



Package leaflet: Information for the user

Tada 20 mg/30mg film-coated tablets

Tadalafil/dapoxetine

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

What is in this leaflet:

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2. What you need to know before you take Tada
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4. Possible side effects
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1. What Tada is and what it is used for

Tada 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. Tada has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

Tada contains the active substance tadalafil and dapoxetine, tadalafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors. dapoxetine belongs to a group of medicines called 'selective serotonin reuptake inhibitors' (SSRIs). Following sexual stimulation Tada 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. increases the time it takes to ejaculate and can improve the control over the ejaculation. Tada may reduce the frustration or worry about fast ejaculation. Tada will not help you if you do not have erectile dysfunction.

It is important to note that Tada 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 Tada

Do not take Tada if you:

- are allergic to tadalafil, dapoxetine 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").
- Do not take Dapocitin at the same time as any of the medicines listed
- Medicines for depression called 'monoamine oxidase inhibitors' (MAOIs)
- Thioridazine used for schizophrenia
- Other medicines for depression
- Lithium a medicine for bipolar disorder
- Linezolid an antibiotic used to treat infections
- Tryptophan a medicine to help you sleep
- St John's wort an herbal medicine
- Tramadol used to treat serious pain
- Medicines used to treat migraines.

Tada 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 Tada, 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 Tada.

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 Tada 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 Tada 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 Tada and contact your doctor immediately.

Tada is not intended for use by women.

Children and adolescents

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

Other medicines and Tada

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

Do not take Tada if you are already taking nitrates.

Some medicines may be affected by Tada or they may affect how well Tada 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.

Tada with drink and alcohol

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well Tada 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 Tada in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

Tada contains lactose

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

3. How to take Tada

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

Tada tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food. Only take the medicine 1 to 3 hours before sexual activity is anticipated.

The recommended dose is one tablet taken once a day

Do not take Tada more than once a day.

Do not take Tada if you are dehydrated (you do not have enough water in your body).

This can happen if:

- You have not had anything to drink in the past 4 to 6 hours
- You have been sweating for a long time
- You have an illness where you have a high temperature, diarrhoea or being sick.

Once a day dosing of Tada may be useful to men who anticipate having sexual activity two or more times per week.

When taken once a day Tada allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day.

It is important to note that Tada 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 and may temporarily lower your blood pressure. If you have taken or are planning to take Tada, avoid drinking.

If you take more Tada 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 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 Tada (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)

- 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 Tada. 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 Tada 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 Tada. Diarrhoea has been reported more frequently in men over 65 years of age taking Tada.

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

5. How to store Tada

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.

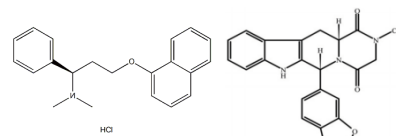
Store in the original package in order to protect from moisture. Do not store above 30°C.

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 Tada contains

- The **active** substance is tadalafil and dapoxetine, Each tablet contains 20mg tadalafil which is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5), and 30 mg dapoxetine as a hydrochloride salt. dapoxetine is a short-acting selective serotonin reuptake inhibitor. The structural formula is:



- The other ingredients are: lactose monohydrate (see end of section 2), croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurilsulfate, magnesium stearate, see section 2 "Tada contains lactose".

What Tada looks like and contents of the pack

Tada is a light orange-yellow film-coated tablet in the shape of an almond and has "TLPH" marked on one side.

Tada is available in blister containing 2 or 6 tablets.

Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd

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Manufacturer

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