain during sexual intercourse
- 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)
- eye disorders that run in your family (such as retinitis pigmentosa)
- severe liver or kidney problems.

Do not take SPEDRA if you have a serious cardiac problem or you have had any of the following conditions within the previous 6 months:

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

Check with 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not give SPEDRA to women.

Children and adolescents

Do not give SPEDRA to children and adolescents under 18 years of age.

3. What if I am taking other medicines?

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

Some medicines and SPEDRA may interfere with each other and affect how it works. 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 hypertension
- other treatments for erectile dysfunction.

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

These medicines, grapefruit juice or alcohol may be affected by SPEDRA, or may affect how well SPEDRA 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SPEDRA.

4. How do I take SPEDRA?

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. Your doctor may increase your dose to 200 mg or decrease your dose to 50 mg.

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

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 SPEDRA

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 SPEDRA

If you think that you have taken too much SPEDRA, you may need urgent medical attention. You may experience more side effects than usual and the side effects may be worse.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking SPEDRA?

Things you should do

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

Remind any doctor, dentist or pharmacist you visit that you are taking SPEDRA.

Things you should not do

- Do not use the recreational drug amyl nitrite (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.
- While you are taking SPEDRA, do not take certain medicines used to treat HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir; or certain medicines for fungal infection such as ketoconazole, itraconazole or voriconazole; or certain antibiotics for bacterial infections such as clarithromycin and telithromycin.
- Do not take more than one dose of SPEDRA in a 24-hour period. 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SPEDRA affects you.

SPEDRA can make you feel dizzy or affect your vision. Dizziness or faintness may be worse if you are also taking alpha-blockers.

Drinking alcohol

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.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

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.

Store it in a cool dry place below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• headache• flushing• dizziness or light-headedness• nasal or sinus congestion, cold, influenza, cough and chest congestion• back pain• indigestion, feeling or being sick in the stomach (nausea), constipation or diarrhoea• rash• joint pain.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• allergic reactions such as rash, hives, wheezing, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul style="list-style-type: none">feel dizzy or have ringing in your ears)• nose bleeds (rare).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What SPEDRA contains

Active ingredient (main ingredient)	avanafil
Other ingredients (inactive ingredients)	mannitol, fumaric acid, hypollose, calcium carbonate, magnesium stearate and iron oxide yellow

Do not take this medicine if you are allergic to any of these ingredients.

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

What SPEDRA looks like

SPEDRA 50 mg tablets (AUST R 228474) are pale yellow oval tablets marked '50' on one side.

SPEDRA 100 mg tablets (AUST R 228475) are pale yellow oval tablets marked '100' on one side.

SPEDRA 200 mg tablets (AUST R 228476) are pale yellow oval tablets marked '200' on one side.

SPEDRA is available in blister packs of 1, 2, 4, 8 or 12 tablets*.

* Not all pack sizes are available for all strengths.

Who distributes SPEDRA

A. Menarini Australia Pty Ltd

Level 8, 67 Albert Ave

Chatswood NSW 2067

Medical Information: 1800 644 542

® = Registered Trademark

This leaflet was prepared in January 2023.

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

[VA03-0]