

TADALAFIL ALPHAPHARM

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TADALAFIL ALPHAPHARM?

TADALAFIL ALPHAPHARM contains the active ingredient tadalafil. TADALAFIL ALPHAPHARM is used to treat erectile dysfunction and urinary symptoms associated with benign prostatic hyperplasia in adult men.

For more information, see Section [1. Why am I using TADALAFIL ALPHAPHARM?](#) in the full CMI.

2. What should I know before I use TADALAFIL ALPHAPHARM?

Do not use if you have ever had an allergic reaction to TADALAFIL ALPHAPHARM or any of the ingredients listed at the end of the CMI.

Do not take TADALAFIL ALPHAPHARM if you are currently taking any nitrates or amyl nitrite.

Talk to your doctor if you have any other medical conditions such as heart problems or if you take any other medicines.

For more information, see Section [2. What should I know before I use TADALAFIL ALPHAPHARM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TADALAFIL ALPHAPHARM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TADALAFIL ALPHAPHARM?

- Always take TADALAFIL ALPHAPHARM exactly as your doctor has told you.
- Follow all directions given to you by your doctor or pharmacist.

More instructions can be found in Section [4. How do I use TADALAFIL ALPHAPHARM?](#) in the full CMI.

5. What should I know while using TADALAFIL ALPHAPHARM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>that you are using TADALAFIL ALPHAPHARM.</p> <ul style="list-style-type: none"> ● If you have emergency treatment for any suspected heart condition, tell the emergency medical or ambulance staff that you are taking TADALAFIL ALPHAPHARM.
Things you should not do	<ul style="list-style-type: none"> ● Do not take TADALAFIL ALPHAPHARM to treat any other complaints. ● Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how TADALAFIL ALPHAPHARM affects you.
Drinking alcohol	<ul style="list-style-type: none"> ● TADALAFIL ALPHAPHARM can be taken with or without food, or alcohol. However, drinking alcohol may affect your

	ability to get an erection, so avoid excessive alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using TADALAFIL ALPHAPHARM?](#) in the full CMI.

6. Are there any side effects?

TADALAFIL ALPHAPHARM may cause chest pain, headache or migraine, flushing, sweating, nausea or vomiting, fatigue, back pain, muscle pain.

TADALAFIL ALPHAPHARM

Active ingredient(s): *tadalafil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TADALAFIL ALPHAPHARM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TADALAFIL ALPHAPHARM.**

Where to find information in this leaflet:

- [1. Why am I using TADALAFIL ALPHAPHARM?](#)
- [2. What should I know before I use TADALAFIL ALPHAPHARM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TADALAFIL ALPHAPHARM?](#)
- [5. What should I know while using TADALAFIL ALPHAPHARM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TADALAFIL ALPHAPHARM?

TADALAFIL ALPHAPHARM contains the active ingredient tadalafil. TADALAFIL ALPHAPHARM belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

TADALAFIL ALPHAPHARM is used to treat:

- erectile dysfunction, also known as impotence, in men. This is when a man cannot get, or maintain, a hard erect penis suitable for sexual activity. Following sexual stimulation, TADALAFIL ALPHAPHARM 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. TADALAFIL ALPHAPHARM will only treat erectile dysfunction 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 erectile dysfunction.
- urinary symptoms associated with a common condition called benign prostatic hyperplasia. This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass urine, a feeling of not completely emptying the bladder and a more frequent need to pass urine even at night. TADALAFIL ALPHAPHARM improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia.

Your doctor may have prescribed you TADALAFIL ALPHAPHARM to treat either, or both of these conditions.

2. What should I know before I use TADALAFIL ALPHAPHARM?

Warnings

Do not use TADALAFIL ALPHAPHARM if:

- You are allergic to tadalafil, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You are currently taking any nitrates - medicines used for the treatment of angina (chest pain) or other heart conditions. TADALAFIL ALPHAPHARM has been shown to increase the effects of these medicines.
- If you use recreational drugs called 'poppers' or 'amyl' like amyl nitrite and butyl nitrite that are normally taken through inhalation.
- If you use guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension.
- If you have heart or blood vessel problems that make sexual intercourse inadvisable. Sexual activity carries a possible risk to patients with a heart condition because it puts extra strain on the heart.
- If you have heart problems such as angina, arrhythmias (change in rhythm or rate of heartbeat), heart failure.

- If you have suffered a heart attack in the last 3 months.
- If you have suffered a stroke in the last 6 months.
- If your blood pressure is unusually high or low or is not effectively treated.
- If you have vision loss in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION).

Check with your doctor if you have or have had:

- Liver or kidney problems
- Heart problems or if you have had a heart attack
- Blood vessel problems
- 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 the penis (such as angulation, cavernosal fibrosis or Peyronie's disease)
- Loss of vision in one or both eyes
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Tell your doctor if you:

- Are aged 75 years and over.

You have a higher chance of experiencing side effects like dizziness and diarrhoea.

Your doctor will assess if TADALAFIL ALPHAPHARM is suitable for you.

Use in women

TADALAFIL ALPHAPHARM is not intended for use by women.

Use in children

TADALAFIL ALPHAPHARM is not intended for use by children under the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TADALAFIL ALPHAPHARM and affect how it works.

These include:

- nitrates, medicines such as glyceryl trinitrate, isosorbide mononitrate and sodium nitroprusside used to treat angina and other heart conditions (see [Section 2. What should I know before I use TADALAFIL ALPHAPHARM?](#))
- guanylate cyclase stimulators such as riociguat, used
- to treat pulmonary arterial hypotension (see [Section 2. What should I know before I use TADALAFIL ALPHAPHARM?](#))

- some antibiotic medicines such as rifampicin, erythromycin and clarithromycin
- some medicines used to treat seizures such as phenytoin, phenobarbitone and carbamazepine
- some medicines used to treat fungal infections such as ketoconazole and itraconazole
- protease inhibitors used to treat HIV such as ritonavir and saquinavir
- medicines used to treat hypertension (high blood pressure) such as metoprolol, irbesartan and enalapril
- alpha-blockers (used to treat hypertension and some prostate problems) such as prazosin and doxazosin
- a 5-alpha reductase inhibitor, such as finasteride (used to treat prostate and hair loss problems)
- warfarin, a medicine used to prevent or treat blood clots
- other PDE5 inhibitors such as sildenafil used to treat erectile dysfunction or pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs)
- grapefruit juice
- large amounts of alcohol

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these effect TADALAFIL ALPHAPHARM.

4. How do I use TADALAFIL ALPHAPHARM?

For erectile dysfunction:

- TADALAFIL ALPHAPHARM can be taken as either on-demand dosing or
- once-a-day dosing:
 - TADALAFIL ALPHAPHARM on-demand (10 mg or 20 mg) is intended for use prior to anticipated sexual activity and is not for continuous daily use.
 - TADALAFIL ALPHAPHARM once-a-day (5 mg) is for patients who anticipate frequent use of TADALAFIL ALPHAPHARM (i.e. at least twice weekly). Your doctor can advise on the appropriateness of once-a-day treatment. When taken once a day, TADALAFIL ALPHAPHARM allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day.
- Do not take once-a-day dosing and on-demand dosing concurrently.
- When taking TADALAFIL ALPHAPHARM once-a-day (5 mg), it may take up to 1 week for a full effect on erectile dysfunction.

For urinary symptoms associated with benign prostate hyperplasia

- TADALAFIL ALPHAPHARM once-a-day (5 mg) is taken daily. It may take up to a week to notice an

improvement and 1 month for a full effect on urinary symptoms such as urinating too frequently during the day or at night, the need to urinate being too urgent, or too soon after relieving your bladder.

How much to take

You should not take TADALAFIL ALPHAPHARM more than once a day.

On-demand dosing for erectile dysfunction

- The maximum recommended dose of TADALAFIL ALPHAPHARM is one 20 mg tablet taken before sexual activity.
- If you have kidney disease, the recommended dose of TADALAFIL ALPHAPHARM is one 10 mg tablet. This dose may be increased up to 20 mg. For patients with severe renal impairment, 10 mg is the maximum recommended dose.
- If you have liver disease, the recommended dose of TADALAFIL ALPHAPHARM is one 10 mg tablet. Patients with severe hepatic impairment should follow their doctor's advice.
- No special dosing consideration is needed for the elderly or people with diabetes.

Once-a-day dosing for erectile dysfunction and/or urinary symptoms associated with benign prostate hyperplasia:

- The recommended dose of TADALAFIL ALPHAPHARM is one 5 mg tablet, taken once per day.
- Dose adjustments are not required in patients with kidney disease unless you have severe renal impairment. Once-a-day dosing of TADALAFIL ALPHAPHARM is not recommended in patients with severe renal impairment.
- Patients with liver disease should follow their doctor's advice. Once-a-day dosing is not recommended in patients with severe hepatic impairment.
- No special dosing consideration is needed for the elderly or people with diabetes.

When to take TADALAFIL ALPHAPHARM

TADALAFIL ALPHAPHARM can be taken with or without food or alcohol. However, drinking alcohol may affect your ability to get an erection, so avoid excessive drinking.

On-demand dosing for erectile dysfunction:

- TADALAFIL ALPHAPHARM (10 mg or 20 mg) should be taken at least 30-60 minutes prior to anticipated sexual activity.
- The amount of time TADALAFIL ALPHAPHARM takes to work, varies from person to person. In some

men, TADALAFIL ALPHAPHARM can work as early as 16 minutes after taking the tablet. However it is recommended that you allow 1 hour the first time you take TADALAFIL ALPHAPHARM.

- TADALAFIL ALPHAPHARM has been proven to be effective for up to 36 hours. This means you can take TADALAFIL ALPHAPHARM and it will allow you to obtain an erection when sexually stimulated, at any time, during the 36 hours after taking it. Sometimes if you're feeling anxious or nervous you may not respond to the first tablet. Don't give up, it may take a few doses before you get the full benefit of TADALAFIL ALPHAPHARM.

Once-a-day dosing for erectile dysfunction and/or urinary symptoms associated with benign prostate hyperplasia:

- TADALAFIL ALPHAPHARM should be taken daily at approximately the same time of day
- TADALAFIL ALPHAPHARM must be taken daily to maintain effect

How to take TADALAFIL ALPHAPHARM

Swallow one tablet whole with a full glass of water.

If you use too much TADALAFIL ALPHAPHARM

If you think that you have used too much TADALAFIL ALPHAPHARM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TADALAFIL ALPHAPHARM?

Things you should do

If you have emergency treatment for any suspected heart condition, tell the emergency medical or ambulance staff that you are taking TADALAFIL ALPHAPHARM.

Remind any doctor, dentist or pharmacist you visit that you are using TADALAFIL ALPHAPHARM.

Things you should not do

- Do not take TADALAFIL ALPHAPHARM for any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TADALAFIL ALPHAPHARM affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may affect your ability to get an erection. Avoid excessive drinking.

When taking TADALAFIL ALPHAPHARM with large amounts of alcohol, some men may experience dizziness.

Looking after your medicine

- Store below 25°C.
- Keep your tablets in the original pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none">• Including skin rash, swelling of the face, and hives <p>Gastrointestinal:</p> <ul style="list-style-type: none">• Indigestion• Nausea or vomiting• Stomach pain• Diarrhoea	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Heart burn ● Nervous system: ● Headache or migraine ● Dizziness ● Fainting ● Musculoskeletal: ● Back pain ● Muscle pain Skin related: ● Sweating ● Vascular: ● Facial flushing ● Tiredness (fatigue) ● Bleeding nose ● Infection: ● Sore throat and discomfort when swallowing ● Nasal congestion (blocked nose) ● Eye related: ● Red eyes, eye pain, swelling of eyelids ● Blurred vision 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • Changes in colour vision 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Heart related: • Chest pain • Increased heart beat <p>If you experience chest pain during or after sexual activity, stop what you are doing, sit up and sit forward. Call an ambulance if the pain does not resolve. Do not use nitrates (medicines used for the treatment of angina (chest pain) or other heart conditions.</p> <p>Urogenital:</p> <ul style="list-style-type: none"> • Prolonged and painful erection • Erection that lasts longer than 4 hours <ul style="list-style-type: none"> • Eye related: • Decrease or loss of vision 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Ear related:</p> <ul style="list-style-type: none"> ● Sudden decrease or loss of hearing* ● Nervous system: ● Seizures* 	

**Sudden loss or decrease in hearing which may be accompanied by ringing in the ears and dizziness, loss of vision in one or both eyes, and seizures have been reported in people taking TADALAFIL ALPHAPHARM. It is not possible to determine whether these events are related directly to TADALAFIL ALPHAPHARM, to other diseases or medications, to other factors, or to a combination of factors. If you experience these symptoms, stop taking TADALAFIL ALPHAPHARM and contact a doctor immediately.*

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TADALAFIL ALPHAPHARM contains

Active ingredient (main ingredient)	Tadalafil
Other ingredients (inactive ingredients)	Povidone Sodium lauryl sulfate Poloxamer Lactose Croscarmellose sodium Microcrystalline cellulose Colloidal anhydrous silica Magnesium stearate OPADRY II complete film coating system 32K12884 YELLOW (ARTG PI. No. 4539)

Potential allergens	Sugars (as lactose)
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Do not take this medicine if you are allergic to any of these ingredients.

What TADALAFIL ALPHAPHARM looks like

TADALAFIL ALPHAPHARM 5 mg tablets are light yellow, film-coated, round, biconvex tablet debossed with 'M' on one side of the tablet and 'TL over 2' on the other side (AUST R 215925).

TADALAFIL ALPHAPHARM 10 mg tablets are light yellow, film-coated, round, biconvex tablet debossed with 'M' on one side of the tablet and 'TL3' on the other side (AUST R 215921).

TADALAFIL ALPHAPHARM 20 mg tablets are light yellow, film-coated, round, biconvex tablet debossed with 'M' on one side of the tablet and 'TL4' on the other side (AUST R 215929).

Who distributes TADALAFIL ALPHAPHARM

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

This leaflet was prepared in May 2021.

