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Avanafil

pronounced as (a van' a fil)

Why is this medication prescribed?

Avanafil is used to treat erectile dysfunction (ED: impotence; inability to get or keep an erection in men). Avanafil is in a class of medications called phosphodiesterase (PDE) inhibitors. It works by increasing blood flow to the penis during sexual stimulation. This increased blood flow can cause an erection. Avanafil does not cure erectile dysfunction or increase sexual desire. Avanafil does not prevent pregnancy or the spread of sexually transmitted diseases such as human immunodeficiency virus (HIV).

How should this medicine be used?

Avanafil comes as a tablet to take by mouth. For men taking the 100- mg or 200-mg doses, avanafil is usually taken with or without food as needed, about 15 minutes before sexual activity. For men taking the 50-mg dose, avanafil is usually taken with or without food as needed, about 30 minutes before sexual activity. Do not take avanafil more often than once in 24 hours. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take avanafil exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on an average dose of avanafil and may increase or decrease your dose depending on how you respond to the medication. Tell your doctor if avanafil is not working well or if you experience side effects.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking avanafil,

- tell your doctor and pharmacist if you are allergic to avanafil, any other medications, or any of the ingredients in avanafil tablets. Ask your pharmacist or check the patient information for a list of the ingredients.

- do not take avanafil if you are taking or have recently taken riociguat (Adempas) or nitrates such as isosorbide dinitrate (Dilatrate-SR, Isordil, in BiDil), isosorbide mononitrate (Monoket), and nitroglycerin (Minitran, Nitro-Dur, Nitromist, Nitrostat, others). Nitrates come as tablets, sublingual (under the tongue) tablets, sprays, patches, pastes, and ointments. Ask your doctor if you are not sure if any of your medications contain nitrates.
- do not take street drugs containing nitrates such as amyl nitrate and butyl nitrate ('poppers') while taking avanafil.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: alpha blockers such as alfuzosin (Uroxatral), doxazosin (Cardura), prazosin (Minipress), tamsulosin (Flomax, in Jalyn), silodosin (Rapaflo), and terazosin; certain antifungal medications such as fluconazole (Diflucan), itraconazole (Onmel, Sporanox), and ketoconazole (Nizoral); aprepitant (Emend); clarithromycin (Biaxin, in Prevpac); diltiazem (Cardizem, Cartia, Tiazac); erythromycin (E.E.S, E-Mycin, Erythrocin); HIV protease inhibitors such as atazanavir (Reyataz, in Evotaz), fosamprenavir (Lexiva), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); other medications or treatments for erectile dysfunction; medications for high blood pressure; nefazodone; verapamil (Calan, Covera, Verelan, others); and telithromycin (Ketek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with avanafil, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you have ever been advised by a doctor to avoid sexual activity for medical reasons, if you have had heart surgery within the past 6 months and if you have ever had an erection that lasted longer than 4 hours. Also tell your doctor if you have or have ever had a condition that affects the shape of the penis such as angulation, cavernosal fibrosis, or Peyronie's disease; a heart attack; a stroke; an irregular heartbeat; a blocked artery; angina (chest pain); high or low blood pressure; heart failure; blood cell problems such as sickle cell anemia (a disease of the red blood cells), multiple myeloma (cancer of the plasma cells), or leukemia (cancer of the white blood cells); ulcers; bleeding problems; or liver or kidney disease. Also tell your doctor if you have or have ever had retinitis pigmentosa (a rare inherited eye disease) or if you have ever had severe vision loss, especially if you were told that the vision loss was caused by a blockage of blood flow to the nerves that help you see.
- you should know that avanafil is only for use in males. Women should not take avanafil, especially if they are or may become pregnant or are breastfeeding. If a pregnant woman takes avanafil, she should call her doctor.
- talk to your doctor about the safe use of alcoholic beverages during your treatment with avanafil. If you drink a large amount of alcohol (more than three glasses of wine or three shots of whiskey) while you are taking avanafil you are more likely to experience certain side effects of avanafil such as dizziness, headache, fast heartbeat, and low blood pressure.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking avanafil.
- you should know that sexual activity may be a strain on your heart, especially if you have heart disease. If you have chest pain, dizziness, or nausea during sexual activity, call your doctor immediately and avoid sexual activity until your doctor tells you otherwise.
- tell all your healthcare providers that you are taking avanafil. If you ever need emergency medical treatment for a heart problem, the healthcare providers who treat you will need to know when you last took avanafil.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medication.

What side effects can this medication cause?

Avanafil may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- flushing
- back pain

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- an erection that lasts longer than 4 hours
- sudden loss of vision in one or both eyes (see below for more information)
- sudden hearing loss (see below for more information)
- ringing in the ears
- dizziness
- rash
- itching
- swollen eyelids

Avanafil may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

Some patients experienced a sudden loss of some or all of their vision after they took medications that are similar to avanafil. The vision loss was permanent in some cases. It is not known if the vision loss was caused by the medication. If you experience a sudden loss of vision while you are taking avanafil, call your doctor immediately. Do not take any more doses of avanafil or similar medications such as sildenafil (Revatio, Viagra), tadalafil (Cialis) or vardenafil (Levitra) until you talk to your doctor.

Some patients experienced a sudden decrease or loss of hearing after they took other medications that are similar to avanafil. The hearing loss usually involved only one ear and did not always improve when the medication was stopped. It is not known if the hearing loss was caused by the medication. If you experience a sudden loss of hearing, sometimes with ringing in the ears or dizziness, while you are taking avanafil, call your doctor immediately. Do not take any more doses of avanafil or similar medications such as sildenafil (Revatio, Viagra), tadalafil (Cialis) or vardenafil (Levitra) until you talk to your doctor.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Stendra®

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