

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 ADCIRCA?

ADCIRCA contains the active ingredient tadalafil. ADCIRCA is used in adults as a treatment for pulmonary arterial hypertension.

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

2. What should I know before I use ADCIRCA?

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

Do not take ADCIRCA 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, 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 ADCIRCA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ADCIRCA 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 ADCIRCA?

- Always take ADCIRCA 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 ADCIRCA?](#) in the full CMI.

5. What should I know while using ADCIRCA?

Things you should do	<ul style="list-style-type: none">• Tell any doctor, dentist or pharmacist you visit that you are using ADCIRCA.• If you are about to be started on any new medicine, especially nitrates (medicines used for the treatment of angina ("chest pain") or other heart condition), remind your doctor and pharmacist.
Things you should not do	<ul style="list-style-type: none">• Do not take ADCIRCA 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">• ADCIRCA can cause dizziness and affect your vision. Be careful driving or operating machinery until you know how ADCIRCA affects you.
Drinking alcohol	<ul style="list-style-type: none">• When taking ADCIRCA with large amounts of alcohol, you may experience dizziness.
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 ADCIRCA?](#) in the full CMI.

6. Are there any side effects?

ADCIRCA may cause chest pain, headache or migraine, flushing, sweating, nausea, back pain, muscle pain.

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.

ADCIRCA®

Active ingredient: *tadalafil*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ADCIRCA?

ADCIRCA contains the active ingredient tadalafil.

ADCIRCA belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

ADCIRCA is used in adults as a treatment for pulmonary arterial hypertension.

ADCIRCA works by helping the blood vessels around your lungs relax, improving the flow of blood in your lungs. The result of this is an improved ability to do physical activity.

2. What should I know before I use ADCIRCA?

Warnings

Do not use ADCIRCA 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. ADCIRCA has been shown to increase the effects of these medicines.
- you use guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension
- you have suffered a heart attack in the last 3 months
- you have vision loss in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION)
- you have severe hypotension.

Check with your doctor if you have or have had:

- liver or kidney problems
- heart problems such as angina, arrhythmias (changes in the rhythm or rate of the heartbeat), heart failure, or if you have had a heart attack
- blood vessel problems
- sickle cell anaemia (an abnormality or 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) or unwanted or persistent erections lasting more than 4 hours

- loss of vision in one or both eyes
- hearing problems such as ringing in the ears, dizziness, or loss of hearing
- pulmonary veno-occlusive disease (PVOD).

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.

It is not known if ADCIRCA will harm your unborn baby or if ADCIRCA passes into your breastmilk.

Use in children

ADCIRCA 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 ADCIRCA and affect how it works.

These include:

- nitrates, medicines such as glyceryl trinitrate, used to treat angina and other heart conditions (see Section [2. What should I know before I use ADCIRCA?](#))
- guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension (see Section [2. What should I know before I use ADCIRCA?](#))
- bosentan and sildenafil (other treatments for pulmonary arterial hypertension)
- 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)
- alpha-blockers (used to treat hypertension and some prostate problems)
- medicines used to treat erectile dysfunction such as PDE5 inhibitors
- 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 affect ADCIRCA.

4. How do I use ADCIRCA?

How much to take

- ADCIRCA is supplied as a 20 mg tablet.
- The usual dose is two 20 mg tablets taken once a day. You should take both tablets at the same time, one after the other.
- If you have a mild or moderate liver or kidney problem, your doctor may advise you to take only one 20 mg tablet per day.

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

When to take ADCIRCA

- ADCIRCA can be taken with or without food.
- Take ADCIRCA tablets at the same time each day. You should take both tablets at the same time, one after the other, every day. Do not split your dose.

How to take ADCIRCA

- Swallow the tablets whole with a glass of water.

If you forget to take ADCIRCA

You must take ADCIRCA every day. If you forget to take ADCIRCA, take a dose as soon as you remember, then continue to take your tablets at the usual times.

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

If you use too much ADCIRCA

If you think that you have used too much ADCIRCA, 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 ADCIRCA?

Things you should do

Stop using ADCIRCA if you have a loss of eyesight in one or both eyes or sudden loss or decrease in hearing. Seek medical attention urgently.

If you are about to be started on any new medicine, especially nitrates (medicines used for the treatment of angina ("chest pain") or other heart condition), remind your doctor and pharmacist who treat you that you are taking ADCIRCA.

Things you should not do

- Do not take ADCIRCA for any other complaints unless your doctor tells you to.
- Do not give you 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 ADCIRCA affects you.

ADCIRCA may cause dizziness and effects on vision.

Drinking alcohol

Tell your doctor if you drink alcohol.

When taking ADCIRCA with large amounts of alcohol, you 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
Allergic reaction: <ul style="list-style-type: none">• including skin rash, swelling of the face and hives Gastrointestinal: <ul style="list-style-type: none">• indigestion• nausea• stomach pain• heart burn Nervous system: <ul style="list-style-type: none">• headache or migraine• dizziness Musculoskeletal: <ul style="list-style-type: none">• back pain• muscle pain Skin related: <ul style="list-style-type: none">• sweating Vascular: <ul style="list-style-type: none">• facial flushing	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> bleeding nose Infection: <ul style="list-style-type: none"> nasal congestion (blocked nose) respiratory tract infection Eye related: <ul style="list-style-type: none"> red eyes, eye pain, swelling of eyelids blurred vision 	

Serious side effects

Serious side effects	What to do
Heart related: <ul style="list-style-type: none"> chest pain increased heart beat Urogenital: <ul style="list-style-type: none"> prolonged and painful erection erection that lasts longer than usual Eye related: <ul style="list-style-type: none"> decrease or loss of vision Ear related: <ul style="list-style-type: none"> sudden decrease or loss of hearing* Nervous system: <ul style="list-style-type: none"> seizures* 	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.

*Sudden loss or decrease in hearing and seizures have been reported in people taking ADCIRCA. It is not possible to determine whether these events are related directly to ADCIRCA, to other diseases or medications, to other factors, or to a combination of factors.

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 that 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 ADCIRCA contains

Active ingredient (main ingredient)	tadalafil
Other ingredients (inactive ingredients)	croscarmellose sodium hypromellose hypromellose

	iron oxide yellow iron oxide red magnesium stearate microcrystalline cellulose sodium lauryl sulfate purified talc titanium dioxide triacetin
Potential allergens	lactose monohydrate

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What ADCIRCA looks like

ADCIRCA 20 mg tablets are orange, film coated, almond shaped tablets, marked "4467" on one side (Aust R 172882).

Who distributes ADCIRCA

Eli Lilly Australia Pty Ltd
Level 9, 60 Margaret Street
Sydney NSW 2000
AUSTRALIA
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