

**PART III: CONSUMER INFORMATION**

**ADCIRCA™**  
(tadalafil tablets)  
20 mg

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

ADCIRCA is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

**What it does:**

ADCIRCA belongs to a group of medicines called phosphodiesterase type 5 inhibitors. ADCIRCA works by helping the blood vessels in your lungs to relax, allowing the flow of blood into your lungs. This results in lowering the arterial blood pressure in your lungs.

**When it should not be used:**

- Do not take ADCIRCA 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 patients who take ADCIRCA. 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 ADCIRCA 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 ADCIRCA if you have had an allergic reaction in the past to tadalafil or other medications that contain tadalafil such as CIALIS, or any of the other ingredients in ADCIRCA.

**What the medicinal ingredient is:**

Tadalafil

**What the nonmedicinal ingredients are:**

Croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, talc, titanium dioxide, and triacetin.

**What dosage forms it comes in:**

ADCIRCA is supplied as 20 mg orange, film-coated tablets. They are in the shape of almonds and have "4467" marked on one side. Each tablet of ADCIRCA contains 20 mg of tadalafil.

**WARNINGS AND PRECAUTIONS**

*Before taking ADCIRCA talk to your doctor if you have or had any of the following conditions:*

- a disease called pulmonary veno-occlusive disease (PVOD)
- lose a large amount of body fluids (dehydration). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot or don't drink enough liquids.
- heart disease or previously had a heart attack. Patients who experience chest pain or shortness of breath after taking ADCIRCA should not use nitrates and should seek immediate medical attention.
- stroke.
- low blood pressure or uncontrolled high blood pressure.
- liver or kidney problem.
- sickle cell anemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), or leukemia (cancer of the blood cells).
- 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 ADCIRCA or 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 ADCIRCA and experience temporary or permanent loss or change in vision, call your doctor.
- retinitis pigmentosa, a rare genetic eye disease.
- are pregnant or planning to become pregnant. It is not known if ADCIRCA could harm your unborn baby.
- are breastfeeding. It is not known if ADCIRCA passes into your breast milk or if it could harm your baby.

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

***Sudden decrease or loss of hearing:***

Sudden decrease or loss of hearing has been reported in a few postmarketing and clinical trial cases with the use of PDE5 inhibitors, including ADCIRCA. It has not been established whether these are related directly to the use of these medications or to other factors. If you experience these symptoms, call your doctor.

***Use in children:***

ADCIRCA is not intended for use in patients under 18 years of age.

***Information for patients intolerant of lactose, one of the ingredients of ADCIRCA:***

ADCIRCA contains a small amount of lactose (about 250 mg), which is unlikely to affect you.

**INTERACTIONS WITH THIS MEDICATION**

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

Drugs that may interact with ADCIRCA 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)
- phenobarbital, phenytoin, carbamazepine.

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 ADCIRCA may add to the blood-pressure-lowering effect of these drugs.

- Grapefruit juice may affect ADCIRCA blood levels.

You should not use ADCIRCA together with CIALIS or any other treatments for erectile dysfunction (impotence).

**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 ADCIRCA:***

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

ADCIRCA is a tablet you take by mouth. Take 2 ADCIRCA tablets together (to provide a 40 mg dose) at the same time every day. DO NOT divide the dose over the course of the day.

You may take ADCIRCA with or without food.

Alcohol consumption may temporarily decrease blood pressure.

**Overdose:**

**If you take too much ADCIRCA, call your doctor or poison control center, or go to an emergency room.**

**Missed Dose:**

If you miss a dose, take it as soon as you remember. If it is close to your next dose, skip the missed dose, and take your next dose at the regular time.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

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

The most common side effects are headache, muscle pain, facial flushing, nausea, pain in the arms or legs, back pain, upset stomach or heartburn, stuffy or congested nose. If you have any of these side-effects and they are troublesome, severe, or do not go away, tell your doctor.

Allergic reactions (including skin rashes) could occur.

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

**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 ADCIRCA. It has not been established whether the loss of vision is related directly to the use of PDE5 inhibitors or other factors. People who have previously experienced a type of vision loss called Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) may be at an increased risk of reoccurrence of NAION. If you experience reduction or loss of vision in one or both eyes, call your doctor.

## IMPORTANT: PLEASE READ

In case of chest pain or shortness of breath you should NOT use nitrates but you should 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	
<i>Common</i>			
Headache	✓		
muscle pain	✓		
facial flushing	✓		
back pain	✓		
indigestion	✓		
nasal congestion	✓		
<i>Uncommon</i>			
Swelling of eyelids	✓		
eye pain	✓		
allergic reaction	✓		
prolonged erection		✓	
chest pain		✓	
vision loss		✓	
hearing loss		✓	
temporary memory loss (transient global amnesia)		✓	

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

### HOW TO STORE IT

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.

### REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

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

Report online at [www.healthcanada.gc.ca/medeffect](http://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
- Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator: 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at [www.healthcanada.gc.ca/medeffect](http://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

Manufacturer: Eli Lilly Canada Inc.

Distributor: Eli Lilly Canada Inc.

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](http://www.lilly.ca).

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