
Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tadalca. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tadalca against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Tadalca is used for

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

Tadalca belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors which work by helping the blood vessels around your lungs relax, improving the flow of blood into your lungs. The result of this is an improved ability to do physical activity.

Ask your doctor if you have any questions about why Tadalca has been prescribed for you.

Your doctor may have prescribed it for another reason.

Tadalca is available only with a doctor's prescription.

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

Before you take Tadalca

When you must not take it

Do not take Tadalca 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. Tadalca 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.

Do not take Tadalca:

- if you have suffered a heart attack in the last 3 months
- if you have vision loss in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION)
- severe hypotension
- if you use guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension

Do not take Tadalca if you have an allergy to:

- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack.

If it has expired, return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or if the seals over the carton ends are missing or broken.

If it is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Tadalca, talk to your doctor.

Before you start to take it

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

Tadalca tablets contain lactose monohydrate

Tell your doctor if you have or have had any of the following medical conditions:

- liver or kidney problems
- heart problems such as angina, arrhythmias (changes in the rhythm or rate of the heart beat), heart failure, or if you have had a heart attack
- blood pressure 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) or unwanted or persistent erections lasting more than 4 hours
- loss of vision in one or both eyes
- have ever had hearing problems such as ringing in the ears, dizziness, or loss of hearing
- have pulmonary veno-occlusive disease (PVOD)
- are pregnant or planning to become pregnant. It is not known if Tadalca will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant
- are breastfeeding or plan to breast feed. It is not known if Tadalca passes into your breast milk. You and your healthcare provider should decide if you will take Tadalca or breastfeed. You should not do both

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Tadalca.

Taking other medicines

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

Some medicines may be affected by Tadalca or may affect how it works. These include:

- Nitrates, medicines such as glyceryl trinitrate used to treat angina and other heart conditions
- 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)
- High doses of alcohol
- Grapefruit juice
- Medicines used to treat erectile dysfunction such as PDE5 inhibitors
- Guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Tadalca

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Tadalca 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.

How to take it

Swallow the tablets whole with a drink of water.

When to take it

Take Tadalca tablets at the same time every day. You should take both tablets at the same time, one after the other, every day. Do not split your dose.

Tadalca can be taken with or without food.

How long to take it

You must take Tadalca every day.

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you forget to take Tadalca, 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 missed tablets.

If you have any questions about taking Tadalca, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or the New Zealand National Poisons Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital, if you

think that you or anyone else may have taken too much Tadalca.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Tadalca

Things you must do

Stop using Tadalca 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, remind your doctor and pharmacist that you are taking Tadalca. Tell any other doctors, dentists and pharmacists who treat you that you are taking Tadalca.

Things you must not do

Do not take Tadalca 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.

Things to be careful of

Tadalca can cause dizziness and effects on vision. Be careful driving or operating machinery until you know how Tadalca affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tadalca.

Tadalca may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The following side effects are usually mild and short-lived.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- facial flushing
- indigestion
- back pain
- chest pain
- muscle aches
- heart burn
- stomach pain
- allergic reactions, including skin rash, swelling of the face and hives
- sweating
- headache or migraine
- nasal congestion
- dizziness
- red eyes, eye pain and swelling of eyelids are uncommon
- decreases or loss of vision are very rare
- blurred vision
- bleeding nose
- prolonged and possibly painful erection
- nausea
- respiratory tract infection

In rare instances it is possible that a prolonged and possibly painful erection may occur after taking Tadalca.

If you have an erection which lasts longer than usual, you should contact a doctor immediately.

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

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

If you experience these symptoms, stop taking Tadalca and contact a doctor immediately.

This is not a complete list of all possible side effects. Others may occur in some people and there may be side effects not yet known.

If you notice any symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything on this list.

After taking Tadalca

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Tadalca or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Tadalca 20 mg tablets are yellow, capsule shaped, biconvex, bevel-edged, film-coated tablets, debossed with "T 20" on one side and plain on the other side.

Ingredients

Active Ingredients

- tadalafil 20 mg

Other Ingredients

- croscarmellose sodium
- hypromellose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- sorbitan stearate

Tadalca tablets also contain Opadry II complete film-coating system 32K520009 Yellow.

Supplier

Tadalca is a product of:

Accord Healthcare Pty Limited
Level 24, 570 Bourke St
Melbourne
VIC 3000

Australian Registration Number

Tadalca 20 mg tablet - AUST R 282111