

Read all of this leaflet carefully before you start taking Avialis 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.
- Avialis 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.

- in this leaflet:**
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1. What Avialis is and what it is used for

Avialis contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Avialis 5 mg is used to treat adult men with:

- **erectile dysfunction.** This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Avialis has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation Avialis works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. Avialis will not help you if you do not have erectile dysfunction. It is important to note that Avialis for the treatment of erectile dysfunction does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

- urinary symptoms associated with a common condition called **benign prostatic hyperplasia.**This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. Avialis improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Avialis has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

2. Before you take Avialis

- 1. Do not take Avialis if you:**
- are allergic to tadalafil or any of the other ingredients of Avialis (listed in section 6).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines ("nitrates") used in the treatment of angina pectoris ("chest pain"). Avialis has

been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.

- have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.

- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".

- are taking riociguat. This drug 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, such as Avialis, have been shown to increase the hypotensive effects of Avialis. If you are taking riociguat or are unsure tell your doctor.

Warnings and precautions
Talk to your doctor before taking Avialis.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor.

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with Avialis for benign prostatic hyperplasia. Avialis does not treat prostate cancer.

- Before taking the tablets, tell your doctor if you have:
- sickle cell anaemia (an abnormality of red blood cells).
 - multiple myeloma (cancer of the bone marrow).
 - leukaemia (cancer of the blood cells).
 - any deformation of your penis.
 - a serious liver problem.
 - a severe kidney problem.

It is not known if Avialis is effective in patients who have had:

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking Avialis and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Avialis and contact your doctor immediately.

Avialis is not intended for use by women.

Children and adolescents
Avialis is not intended for use by children and adolescents under the age of 18.

Other medicines and Avialis
Tell your doctor if you are taking, have recently taken or might take any other medicines

Do not take Avialis if you are already taking nitrates.

Some medicines may be affected by Avialis or they may affect how well Avialis will work. Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- riociguat.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin , clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

Avialis with drink and alcohol
Information on the effect of alcohol is in section 3.
Grapefruit juice may affect how well Avialis will work and should be taken with caution.
Talk to your doctor for further information.

Fertility
When dogs were treated there was reduced sperm development in the testes.
A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

Driving and using machines
Some men taking Avialis in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

Avialis contains lactose:
If you have an intolerance to some sugars, contact your doctor before taking Avialis.

3. How to take Avialis

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

Avialis tablets are for oral use in men only. Swallow the tablet whole with some water.

The tablets can be taken with or without food.

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take Avialis, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

For the treatment of erectile dysfunction
The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day. Your doctor may adjust the dose to 2.5 mg based on your response to Avialis. This will be given as a 2.5mg tablet.
Do not take Avialis more than once a day.

When taken once a day Avialis allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of Avialis may be useful to men who anticipate having sexual activity two or more times per week.
It is important to note that Avialis does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Drinking alcohol may affect your ability to get an erection.

For the treatment benign prostatic hyperplasia
The dose is one 5 mg tablet taken once a day at approximately the same time of the day.
If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet taken once a day.
Do not take Avialis more than once a day.

If you take more Avialis than you should
Contact your doctor. You may experience side effects described in section 4.

If you forget to take Avialis
Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take Avialis more than once a day.

If you have any further questions on the use of Avialis, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Avialis can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).

- priapism, a prolonged and possibly painful erection after taking Avialis (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.

- sudden loss of vision (frequency rare).

Other side effects have been reported:

- Common** (seen in 1 to 10 in every 100 patients)
 - headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, and indigestion.

- Uncommon** (seen in 1 to 10 in every 1,000 patients)
 - dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired.

- Rare** (seen in 1 to 10 in every 10,000 patients)
 - priapism, a prolonged and possibly painful erection after taking Avialis (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.

Heart attack and stroke have also been reported rarely in men taking Avialis. Most of these men had known heart problems before taking Avialis.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects have been reported in men taking Avialis that were not seen in clinical trials. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

The side effect dizziness has been reported more frequently in men over 75 years of age taking Avialis. Diarrhoea has been reported more frequently in men over 65 years of age taking Avialis.

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 via the national reporting system. By reporting side effects you can help provide more information on the safety of Avialis.

5. How to store Avialis

Keep Avialis out of the sight and reach of children.

Store below 30°C.

Do not use Avialis after the expiry date which is stated on the carton or on the blister 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. Further information

What Avialis contains

- The **active substance** is tadalafil. Each tablet contains 5 mg of tadalafil.
- The **other ingredients** are: lactose monohydrate, croscarmellose sodium, Sodium lauryl sulphate, hydroxypropylcellulose, microcrystalline cellulose, magnesium stearate and Opadry yellow 32K220032.

What Avialis looks like and contents of the pack

- Avialis 5 mg is a yellow film-coated tablet.
- Avialis 5 mg is available in blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer:
Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)
P.O.Box 4180 Riyadh 11491, Kingdom of Saudi Arabia
2nd Industrial City, Riyadh, Kingdom of Saudi Arabia
Tel: +966 (11) 2653948 -2653427
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Shelf life: 24 months

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To report any side effect(s):
• Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC) • Fax: +966-11-205-7662 • Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340. • Toll free phone: 8002490000 • E-mail: npc.drug@sfgda.gov.sa • Website: www.sfgda.gov.sa/npc
• Other GCC States:
Please contact the relevant competent authority.
THIS IS A MEDICAMENT - Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. -The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the period of treatment prescribed for you. - Do not repeat the same prescription without consulting your doctor. -Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists

