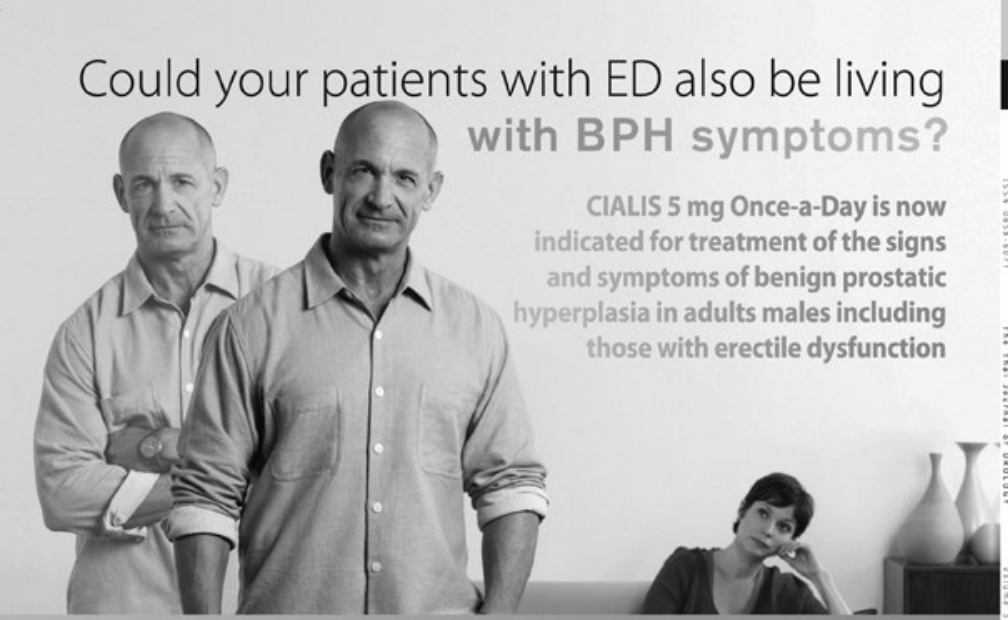
Could your patients with ED also be living with BPH symptoms?



CIALIS 5 mg Once-a-Day is now indicated for treatment of the signs and symptoms of benign prostatic hyperplasia in adults males including those with erectile dysfunction

Two conditions. One patient.

CIALIS is indicated to treat both ED + BPH symptoms

ED = erectile dysfunction; BPH = benign prostatic hyperplasia.

Convenient dosing options*

Lilly | Men's Health

Cialis ONCE-A-DAY
tadalafil 5 mg

For the treatment of ED, BPH and ED + BPH

- Taken once-a-day at approximately the same time of day
- With or without food
- Sexual stimulation is required (men with ED)

Pharmacokinetics† Steady-state plasma concentrations attained within 5 days of Once-a-Day dosing †Clinical significance unknown.

CIALIS® Tadalafil 5 mg film-coated tablet **Indications** Treatment of erectile dysfunction in adult males. In order for Tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required. Tadalafil 5 mg is also indicated for treatment of the signs and symptoms of benign prostatic hyperplasia in adult males including those with erectile dysfunction. **Dosage and administration** For oral use **Erectile dysfunction in adult men** In responder patients to on-demand regimen who anticipate a frequent use of Tadalafil 5 g, at least twice weekly, a preset daily regimen with the lowest doses of Tadalafil might be considered available, based on patient choice and the physicians's judgement. In these patients, the recommended dose is 2.5 mg taken once a day at approximately the same time of day. **Benign prostatic hyperplasia in adult men** The recommended dose is 5 mg, taken at approximately the same time every day with or without food. For adult men being treated for both benign prostatic hyperplasia and erectile dysfunction, the recommended dose is also 5 mg taken at approximately the same time every day. **Renal impairment** Dosage adjustments are not required in patients with mild to moderate renal impairment. Once-a-day dosing of 2.5 or 5 mg Tadalafil both for the treatment of erectile dysfunction or benign prostatic hyperplasia is not recommended in patients with severe renal impairment. **Hepatic impairment** Once-a-day dosing of Tadalafil both for the treatment of erectile dysfunction and benign prostatic hyperplasia has not been evaluated in patients with hepatic impairment; therefore, if prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. In clinical studies, Tadalafil was chosen to augment the hypotensive effects of nitrates. This is thought to result from the combined effects of nitrates and Tadalafil on the nitric oxide/cGMP pathway. Therefore, administration of Tadalafil to patients who are using any form of organic nitrate is contraindicated. Agents for the treatment of erectile dysfunction, including Tadalafil, should not be used in men with cardiac disease for whom sexual activity is inadvisable. Physicians should consider the potential cardiac risk of sexual activity in patients with pre-existing cardiovascular disease. The following groups of patients with cardiovascular disease were not included in clinical trials and the use of Tadalafil is therefore contraindicated: patients with myocardial infarction within the last 90 days, patients with unstable angina or angina occurring during sexual intercourse, patients with New York Heart Association Class 2 or greater heart failure in the last 6 months, patients with uncontrolled arrhythmias, hypotension (< 90/50 mm Hg), or uncontrolled hypertension, patients with a stroke within the last 6 months. Tadalafil is contraindicated in patients who have lost of vision in one eye because of non-arteritic anterior ischemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure **Warnings and precautions** Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Tadalafil has vasodilator properties, resulting in mild and transient decreases in blood pressure and as such potentiates the hypotensive effects of nitrates. In patients receiving concomitant antihypertensive medications, Tadalafil may induce a blood pressure decrease. Where initiating daily treatment with Tadalafil, appropriate clinical considerations should be given to a possible dose adjustment of the antihypertensive therapy. Visual defects and cases of non-arteritic anterior ischemic optic neuropathy have been reported in connection with the intake of Tadalafil and other PDE-5 inhibitors. The patient should be advised that in case of sudden visual defect, he should stop taking Tadalafil and consult a physician immediately. Patients who experience erections lasting 4 hours or more should be instructed to seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result. Agents for the treatment of erectile dysfunction, including Tadalafil, should not be used with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease), or in patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia). In patients who are taking alpha (1) blockers, such as doxazosin, concomitant administration of Tadalafil may lead to symptomatic hypotension in some patients. Therefore, the combination of Tadalafil and alpha blockers is not recommended. The safety and efficacy of combinations of Tadalafil and other PDE-5 inhibitors or other treatments for erectile dysfunction have not been studied. Therefore, the use of such combinations is not recommended. Tadalafil contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Interaction with other medicinal products** Tadalafil is principally metabolised by CYP3A4. A selective inhibitor of CYP3A4, ketoconazole (200mg daily), increased Tadalafil (10 mg) exposure (AUC) 2-fold and C_{max} by 15% relative to the AUC and C_{max} values for Tadalafil alone. Ketoconazole (400mg daily) increases Tadalafil (20mg) exposure (AUC) 4-fold and C_{max} by 22%. Ritonavir, a protease inhibitor (200mg, dose given twice daily), which is an inhibitor of CYP3A4, CYP2C9, CYP2C19, and CYP2D6, increased Tadalafil (20mg) exposure (AUC) 2-fold with no change in C_{max}. Although specific interactions have not been studied, other protease inhibitors, such as indinavir, and other CYP3A4 inhibitors, such as erythromycin, clarithromycin, telaprevir and grapefruit juice should be co-administered with caution as they would be expected to increase plasma concentrations of Tadalafil. The role of transporters, for example p-glycoprotein in the disposition of Tadalafil is not known. There is thus the potential of drug interactions mediated by inhibition of transporters. A CYP3A4 inducer, rifampicin, reduced Tadalafil AUC by 88 % relative to the AUC values for Tadalafil alone. This reduced exposure can be anticipated to decrease the efficacy of Tadalafil; the magnitude of decreased efficacy is unknown. Other inducers of CYP3A4 such as phenobarbital, phenytoin and carbamazepine, may also decrease plasma concentrations of Tadalafil. In clinical studies, Tadalafil (5 mg) was chosen to augment the hypotensive effects of nitrates. Therefore, administration of Tadalafil to patients who are using any form of organic nitrate is contraindicated. In a patient prescribed Tadalafil (2.5 mg, 20mg), where nitrate administration is deemed medically necessary in a life-threatening situation, at least 48 hours should have elapsed after the last dose of Tadalafil before nitrate administration is considered. In such circumstances, nitrates should only be administered under close medical supervision with appropriate haemodynamic monitoring. The co-administration of doxazosin (4 and 8 mg daily) and Tadalafil (5 mg daily dose) increases the blood pressure-lowering effect of the alpha-blocker in a significant manner. This effect lasts at least twelve hours and may be symptomatic, including syncope. Therefore this combination is not recommended. In interaction studies performed in a limited number of healthy volunteers, these effects were not aggravated with alfuzosin or tamsulosin. However, caution should be exercised when using Tadalafil in patients treated with any alpha-blockers, and notably in the elderly. Treatments should be initiated at minimal dosage and progressively adjusted. Tadalafil has been demonstrated to produce an increase in the oral bioavailability of ethinylestradiol a similar increase may be expected with oral administration of terbutaline, although the clinical consequence of this is unknown. Tadalafil is not expected to cause clinically significant inhibition or induction of the clearance of medicinal products metabolised by CYP450 isoforms. Studies have confirmed that Tadalafil does not inhibit or induce CYP450 isoforms, including CYP3A4, CYP1A2, CYP2D6, CYP2E1, CYP2C9 and CYP2C19. **Pregnancy and lactation** Tadalafil is not indicated for use by women. There are limited data from the use of Tadalafil in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of Tadalafil during pregnancy. Available pharmacodynamic/toxicological data in animals have shown excretion of Tadalafil in milk. A risk to the suckling child cannot be excluded. Tadalafil should not be used during breast feeding. **Adverse reactions** Common Headache, Flushing, Nasal congestion, Dyspepsia, Back pain, Myalgia, Pain in extremity Uncommon Hypersensitivity reactions, Dizziness, Blurred vision, Sensations described as eye pain, Tachycardia, Palpitations, Hypotension, Hypertension, Epistaxis, Dyspnoea, Abdominal pain, Gastro-oesophageal reflux, Rash, Hyperhydrosis (sweating), Chest pain **Shelf life** 3 years. **Storage** Do not store above 25°C.

"โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา"
ใบอนุญาตโฆษณาเลขที่ อศ. 3342/2558

Reference: Thailand package insert.
Identifying Code: CIA-15-01-007

Further information is available on request at
Eli Lilly Asia Inc., Thailand
9th Floor, CRC Tower, All seasons place, 87/2 Wireless road, Patumwan, Bangkok
Tel +662 612 6200 Fax +662 612 6222

Lilly

ปีที่ 37 ฉบับที่ 2 กรกฎาคม - ธันวาคม 2559 Volume 37 No.2 July - December 2016

สมาคมศัลยแพทย์ระบบปัสสาวะแห่งประเทศไทย ในพระบรมราชูปถัมภ์ | The Thai Urological Association under the Royal Patronage

ISSN 0858-6071

วารสารยูโรโลยี
The Thai Journal of UROLOGY