

Consumer Medicine Information

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

Where to find information in this leaflet:

1. Why am I using CILATIL?
2. What should I know before I use CILATIL?
3. What if I am taking other medicines?
4. How do I use CILATIL?
5. What should I know while using CILATIL?
6. Are there any side effects?
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1. Why am I using CILATIL?

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

CILATIL is used to treat:

- erectile dysfunction, also known as impotence, in men. This is when a man cannot get, or maintain, a hard erect penis suitable for sexual activity. Following sexual stimulation, CILATIL works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. CILATIL will only treat erectile dysfunction if you are sexually aroused. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.
- urinary symptoms associated with a common condition called benign prostatic hyperplasia. This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass urine, a feeling of not completely emptying the bladder and a more frequent need to pass urine even at night. CILATIL improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia.

Your doctor may have prescribed you CILATIL to treat either, or both of these conditions.

2. What should I know before I use CILATIL?

Warnings

Do not use CILATIL 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. CILATIL has been shown to increase the effects of these medicines.
- 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.
- If you have 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.
- If you have heart problems such as angina, arrhythmias (change in rhythm or rate of heartbeat), 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 anterior ischaemic optic neuropathy (NAION).

Check with your doctor if you have or have had:

- Liver or kidney problems
- Heart problems or if you have had a heart attack
- Blood vessel problems
- Sick 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

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?

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 CILATIL is suitable for you.

Use in women

CILATIL is not intended for use by women.

Use in children

CILATIL 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 CILATIL and affect how it works.

These include:

- nitrates, medicines such as glyceryl trinitrate, isosorbide mononitrate and sodium nitroprusside used to treat angina

and other heart conditions (see Section 2. What should I know before I use CILATIL?)

- guanylate cyclase stimulators such as riociguat, used to treat pulmonary arterial hypotension (see Section 2. What should I know before I use CILATIL?)
- 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

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