PACKAGE LEAFLET

Package leaflet: Information for the user

Avarante Prescription Free 10 mg film-coated tablets

tadalafil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you have taken Avarante Prescription Free as directed (see section 3) and were not able to get or keep an erection hard enough for satisfactory sex.

What is in this leaflet

1. What Avarante Prescription Free is and what it is used for
2. What you need to know before you take Avarante Prescription Free
3. How to take Avarante Prescription Free
4. Possible side effects
5. How to store Avarante Prescription Free
6. Contents of the pack and other information

1. What Avarante Prescription Free is and what it is used for

Avarante Prescription Free is a treatment for adult men with impotence (erectile dysfunction). This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

Avarante Prescription Free contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation Avarante Prescription Free 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. Avarante Prescription Free will not help you if you do not have impotence.

It is important to note that Avarante Prescription Free does not work if there is no sexual stimulation.

2. What you need to know before you take Avarante Prescription Free

Do not take Avarante Prescription Free if you:
- do not have an erection problem, as this medicine will not provide any benefit to you.
- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- take any medicines called nitrates or nitric oxide donors for chest pain (angina pectoris) or heart failure (see “Other medicines and Avarante Prescription Free”).
- take amyl nitrite, so called “poppers” as recreational drugs.
- have been advised by your doctor to avoid sexual activity because of a problem with your heart or blood vessels.
- get chest pain during sexual intercourse.
- have a severe heart or blood vessel problem such as recent heart attack (within the last 90 days) or stroke (within the last 6 months), unstable angina (chest pain caused by reduced blood flow to the heart muscle) or severe heart failure.
- have low blood pressure or uncontrolled high blood pressure.
- have ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.

- take riociguat (or other medicines belonging to a group called guanylate cyclase stimulators) for high blood pressure in the lungs (see "Other medicines and Avarante Prescription Free").
- are a woman.
- are under 18 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking Avarante Prescription Free.

Sexual activity can put extra strain on your heart. If you have a heart problem or think you might have a heart problem you should tell your doctor or pharmacist.

Even if you feel healthy, your erection problems may be linked to a serious health condition. Impotence may be an early sign of:
- heart and blood vessel problems
- diabetes
- high blood pressure
- depression

You should discuss your symptoms and these conditions with your doctor if you have not already done so. Make an appointment with your doctor at the earliest opportunity to discuss your health when using Avarante Prescription Free.

Before taking Avarante Prescription Free, in order to ensure this medicine is suitable for you and that you are fit enough to have sex, talk to your doctor if you:
- get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex.
- have or have ever had any heart disease or heart surgery, e.g., valvular heart disease (damaged or diseased heart valve), cardiomyopathy (disease of the heart muscle), arrhythmia (irregular heart-beat).

Before taking Avarante Prescription Free, talk to your doctor if you:
- have ever had an erection that lasted more than 4 hours (called priapism) or have any condition which can cause priapism which include sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow). Use of medicines for impotence may increase the risk of priapism. Long lasting erection may cause damage to the tissue in the penis and permanent loss of ability to have an erection.
- take any other medicines listed in this leaflet. Please refer to section 2 'Other medicines and Avarante Prescription Free.
- have any deformation of your penis.
- have a serious liver problem.
- have a severe kidney problem.

It is not known if Avarante Prescription Free 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 or your vision is distorted, dimmed while you are taking Avarante Prescription Free, stop taking Avarante Prescription Free 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 Avarante Prescription Free and contact your doctor immediately.

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

Other medicines and Avarante Prescription Free
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Avarante Prescription Free or they may affect how Avarante Prescription Free works and this may result in side effects.

Before taking other medicines you should also tell your doctor or pharmacist if you have taken Avarante Prescription Free within the last 48 hours as Avarante Prescription Free may still be in your body.

Do not use Avarante Prescription Free if you take:
NITRATE medicines: Do NOT take Avarante Prescription Free if you are taking nitrate medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) or nitric oxide donors (such as amyl nitrite ("poppers"), nicorandil, molsidomine or sodium nitroprusside).
These are often used for the relief of chest pain (angina pectoris), or heart failure. Using Avarante Prescription Free with any of these medicines may lead to a dangerous fall in blood pressure.

Riociguat: Do not take Avarante Prescription Free if you are taking a medicine called riociguat (or other medicines of a group called guanylate cyclase stimulators). Riociguat is used to treat high blood pressure in the lungs and can lead to a dangerous fall in blood pressure if taken together with Avarante Prescription Free.

Talk to your doctor or pharmacist before taking Avarante Prescription Free if you are already taking:
- an alpha-blocker such as alfuzosin, doxazosin or tamsulosin, which are medicines used to treat urinary problems due to an enlarged prostate (benign prostatic hyperplasia) or occasionally high blood pressure, as use of Avarante Prescription Free may not be suitable for you. It may lead to dizziness, light-headedness, nausea, fainting, lack of concentration, or blurred vision due to low blood pressure (symptomatic hypotension).
- other medicines to treat high blood pressure as use of Avarante Prescription Free may lead to low blood pressure.
- medicines to treat fungal infections called itraconazole or ketoconazole as they increase the concentration of Avarante Prescription Free and may result in side effects.
- protease inhibitors (ritonavir, saquinavir) for treatment of AIDS or HIV infection as they increase the concentration of Avarante Prescription Free and may result in side effects.
- an antibiotic called rifampicin as it decreases the concentration of Avarante Prescription Free and may reduce efficacy of Avarante Prescription Free.
- antibiotics called erythromycin or clarithromycin as they increase the concentration of Avarante Prescription Free and may result in side effects.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines) as they reduce the concentration of Avarante Prescription Free and may result in reduced efficacy of Avarante Prescription Free.
- other treatments for impotence. The safety and efficacy of combinations of Avarante Prescription Free with other treatments for impotence have not been studied and this combination is therefore not recommended.
- theophylline (to treat asthma).
- a 5- alpha reductase inhibitor (finasteride) to treat benign prostatic hyperplasia.

Avarante Prescription Free with drink and alcohol
Grapefruit juice may affect how well Avarante Prescription Free will work and should be taken with caution.

Drinking large amounts of alcohol may temporarily affect your ability to get an erection and may temporarily lower your blood pressure and make you feel dizzy. To get the maximum benefit from your medicine avoid excessive alcohol intake.

Talk to your doctor or pharmacist for further information.

Pregnancy, breast-feeding and fertility
This medicine should not be used by women.

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 Avarante Prescription Free in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

Avarante Prescription Free contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Avarante Prescription Free

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

- Take one tablet, when needed, approximately 30 minutes before you expect to have sexual activity.
- Swallow tablet whole with some water. The tablets can be taken with or without food.
- Do not take more than one tablet a day. You can get an erection, when sexually stimulated, in 30 minutes and for up to 36 hours after taking.

You will not get an erection just by taking Avarante Prescription Free. This medicine will only help you get an erection if you are sexually aroused. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for impotence.

Remember to relax and be patient. There is no rush. If you are not successful the first time, try to have sex again, but remember **do not take more than one tablet a day**. For most men, Avarante Prescription Free will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take a couple of attempts before you are able to achieve an erection. If you feel the effect of Avarante Prescription Free is too strong or too weak, talk to your pharmacist or doctor.

Talk to your doctor or pharmacist if you have taken Avarante Prescription Free as directed and are still not able to get and keep an erection.

Avarante Prescription Free is not recommended for continuous daily use. Talk to your doctor if you feel you need to take this medicine frequently (i.e., at least twice weekly).

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These effects are normally mild or moderate in nature.
If you experience any of the following side effects stop using the medicine and **seek medical help immediately**:
- an allergic reaction: this occurs uncommonly. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat, rashes.
- chest pain: this occurs uncommonly. If this occurs before, during or after intercourse get in a semi-sitting position and try to relax. Do not use nitrates but seek immediate medical assistance.
- priapism, a prolonged and possibly painful erection after taking Avarante Prescription Free (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- a sudden loss of vision (frequency rare), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known)

Other side effects have been reported:

Common (may affect up to 1 in 10 people)
- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion.

Uncommon (may affect up to 1 in 100 people)
- 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 (may affect up to 1 in 1 000 people)
- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking Avarante Prescription Free. Most of these men had known heart problems before taking this medicine.

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 Avarante Prescription Free that were not seen in clinical studies. 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.
- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

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

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 ADR reporting system at www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Avarante Prescription Free

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

This medicine does not require any special storage conditions.

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 Avarante Prescription Free contains
- The active substance is tadalafil. Each film-coated tablet contains 10 mg of tadalafil.
- The other ingredients are:
  - Tablet core: povidone (K-25), sodium lauryl sulfate, poloxamer, lactose, microcrystalline cellulose, croscarmellose sodium anhydrous colloidal silica and magnesium stearate.
  - Film-coating: lactose, hypromellose (15cP), titanium dioxide (E171), iron oxide yellow (E172) and triacetin.

What Avarante Prescription Free looks like and contents of the pack
Avarante Prescription Free is a light yellow, round, biconvex film-coated tablet, debossed with ‘M’ on one side of the tablet and ‘TL3’ on the other side. The diameter of the tablet is approximately 8 mm.

Avarante Prescription Free is available in blister packs containing 2, 4 or 8 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatris Limited,
Damastown Industrial Park
Dublin 15, DUBLIN
Ireland

Manufacturer
Mylan Hungary Kft.
Mylan utca 1
Komárom
2900
Hungary

This medicine is authorised in the Member States of the European Economic Area under the following names:

Norway	Avarante Reseptfri
Malta	Avarante Prescription Free

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