



## Information for the user

### Tada ( Tada-T /Tada-D )

Tadalafil film-coated tablets 20 mg /Dapoxetine film-coated tablets 30mg  
Co-packaged

#### 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:

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

#### 1. What Tada is and what it is used for

Tada is a combination package of Tada-T and Tada-D.

Tada-T is used for the treatment of adult men with erectile dysfunction . Erectile dysfunction is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

Tada-T contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation Tada-T 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. Tada-T will not help you if you do not have erectile dysfunction. It is important to note that Tada-T 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.

Tada-D is used to treat premature ejaculation, in men between 18 and 64 years old.

Premature ejaculation is when a man ejaculates with little sexual stimulation and before the man wants. This can cause problems for the man and may cause problems in sexual relationships.

Tada-D contains an active substance called 'dapoxetine'. This belongs to a group of medicines called 'selective serotonin reuptake inhibitors' (SSRIs).

Tada-D increases the time it takes to ejaculate and can improve the control over the ejaculation. This may reduce the frustration or worry about fast ejaculation.

#### 2. What you need to know before you take Tada

##### 2.1 What you need to know before you take Tada-T

Do not take Tada-T 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").

Tada-T 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). PDES inhibitors, such as Tada-T, 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-T.

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 Tada-T 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-T 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-T 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-T and contact your doctor immediately.

Tada-T is not intended for use by women.

#### Children and adolescents

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

#### Other medicines and Tada-T

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

Do not take Tada-T if you are already taking nitrates.

Some medicines may be affected by Tada-T or they may affect how well Tada-T 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-T with drink and alcohol

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

#### Tada-T 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.

#### Tada-T contains sodium

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

##### 2.2 What you need to know before you take Tada-D

Do not take Tada-D if:

- You are allergic (hypersensitive) to dapoxetine or any of the other ingredients of Tada-D (listed in section 6)

- You have heart problems, such as heart failure or problems with the heart rhythm

- You have a history of fainting

- You have ever had mania (symptoms include feeling over excited, irritable or not being able to think clearly) or severe depression

- You are taking:

oMedicines for depression called 'monoamine oxidase inhibitors' (MAOIs)

oThioridazine used for schizophrenia

oOther medicines for depression

oLithium - a medicine for bipolar disorder

oLinezolid - an antibiotic used to treat infections

oTryptophan - a medicine to help you sleep

oSt John's wort - herbal medicine

oTramadol - used to treat serious pain

oMedicines used to treat migraines.

Do not take Tada-D at the same time as any of the medicines listed above. If you have taken any of these medicines, you will need to wait 14 days after you stop taking it before you can start taking Tada-D. Once you have stopped taking Tada-D, you will need to wait 7 days before taking any of the medicines listed above. If you are not sure about what to do, talk to your doctor or pharmacist before taking Tada-D (see section "Taking other medicines")

oCertain medicines for fungal infection, including ketoconazole and itraconazole (see section "Taking other medicines")

oCertain medicines for HIV, including ritonavir, saquinavir, nelfinavir and atazanavir (see section "Taking other medicines")

oCertain antibiotics for treating infection, including telithromycin (see section "Taking other medicines")

oNefazodone - an antidepressant (see section "Taking other medicines")

- You have moderate or severe liver problems.

Do not take Tada-D if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tada-D

#### Take special care with Tada-D

Check with your doctor or pharmacist before taking your medicine if:

- You drink alcohol (see section "Taking Tada with food and drink")

- You have not been diagnosed with premature ejaculation

- You use recreational drugs such as ecstasy, LSD, narcotics or benzodiazepines

- You have ever had a mental health problem such as depression, mania (symptoms include feeling over excited, irritable or not being able to think clearly), bipolar disorder (symptoms include serious mood swings between mania and depression) or schizophrenia (a psychiatric disease)

- You have a history of bleeding or blood clotting problems

- You have kidney problems

- You have epilepsy

- You have a history of dizziness from low blood pressure

- You also have another sexual problem, such as erectile dysfunction.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Tada-D.

Before you start taking Tada-D, your doctor should perform a test to make sure that your blood pressure doesn't drop too much when you stand up from lying down.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines as certain medicines may increase your risk of side effects. This includes medicines you get without a prescription, such as herbal medicines. This is because Tada-D can affect the way some other medicines work. Also some other medicines can affect the way Tada-D works. Therefore, use of other medicines may affect the maximum dose of Tada-D you're allowed to take.

**Do not take Tada-D at the same time as any of the following medicines:**

-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.

Do not take Tada-D at the same time as any of the medicines listed above. If you have taken any of these medicines, you will need to wait 14 days after you stop taking it before you can start taking Tada-D. Once you have stopped taking Tada-D, you will need to wait 7 days before taking any of the medicines listed above. If you are not sure about what to do, talk to your doctor or pharmacist before taking Tada-D

oCertain medicines for fungal infection, including ketoconazole and itraconazole

oCertain medicines for HIV, including ritonavir, saquinavir, nelfinavir and atazanavir

oCertain antibiotics for treating infection, including telithromycin

-Nefazodone - an antidepressant.

**Tell your doctor or pharmacist if you are taking any of the following medicines:**

-Medicines for mental health problems other than depression

-Non steroidal anti inflammatory medicines such as ibuprofen or acetylsalicylic acid

-Medicines to thin your blood, such as warfarin

-Certain medicines used to treat erectile dysfunction, such as sildenafil, tadalafil or vardenafil, as these medicines may lower your blood pressure, possibly upon standing

-Certain medicines used to treat high blood pressure and chest pain (anginal) (such as verapamil and diltiazem), or enlarged prostate, as these medicines may also lower your blood pressure, possibly upon standing

-Certain other medicines for fungal infection, such as fluconazole

-Certain other medicines for HIV, such as amprenavir and fosamprenavir

-Certain other antibiotics for treating infection, such as erythromycin and clarithromycin

-Aprepitant - used to treat nausea.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Tada-D.

#### Taking Tada-D with food and drink

- Tada-D can be taken with or without food.

- You should take Tada-D with at least one full glass of water.

-Avoid alcohol when taking Tada-D.

•The effects of alcohol such as feeling dizzy, sleepy and having slow reactions, may be increased if taken with Tada-D.  
•Drinking alcohol while taking Tada-D may increase your risk of injury from fainting or from other side effects.

#### Pregnancy and breast feeding

Tada-D should not be taken by women.

#### Driving and using machines

You may feel sleepy, dizzy, faint, have difficulty concentrating and blurred vision while taking Tada-D.

If you experience any of these or similar effects, you should avoid driving or operating hazardous machinery. The effects of alcohol may be increased if taken with Tada-D and you may be more at risk of injury from fainting or from other side effects if you take Tada-D with alcohol.

#### Important information about some of the ingredients of Tada-D

Tada-D contains lactose (a type of sugar). 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 Tada

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

Tada-T and Tada-D tablets are for oral use in men only. Swallow the tablet whole with at least one full glass of 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 Tada-T tablet and one Tada-D tablet taken once.

Tada is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

Do not take Tada more than once a day.

Tada should not be used by either men under the age of 18 or men 65 years or older

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).
- You have fits (seizures)
- You faint or feel light headed when you stand up
- You have any thoughts of suicide or harming yourself.

Tada-D can make you faint or make your blood pressure drop when you stand up. To help lower the chance of this happening:

- Take Tada with at least one full glass of water.
- Do not take Tada-D 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.

•If you feel like you might faint (such as feeling sick, feeling dizzy, light headed, confused, sweaty or an abnormal heart beat), or feel light headed when you stand up, immediately lie down so your head is lower than the rest of your body or sit down with your head between your knees until you feel better. This will stop you from falling and hurting yourself if you do faint.

- Do not stand up quickly after you have been sitting or lying down for a long time.
- Do not drive or use any tools or machines if you feel faint when taking this medicine.

•Tell your doctor if you faint when taking this medicine.

#### 4.1 Other side effects have been reported in men taking Tada-T:

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-T. 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-T 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.

#### 4.2 Other side effects have been reported in men taking Tada-D:

Very common side effects (affects more than 1 user in 10):

- Feeling dizzy
- Headache
- Feeling sick

Common side effects (affects 1 to 10 users in 100):

- Feeling irritable, anxious, agitated or restless
- Feeling numb or having 'pins and needles'
- Difficulty getting or keeping an erection
- Sweating more than normal or flushing
- Diarrhoea, constipation or having wind
- Stomach pain, bloating or being sick
- Problems sleeping or strange dreams
- Feeling tired or sleepy, yawning
- Blocked nose (nasal congestion)
- A rise in blood pressure
- Difficulty concentrating
- Shaking or trembling
- Lower interest in sex
- Ringing in the ears
- Blurred vision
- Indigestion
- Dry mouth.

Uncommon side effects (affects 1 to 10 users in 1,000):

- Fainting or feeling dizzy upon standing (see advice above)
  - Change in mood, feeling overly excited or feelings of paranoia
  - Feeling confused, disoriented or unable to think clearly
  - Slow or irregular heartbeat or increase in heart rate
  - Loss of sex drive, problems reaching orgasm
  - Feeling weak, sedated, lethargic or fatigued
  - Feeling depressed, nervous or indifferent
  - Feeling hot, jittery, abnormal or drunk
  - Vision problems or dilated pupils
  - Low or high blood pressure
  - Feeling itchy or cold sweat
  - Spinning sensation
  - Abnormal taste
  - Teeth grinding.
- Rare side effects (affects 1 to 10 users in 10,000):
- Feeling dizzy following exertion
  - Sudden onset of sleep
  - Urgency of bowel action.

#### 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'.

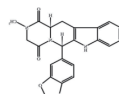
Store in the original package in order to protect from moisture. Do not store above 30°C.

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.

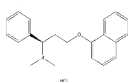
### 6. Contents of the pack and other information

#### What Tada contains

- Tada-T contains the active substance " tadalafil ". Tadalafil is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). Tadalafil has the empirical formula C<sub>22</sub>H<sub>19</sub>N<sub>3</sub>O<sub>4</sub> representing a molecular weight of 389.41. The structural formula is:



- Tada-D contains the active substance "dapoxetine" as a hydrochloride salt. Dapoxetine is a short-acting selective serotonin reuptake inhibitor. The structural formula is:



Each Tada-T tablet contains 20mg tadalafil.

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

Each Tada-D tablet contains 30mg dapoxetine.

The other ingredients are: lactose monohydrate (see end of section 2), microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

#### What Tada looks like and contents of the pack

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

Tada-D is film-coated tablet, round and marked "TLPH" on one side.

Tada is available in one box containing 4, 10 Tada-T tablets and 4, 10 Tada-D tablets.

#### Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd

Rd13 South,31km,Ban Naphasuk,Saithany District ,Vientiane ,Lao PDR

#### Manufacturer

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd

Rd13 South,31km,Ban Naphasuk,Saithany District. Vientiane. Lao PDR

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

