

NEW ZEALAND CONSUMER MEDICINE INFORMATION

CILATIL[®]

tadalafil film coated tablet 5 mg, 10 mg & 20 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Cilatil.

This leaflet answers some common questions about Cilatil.

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 Cilatil against the benefits they expect it will have for you.

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

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

What Cilatil is used for

Cilatil is used to treat:

- erectile dysfunction (ED) in adult men
- lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH)
- co-existing ED and LUTS associated with BPH.

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

It works by helping the blood vessels in the penis to relax, allowing the flow of blood into the penis, resulting in improved erectile function.

Your doctor may have prescribed this medicine for another reason.

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

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

Before you take Cilatil

When you must not take it

Do not take Cilatil if you are

- allergic any medicine containing tadalafil
- allergic any of the ingredients listed at the end of this leaflet
- currently taking any nitrates, medicines used to treat angina (chest pain) or other heart conditions. Cilatil has been shown to increase the effects of these medicines
- using recreational drugs called "poppers" or "amyl" like amyl nitrite and butyl nitrite that are normally taken through inhalation
- using guanylate cyclase stimulators such as riociguat to treat pulmonary arterial hypertension
- having 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.
- having heart problems such as angina, arrhythmias, heart failure
- suffered heart attack in the last 3 months
- suffered stroke in the last 6 months
- having unusually high or low blood pressure and is not effectively treated
- having vision loss in one eye because of non-arteritic anterior



ischaemic optic neuropathy (NAION)

Cilatil is not intended for use by women.

Cilatil is not intended for use by children and adolescents under the age of 18.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, 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.

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

- liver or kidney problems
- heart problems or if you have had a heart attack
- blood vessel problems
- red blood cell abnormality (sickle cell anaemia)
- bone marrow cancer (multiple myeloma)
- blood cell cancer (leukaemia)
- any deformation of the penis
- loss of vision in one or both eyes.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a

prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Cilatil.

Some medicines may interfere with Cilatil. These include:

- nitrates, medicines such as glyceryl trinitrate, isosorbide mononitrate and sodium nitroprusside used to treat angina and other heart conditions
- guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension
- 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.

These medicines may be affected by Cilatil 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 Cilatil

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 box, ask your doctor or pharmacist for help.

For erectile dysfunction

How much to take

Cilatil can be taken as either on-demand dosing or once-a-day dosing.

It is important to note that Cilatil does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay.

On-demand dosing for Erectile Dysfunction

Cilatil on-demand (10 mg or 20 mg) is intended for use prior to anticipated sexual activity and is not for continuous daily use. The maximum recommended dose of Cilatil is one 20 mg tablet taken before sexual activity. Cilatil may still be effective up to 36 hours after taking the tablet.

Once-a-day dosing for Erectile Dysfunction:

Cilatil once-a-day (5 mg) is for patients who anticipate frequent use of Cilatil (i.e., at least twice weekly). Your doctor can advise on the appropriateness of once-a-day treatment. When taken once a day, Cilatil allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day.

When taking Cilatil once-a-day (5 mg), it may take up to 1 week for a full effect on erectile dysfunction.

Do not take once-a-day dosing and on-demand dosing concurrently.

You should not take Cilatil more than once a day.

If you have liver or kidney disease, the recommended dose is lower. Please follow your doctor's advice.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Cilatil 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

Cilatil should be taken at least 30-60 minutes prior to anticipated sexual activity.

The amount of time Cilatil takes to work varies from person to person. In some men Cilatil can work as early as 16 minutes after taking the tablet.

Cilatil has been proven to be effective for up to 36 hours. This means you can take Cilatil 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 are 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 Cilatil.

Once-a-day dosing for erectile dysfunction

Cilatil should be taken daily at approximately the same time of day.

Cilatil must be taken daily to maintain effect.

For urinary symptoms associated with benign prostate hyperplasia

How much to take

Cilatil once-a-day (5 mg) is taken daily.

You should not take Cilatil more than once a day.

Please follow your doctor's advice if you have liver or kidney disease.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Cilatil can be taken with or without food or alcohol.

Cilatil should be taken daily at approximately the same time of day.

Cilatil must be taken daily to maintain effect.

How long to take it

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

This medicine helps to control your condition but does not cure it.

If you forget to take it

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Cilatil

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Cilatil 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

Be careful driving or operating machinery until you know how Cilatil affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, it may affect your ability to get an erection. Avoid excessive drinking.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Cilatil. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

This medicine helps most people with erectile dysfunction or urinary symptoms associated with BPH but it 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 treatment if you get some of the side effects.

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

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

- skin rash
- swelling of the face and hives
- indigestion
- nausea or vomiting
- stomach pain
- diarrhoea
- heart burn
- headache or migraine
- dizziness
- fainting
- back pain
- muscle pain
- sweating
- facial flushing
- tiredness (fatigue)
- bleeding nose
- sore throat, discomfort when swallowing

- nasal congestion (blocked nose)
- red eyes, eye pain, swelling of eyelids
- blurred vision
- changes in colour vision

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- increased heartbeat.

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).

- prolonged and painful erection
- erection that lasts longer than 4 hours
- decrease or loss of vision
- sudden decrease or loss of hearing
- seizures.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After taking Cilatil

Storage

Keep your tablets in the pack until it is time to take it.

If you take the tablets out of the pack they may not keep well.

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

Do not store Cilatil 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 it where children cannot reach it.

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

Cilatil 5 mg: A yellow film coated, almond shaped, biconvex tablet debossed with 'M' on one side of the tablet and 'TL6' on the other side. Pack size of 28 tablets.

Cilatil 10 mg: A yellow film coated, almond shaped, biconvex tablet debossed with 'M' on one side of the tablet and 'TL7' on the other side. Pack size of 4 tablets.

Cilatil 20 mg: A yellow film coated, almond shaped, biconvex tablet debossed with 'M' on one side of the tablet and 'TL8' on the other side. Pack size of 1, 4, or 8 tablets.

Ingredients

Active ingredient:

Cilatil contains 5, 10 or 20 mg of tadalafil as the active ingredient.

Inactive ingredients:

Cilatil also contains:

- povidone
- sodium laurylsulfate
- poloxamer
- lactose
- microcrystalline cellulose
- croscarmellose sodium

- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide (E171)
- triacetin
- talc (5 mg)
- iron oxide yellow
- iron oxide black (10 mg & 20 mg).

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Cilatil is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

4 May 2023

(Based on datasheet dated 22 October 2021)

Cilatil® is a Viatrix company trade mark.