

1.3.2 PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

AMOTAD 5 mg

AMOTAD 20 mg

Tadalafil 5 mg and 20 mg film coated tablets.

Contains sugar:

AMOTAD 5 mg: (lactose 60,66 mg/tablet)

AMOTAD 20 mg: (lactose 242,64 mg/tablet)

Read all of this leaflet carefully before you start taking AMOTAD

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- AMOTAD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What AMOTAD is and what it is used for

AMOTAD is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

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

It is important to note that AMOTAD 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.

2. What you need to know before you take AMOTAD

Do not take AMOTAD if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (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”). AMOTAD 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.
- have severe hepatic insufficiency (conditions in which the liver functions fall below the normal ranges)
- have impaired or loss of hearing in one or both ears with or without associated vestibular symptoms (dizziness and trouble with balance)
- 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, medicine 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 AMOTAD, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Warnings and precautions

Talk to your doctor before taking AMOTAD.

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.

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 AMOTAD 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 nonnerve-sparing prostatectomy).

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

AMOTAD is not intended for use by women.

Children and adolescents

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

Other medicines and AMOTAD

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

Do not take AMOTAD if you are already taking nitrates.

Some medicines may be affected by AMOTAD or they may affect how well AMOTAD 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.
- phenobarbitone, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin , clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

AMOTAD with drink and alcohol

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take AMOTAD, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up. Grapefruit juice may affect how well AMOTAD will work and should be taken with caution. Talk to your doctor for further information.

Pregnancy, breastfeeding and fertility

AMOTAD is not to be taken by women.

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

AMOTAD may cause dizziness. Check carefully how you react to the tablets before driving or using machines.

AMOTAD contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take AMOTAD

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

AMOTAD tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

The recommended dose is one 5 mg tablet taken once a day. The maximum recommended dose of AMOTAD is 20 mg tablet taken once a day.

You may take a AMOTAD tablet at least 16 minutes before sexual activity.

AMOTAD may still be effective up to 36 hours after taking the tablet.

Do not take AMOTAD more than once a day. AMOTAD 5 mg and 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

It is important to note that AMOTAD 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.

If you take more AMOTAD than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. You may experience side effects described in section 4.

4. Possible side effects

AMOTAD can cause side effects. Not all side effects reported for AMOTAD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMOTAD please consult your health care provider for advice.

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

- allergic reactions including rashes
- chest pain - do not use nitrates but seek immediate medical assistance .
- priapism, a prolonged and possibly painful erection after taking AMOTAD. If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision.

Other side effects have been reported:

Frequent

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, and indigestion.

Less frequent

- 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.

Unknown frequency

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, retinal detachment, 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 AMOTAD. 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 AMOTAD 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 AMOTAD. Diarrhoea has been reported more frequently in men over 65 years of age taking AMOTAD.

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 to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AMOTAD

5. How to store AMOTAD

Store all medicines out of reach of children.

Store at or below 25^o C

Store in the original package in order to protect from moisture

Protect from light / moisture

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Ask your pharmacist how to dispose of medicines you no longer use.

6. Contents of the pack and other information

What AMOTAD contains

- The active substance is tadalafil
- The other ingredients are:
 - *Tablet core:* hydroxyl propyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate
 - *Film coat:* Hypromellose, lactose monohydrate, talc, titanium dioxide, triacetin, yellow iron oxide

What AMOTAD looks like and contents of the pack

AMOTAD 5 mg: Yellow, almond shaped, film-coated tablets, debossed with 'T5' on one side and plain on other side.

AMOTAD 20 mg: Yellow, almond shaped, film-coated tablets, debossed with 'T20' on one side and plain on other side.

AMOTAD 5 and 20 mg is available in blister packs containing 2, 4, 8, 12 or 28 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd

Ruby Pharmaceuticals
Status: Approved

Amotad 5, 20, mg tablets
Ver: Vfa_1a

15 February 2024

P.O. Box 431

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This leaflet was last revised in

15 February 2024

Registration number(s)

AMOTAD 5 – 54/7.1.5/0034

AMOTAD 20 – 54/7.1.5/0035