

# TADALIS 20

tadalafil

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about TADALIS 20. 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 TADALIS 20 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 TADALIS 20 is used for

TADALIS 20 is used in adults as a treatment for pulmonary arterial hypertension.

TADALIS 20 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 TADALIS 20 has been prescribed for you.**

Your doctor may have prescribed it for another reason.

TADALIS 20 is available only with a doctor's prescription.

TADALIS 20 is not intended for use by children under the age of 18 years.

### Before you take TADALIS 20

*When you must not take it*

**Do not take TADALIS 20 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. TADALIS 20 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 TADALIS 20:**

- 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 TADALIS 20 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 TADALIS 20, 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.**

TADALIS 20 tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), talk to your doctor before taking this medicine.

**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 TADALIS 20 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 tadalafil passes into your breast milk. You and your healthcare provider should decide if you will take TADALIS 20 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 TADALIS 20.**

*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 TADALIS 20 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 TADALIS 20 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 TADALIS 20

**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*

TADALIS 20 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 TADALIS 20 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.

TADALIS 20 can be taken with or without food.

*How long to take it*

You must take TADALIS 20 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 TADALIS 20, 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 TADALIS 20, 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 go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TADALIS 20.**

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

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### While you are taking TADALIS 20

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#### *Things you must do*

**Stop using TADALIS 20 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 TADALIS 20. Tell any other doctors, dentists and pharmacists who treat you that you are taking TADALIS 20.**

#### *Things you must not do*

Do not take TADALIS 20 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*

**Tadalafil can cause dizziness and effects on vision. Be careful driving or operating machinery until you know how TADALIS 20 affects you.**

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### Side effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TADALIS 20.

TADALIS 20 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 TADALIS 20.

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

When taking TADALIS 20 with large amounts of alcohol, you may experience dizziness.

Sudden loss or decrease in hearing and seizures have been reported in people taking TADALIS 20. It is not possible to determine whether these events are related directly to TADALIS 20, to other diseases or medications, to other factors, or to a combination of factors.

**If you experience these symptoms, stop taking TADALIS 20 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.**

#### *Reporting of side effects*

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at <http://www.tga.gov.au/reporting-problems>. By reporting side effects you can help provide more information on the safety of this medicine.

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### After taking TADALIS 20

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#### *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 TADALIS 20 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.**

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### Product description

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#### *What it looks like*

TADALIS 20, 20 mg film coated tablets are brown coloured, capsule shaped, biconvex film coated tablets with "T20" debossed on one side and plain on the other side.

### *Ingredients*

#### **Active Ingredients**

- tadalafil 20 mg

#### **Other Ingredients**

Tablet core:

- croscarmellose sodium,
- hydroxy propyl cellulose,
- lactose monohydrate,
- magnesium stearate,
- microcrystalline cellulose,
- sodium lauryl sulphate,
- purified water.

Tablet coating:

- hypromellose,
- iron oxide red,
- iron oxide yellow,
- lactose monohydrate,
- titanium dioxide,
- triacetin.

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

#### *Supplier*

TADALIS 20 is a product of Cipla Australia Pty Limited Level 1, 132-136 Albert Road, Melbourne, VIC 3205 AUSTRALIA.

Phone: 1800-569-074

#### *Australian Registration Number*

TADALIS 20, 20 mg

film coated tablet -

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