

PART III: CONSUMER INFORMATION

PrCIALIS® (Pronounced See-AL-iss)

(Tadalafil Tablets)

This leaflet is part III of a three-part "Product Monograph" published when CIALIS was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CIALIS. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or your pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:

CIALIS is used for treatment of

- erectile dysfunction (ED) in men (when a man cannot get, or keep a hard, erect penis suitable for sexual activity).
- the signs and symptoms of benign prostatic hyperplasia (BPH). These symptoms include a frequent need to urinate, a sensation of not emptying the bladder completely, or painful urination.
- both ED and the signs and symptoms of BPH.

What it does:

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

Treatment of ED: Following sexual stimulation CIALIS works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. This results in improved erectile function.

It is important to note that CIALIS works only with sexual stimulation. CIALIS alone does not increase sexual desire.

Treatment of BPH and ED/BPH: CIALIS works by relaxing muscles in the prostate and bladder, which may reduce BPH symptoms.

When it should not be used:

Do not take CIALIS:

- If you are taking any medicines that contain nitrates in any form (oral, sublingual [under the tongue], skin-patch, or by inhalation). Similarly, nitrates must never be used by men who take CIALIS. Nitrates are found in many prescription medicines used in the treatment of angina pectoris (chest pain due to heart disease), such as nitroglycerin, isosorbide mononitrate, or isosorbide dinitrate. If nitrates have previously been prescribed to you, even though you may not have used them, or are unsure, tell your doctor.

If you take CIALIS with any nitrate-containing medicines or any other nitrates (e.g., amyl nitrite "poppers"), your blood pressure could suddenly drop to a life-threatening level. You could get dizzy, faint, or even have a heart attack or stroke.

- Do not take CIALIS if you have had an allergic reaction in the past to tadalafil or any of the other ingredients in CIALIS listed below.
- If you have had a previous episode of an eye condition called NAION which causes a sudden decrease or loss of vision in one or both eyes.
- If you are taking **riociguat (ADEMPAS®)**.

What the medicinal ingredient is:

Tadalafil

What the nonmedicinal ingredients are:

The other ingredients are: croscarmellose sodium, hydroxypropylcellulose, hydroxypropylmethylcellulose, iron oxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, talc, titanium dioxide and triacetin.

What dosage forms it comes in:

CIALIS comes as yellow or yellow-orange film-coated tablets. They are in the shape of almonds and have "C2½", "C5", "C10", or "C20" marked on one side. The active substance is tadalafil. Each tablet of CIALIS contains 2.5 mg, 5 mg, 10 mg or 20 mg of tadalafil.

WARNINGS AND PRECAUTIONS

Before taking CIALIS talk to your doctor if you:

have or had any of the following conditions:

- Heart disease or previously had a heart attack: Sexual activity carries a possible risk to patients with heart disease because it puts extra strain on your heart. Before you start any treatment for erectile dysfunction, ask your doctor if your heart is healthy enough to handle the extra strain of having sex. If you have chest pains, dizziness or nausea during sex, stop exerting yourself and tell your doctor you have had this problem.
- Stroke.
- Low blood pressure or uncontrolled high blood pressure.
- Liver or kidney problem.
- Sick cell anemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), or leukemia (cancer of the blood cells).
- Peptic ulcer or other bleeding disorders.
- Deformation of the penis.
- Ever had severe loss of vision, including a condition called Non-Arteritic Ischemic Optic Neuropathy (NAION). The specific type of vision decrease or loss known as NAION has been reported rarely after the intake of CIALIS or

IMPORTANT: PLEASE READ

other PDE5 inhibitors. Vision decrease or loss may be partial or complete, in one or very occasionally in both eyes. While in some cases the condition may improve over time, it can also be irreversible. If you are taking CIALIS and experience temporary or permanent loss or change in vision, stop taking CIALIS and immediately call your doctor.

- Hearing problems: Sudden decrease or loss of hearing has been reported with the use of PDE5 inhibitors, including CIALIS, although it is not known if it is due to drug or other factors.
- Lactose or milk sugar intolerance. CIALIS contains a small amount of lactose (about 250 mg).

CIALIS is not recommended to be used in combination with alpha blockers if you have symptoms of BPH.

CIALIS does not protect against sexually transmitted diseases including HIV/ AIDS.

Long-term studies have shown that CIALIS therapy may decrease sperm concentration in some men. The effect on fertility in men is unknown.

CIALIS is not intended for use by women or by children under 18 years of age.

When Cialis is used for the treatment of erectile dysfunction, diarrhea was reported more frequently in patients 65 years of age and older (2.5% of patients).

Only your doctor can decide if CIALIS is right for you. If you have ED, you will need to have a physical examination to diagnose your erectile dysfunction and to find out if you can take CIALIS alone or with your other medicines. If you have urinary problems, you will need to have a physical examination to diagnose your BPH and not a more serious condition such as prostate cancer.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including the medicine you can buy without prescription and natural health products.

Drugs that may interact with CIALIS include:

- nitrates (see previous section)
- rifampin (an antibacterial product used against tuberculosis)
- ketoconazole or itraconazole (used against fungal infections)
- erythromycin (an antibacterial product)
- protease inhibitors such as ritonavir and saquinavir (HIV treatments)

You should not use CIALIS together with any other treatments for erectile dysfunction or PDE5 inhibitors for treatment of pulmonary arterial hypertension (PAH), such as ADCIRCA® (tadalafil) or REVATIO® (sildenafil).

Tell your doctor if you are taking:

- medicines to treat high blood pressure
- alpha-blockers (such as doxazosin) for the treatment of prostate problems.

The combination of these medicines with CIALIS may add to the blood-pressure-lowering effect of these drugs.

PROPER USE OF THIS MEDICATION

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

How To Take CIALIS:

Always take CIALIS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not take a higher dose than the one which your doctor prescribed for you.

CIALIS tablets are for oral use. Swallow the tablet whole, with some water.

You may take CIALIS with or without food.

Alcohol consumption may decrease the ability to attain an erection and may also temporarily decrease blood pressure.

There are two different ways of taking CIALIS tablets to treat ED: a 20 mg *On-Demand* dose taken as needed, or a lower 5 mg daily dose. It may take up to 5 days for CIALIS *Once-a-Day* to reach steady blood levels.

For patients with ED:

- Try sex at different times to find out what works best for you and your partner.
- CIALIS works only if you are sexually stimulated.
- If you don't get the results you expect — talk to your doctor or pharmacist.

CIALIS for “On-Demand” Dosing: The recommended dose is one tablet (20 mg) before sexual activity, as needed. You should NOT take more than the prescribed dose of one CIALIS 10 mg or 20 mg tablet per day. The 10 mg and 20 mg doses are not recommended for continuous daily use.

You can engage in sexual activity within 30 minutes of taking the tablet and up to 36 hours later. The amount of time CIALIS takes to work varies from person to person.

CIALIS for Once-a-Day Use:

Treatment of ED: Your doctor may recommend that you take one tablet of CIALIS (5 mg or 2.5 mg) *Once-a-Day* every day, at approximately the same time each day, regardless of when you are planning to have sex.

Treatment of BPH and ED/BPH: Your doctor may recommend that you take one tablet of CIALIS 5 mg *Once-a-Day* every day, at approximately the same time each day.

Overdose:

If you have taken more CIALIS than you should, contact your doctor or a Poison Control Centre immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CIALIS can have some side-effects. These effects are usually mild to moderate in nature.

The most common side effects are headache, indigestion, back pain, muscle aches, nasal congestion, facial flushing, dizziness and high blood pressure.

Uncommon side-effects: swelling of the eyelids, eye pain, conjunctival hyperemia (red eyes) and allergic reactions (including skin rashes).

Rarely, a prolonged and possibly painful erection may occur after taking CIALIS. **If you have such an erection which lasts continuously for more than 4 hours, you should contact a doctor immediately. If this is not treated immediately, permanent penile tissue damage and erectile dysfunction may result.**

Sudden decrease or loss of vision has occurred rarely after the use of oral erectile dysfunction medications, including CIALIS. People who have previously experienced a type of vision loss called Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) are at an increased risk of reoccurrence of NAION. If you experience reduction or loss of vision in one or both eyes, stop taking CIALIS and immediately call your doctor.

If you take CIALIS and have chest pain during or after sexual activity, DO NOT use nitrates, and seek immediate medical assistance.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<u>Common</u> headache indigestion back pain muscle aches nasal congestion facial flushing	✓ ✓ ✓ ✓ ✓ ✓		
<u>Uncommon</u> Swelling of eyelids eye pain red eyes dizziness allergic reaction	✓ ✓ ✓ ✓		
<u>Rare</u> prolonged erection chest pain vision loss hearing loss transient amnesia		✓	✓ ✓ ✓ ✓ ✓

This is not a complete list of side effects. For any unexpected effects while taking CIALIS, contact your doctor or pharmacist.

HOW TO STORE IT

STORING CIALIS TABLETS

Keep out of the reach and sight of children.

Store your tablets at 15 to 30°C.

Store in the original package.

Do not use after the expiry date stated on the carton and blister.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at

www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your healthcare professionals or pharmacist first, or Eli Lilly Canada Inc. at: 1-888-545-5972 or visit the website at www.lilly.ca.

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

CIALIS is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

This leaflet was prepared by Eli Lilly Canada Inc.

Last revised: May 28, 2020

CLS-0003-CAPMI-20200528