

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 TADACIP?

TADACIP contains the active ingredient tadalafil. TADACIP is used to treat erectile dysfunction and urinary symptoms associated with benign prostatic hyperplasia

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

2. What should I know before I use TADACIP?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with TADACIP 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 TADACIP?

- For erectile dysfunction: can be taken as either on- demand dosing or once-a-day dosing. TADACIP on-demand (10 mg and 20 mg) is intended for use prior to anticipated sexual activity and is not for continuous daily use. TADACIP once-a-day (5 mg) is for patients who anticipate frequent use of TADACIP (i.e. at least twice weekly).
- For urinary symptoms associated with benign prostate hyperplasia: TADACIP once-a-day (5mg) is taken daily.

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

5. What should I know while using TADACIP?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using TADACIP.If you have emergency treatment for any suspected heart condition tell the emergency medical or ambulance staff that you are taking TADACIP.
Things you should not do	<ul style="list-style-type: none">Do not take TADACIP to treat 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	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how TADACIP affects you.
Drinking alcohol	<ul style="list-style-type: none">When taking TADACIP with large amounts of alcohol, some men may experience dizziness.
Looking after your medicine	<ul style="list-style-type: none">Keep your tablets in the original pack until it is time to take them.Keep your tablets in a cool dry place where the temperature stays below 25°C.Do not store TADACIP or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.Keep your medicine where children cannot reach.

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

6. Are there any side effects?

Common side effects: facial flushing, indigestion, chest pain, increased heart beat, back pain, tiredness (fatigue), feeling sick (nausea) or vomiting, muscle aches including pain in the arms and legs, stomach pain, diarrhoea, heart burn, allergic reactions, including skin rash, swelling of the face and hives, sweating, headache or migraine, nasal congestion, dizziness, fainting, infection, sore throat and discomfort when swallowing, red eyes, eye pain and swelling of eyelids, changes in colour vision, decreases or loss of vision, blurred vision, bleeding nose, prolonged erection

Serious side effects: chest pain during or after sexual activity, erection which lasts longer than 4 hours, TADACIP with large amounts of alcohol may cause dizziness, 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TADACIP*

Tadalafil: (ta-DAL-a-fil)

Consumer Medicine Information (CMI)

This leaflet provides important information about using TADACIP. **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 TADACIP.**

Where to find information in this leaflet:

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

1. Why am I using TADACIP?

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

TADACIP is used to:

- erectile dysfunction, also known as impotence, in men.
- urinary symptoms associated with a common condition called benign prostatic hyperplasia. This is when the prostate gland gets bigger with age.

2. What should I know before I use TADACIP?

Warnings

Do not use TADACIP 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.
- if you are currently taking any nitrates or amyl nitrite. Nitrates are medicines used for the treatment of angina ("chest pain") or other heart conditions. TADACIP has been shown to increase the effects of these medicines.
If you are taking any form of nitrate or are unsure talk to your doctor.
- 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 (changes in rhythm or rate of heart beat), 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 interior ischaemic optic neuropathy (NAION)
- if the packaging is torn or if the seals over the carton ends are missing or broken. There are no seals over the carton ends of the 5mg physician sample pack.

Check with your doctor if you:

- have any other medical conditions
 - 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
 - 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

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?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Allergies

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

TADACIP tablets contain a small amount of lactose.

Elderly

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 TADACIP is suitable for you.

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 be affected by TADACIP or may affect how it works. These include:

- Nitrates, medicine such as glyceryl trinitrate, isosorbide mononitrate and sodium nitroprusside used to treat angina and other heart conditions
- 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
- High doses of alcohol
- Grapefruit juice
- 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)
- Guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension.

These medicines may be affected by TADACIP or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

You should not take TADACIP together with any other treatments for erectile dysfunction.

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

4. How do I use TADACIP?

How much to take / use

You should not take TADACIP more than once a day.

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

ON-DEMAND DOSING FOR ERECTILE DYSFUNCTION

The maximum recommended dose of TADACIP is one 20 mg tablet taken before sexual activity.

If you have kidney disease, the recommended dose of TADACIP 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 TADACIP is one 10mg 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 TADACIP is one 5 mg tablet taken once per day.. Dosage adjustments are not required in patients with kidney disease, unless you have severe renal impairment. Once-a-day dosing of TADACIP is not recommended in patients with severe renal impairment.

Patients with liver disease should follow their doctor's advice. Once-a-day dosing of TADACIP is not recommended in patients with severe hepatic impairment.

No special dosing consideration is needed for the elderly or people with diabetes.

Follow the instructions provided and use TADACIP until your doctor tells you to stop.

When to take / use TADACIP

TADACIP can be taken with or without food or alcohol.

ON-DEMAND DOSING FOR ERECTILE DYSFUNCTION

TADACIP (10 mg or 20 mg) should be taken at least 30-60 minutes prior to anticipated sexual activity.

The amount of time TADACIP takes to work varies from person to person. In some men TADACIP can work as early as 16 minutes after taking the tablet but it is recommended that you allow 1 hour the first time you take it. TADACIP has been proven to be effective for up to 36 hours. This means you can take TADACIP 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 TADACIP.

ONCE-A-DAY DOSING FOR ERECTILE DYSFUNCTION AND/OR URINARY SYMPTOMS ASSOCIATED WITH BENIGN PROSTATE HYPERPLASIA

TADACIP 5 mg should be taken daily at approximately the same time of day. TADACIP must be taken daily to maintain effect..

How to take TADACIP

- Swallow one tablet whole with a full glass of water.
- **Follow all directions given to you by your doctor or pharmacist carefully.**
They may differ from the information contained in this leaflet.

For Erectile Dysfunction

- TADACIP can be taken as either on-demand dosing or once-a-day dosing. TADACIP on-demand (10 mg and 20 mg) is intended for use prior to anticipated sexual activity and is not for continuous daily use.
- TADACIP once-a-day (5 mg) is for patients who anticipate frequent use of TADACIP (i.e. at least twice weekly). Your Doctor can advise on the appropriateness of once-a-day treatment. When taken once a day, TADACIP 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 TADACIP once-a-day (5mg), it may take up to 1 week for a full effect on Erectile Dysfunction.

For urinary symptoms associated with Benign Prostate Hyperplasia

- TADACIP once-a-day (5mg) is taken daily. For urinary symptoms associated with benign prostatic hyperplasia 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. TADACIP must be taken daily to maintain effect.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

If you forget to use TADACIP

TADACIP should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much TADACIP

If you think that you have used too much TADACIP, 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.

Symptoms of an overdose may include headache, dyspepsia (indigestion), back pain, muscular aches, nasal congestion and facial flushing.

5. What should I know while using TADACIP?

Things you should do

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

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TADACIP.

Things you should not do

- Do not take TADACIP to treat 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 TADACIP affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

When taking TADACIP with large amounts of alcohol, you may experience dizziness.

Drinking alcohol may affect your ability to get an erection, so avoid excessive drinking.

Looking after your medicine

- **Keep your tablets in the original pack until it is time to take them.**
If you take the tablets out of the pack they may not keep as well.
- Store below 25°C.

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.

When to discard your medicine

If your doctor tells you to stop taking this medicine.

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
<ul style="list-style-type: none">• facial flushing• indigestion• chest pain• increased heart beat• back pain• tiredness (fatigue)• feeling sick (nausea) or vomiting• muscle aches, including pain in the arms and legs• stomach pain• diarrhoea• heart burn• allergic reactions, including skin rash, swelling of the face and hives• sweating• headache or migraine• nasal congestion• dizziness• fainting• infection• sore throat and discomfort when swallowing• red eyes, eye pain and swelling of eyelids are uncommon• changes in colour vision are rare• decreases or loss of vision are very rare• blurred vision• bleeding nose	Speak to your doctor if you have any of these less serious side effects and they worry you.

• prolonged erection	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• If you experience chest pain during or after sexual activity, stop what you are doing, sit up and sit forward.• In rare instances it is possible that a prolonged and possibly painful erection may occur after taking TADACIP. Penile bleeding or presence of blood in semen may occur rarely.• When taking TADACIP with large amounts of alcohol, some men may experience dizziness.• 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 TADACIP.	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.

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 TADACIP contains

Active ingredient (main ingredient)	Tadalafil
Other ingredients (inactive ingredients)	croscarmellose sodium, hydroxypropylcellulose, lactose, magnesium stearate, cellulose – microcrystalline, sodium lauryl sulfate, Opadry Yellow 03K520010 (ARTG# 110451) *, Opadry II Yellow 32K12884 (ARTG# 4539)**

Potential allergens	TADACIP tablets contain a small amount of lactose. This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.
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Do not take this medicine if you are allergic to any of these ingredients.

What TADACIP looks like

TADACIP 2.5 is 2.5 mg film-coated tablet AUST R 274231

TADACIP 5 is 5 mg film-coated tabletAUST R 274230

TADACIP 10 is 10 mg film-coated tabletAUST R 274224

TADACIP 20 is 20 mg film-coated tabletAUST R 274228

Who distributes TADACIP

Cipla Australia Pty Limited
Level 1, 132-136 Albert Road,
Melbourne, VIC 3205
AUSTRALIA. :
drugsafety@cipla.com
Phone: 1800-569-074

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