

CIALIS® is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of:

- erectile dysfunction (ED) ([1.1](#))
- the signs and symptoms of benign prostatic hyperplasia (BPH) ([1.2](#))
- ED and the signs and symptoms of BPH (ED/BPH) ([1.3](#))

If CIALIS is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks ([1.4](#)).

### **DOSAGE AND ADMINISTRATION**

- *CIALIS for use as needed:*
  - ED: Starting dose: 10 mg as needed prior to sexual activity. Increase to 20 mg or decrease to 5 mg based upon efficacy/tolerability. Improves erectile function compared to placebo up to 36 hours post dose. Not to be taken more than once per day ([2.1](#)).
- *CIALIS for once daily use:*
  - ED: 2.5 mg taken once daily, without regard to timing of sexual activity. May increase to 5 mg based upon efficacy and tolerability ([2.2](#)).
  - BPH: 5 mg, taken at approximately the same time every day ([2.3](#))
  - ED and BPH: 5 mg, taken at approximately the same time every day ([2.3](#), [2.4](#))
- CIALIS may be taken without regard to food ([2.5](#)).

### **DOSAGE FORMS AND STRENGTHS**

Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg ([3](#)).

### **CONTRAINDICATIONS**

- Administration of CIALIS to patients using any form of organic nitrate is contraindicated. CIALIS was shown to potentiate the hypotensive effect of nitrates ([4.1](#)).
- History of known serious hypersensitivity reaction to CIALIS or ADCIRCA® ([4.2](#)).
- Administration with guanylate cyclase (GC) stimulators, such as riociguat ([4.3](#)).

### **WARNINGS AND PRECAUTIONS**

- Patients should not use CIALIS if sex is inadvisable due to cardiovascular status ([5.1](#)).
- Use of CIALIS with alpha-blockers, antihypertensives or substantial amounts of alcohol (≥5 units) may lead to hypotension ([5.6](#), [5.9](#)).
- CIALIS is not recommended in combination with alpha-blockers for the treatment of BPH because efficacy of the combination has not been adequately studied and because of the risk of blood pressure lowering. Caution is advised when CIALIS is used as a treatment for ED in men taking alpha-blockers. ([2.7](#), [5.6](#), [7.1](#), [12.2](#))
- Patients should seek emergency treatment if an erection lasts >4 hours. Use CIALIS with caution in patients predisposed to priapism ([5.3](#)).
- Patients should stop CIALIS and seek medical care if a sudden loss of vision occurs in one or both eyes, which could be a sign of non-arteritic anterior ischemic optic neuropathy (NAION). CIALIS should be used with caution, and only when the

anticipated benefits outweigh the risks, in patients with a history of NAION. Patients with a "crowded" optic disc may also be at an increased risk of NAION ([5.4](#), [6.2](#)).

- Patients should stop CIALIS and seek prompt medical attention in the event of sudden decrease or loss of hearing ([5.5](#)).
- Prior to initiating treatment with CIALIS for BPH, consideration should be given to other urological conditions that may cause similar symptoms ([5.14](#)).

### **ADVERSE REACTIONS**

Most common adverse reactions ( $\geq 2\%$ ) include headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb ([6.1](#)).

**To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

### **DRUG INTERACTIONS**

- CIALIS can potentiate the hypotensive effects of nitrates, alpha-blockers, antihypertensives or alcohol ([7.1](#)).
- CYP3A4 inhibitors (e.g. ketoconazole, ritonavir) increase CIALIS exposure ([2.7](#), [5.10](#), [7.2](#)) requiring dose adjustment:
  - CIALIS for use as needed: no more than 10 mg every 72 hours
  - CIALIS for once daily use: dose not to exceed 2.5 mg
- CYP3A4 inducers (e.g. rifampin) decrease CIALIS exposure ([7.2](#)).

### **USE IN SPECIFIC POPULATIONS**

Hepatic Impairment ([2.6](#), [5.8](#), [8.6](#)):

- Mild or Moderate: Dosage adjustment may be needed.
- Severe: Use is not recommended.

Renal Impairment ([2.6](#), [5.7](#), [8.7](#)):

- Patients with creatinine clearance 30 to 50 mL/min: Dosage adjustment may be needed.
- Patients with creatinine clearance less than 30 mL/min or on hemodialysis: For use as needed: Dose should not exceed 5 mg every 72 hours. Once daily use is not recommended.