### Advice to provide to patients

Consider whether the patient is taking a medication that could be causing ED.

For example, medication for hypertension (e.g. thiazide diuretics and beta-blockers), prostate cancer (e.g. anti-androgens and luteinising hormone-releasing hormone agonists and antagonists), pain (e.g. opiates) and psychological conditions (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors, benzodiazepines and antipsychotics). You may still supply Cialis for men but should advise the patient to see a doctor to review their other medication.

Consider whether there are any psychological causes for ED.

For example, depression, anxiety, stress.

# Advice for patients who have been supplied Cialis for men

How to take Cialis for men	<ul> <li>One 10mg tablet as needed</li> <li>Can be taken with or without food</li> <li>Avoid drinking grapefruit juice as this may increase the risk of side effects</li> <li>Drinking excessive alcohol can temporarily reduce patients' ability to get an erection and increase the risk of postural hypotension, causing dizziness. To get the maximum benefit from their medicine, patients are advised not to drink large amounts of alcohol before sexual activity</li> </ul>
When to take Cialis for men	<ul> <li>Should be taken at least 30 minutes before anticipated sexual activity</li> <li>Maximum recommended dose of one tablet a day</li> <li>Not recommended for continuous daily use – patients requiring frequent use (i.e. at least twice weekly) should see their doctor</li> </ul>
What to expect	<ul> <li>Sexual stimulation is required for Cialis for men to be effective</li> <li>Starts working 30 minutes after taking</li> <li>Effects last for up to 36 hours (1.5 days)</li> <li>For most patients, Cialis for men will work the first or second time they try it. If it has been some time since they were able to get or keep an erection, it may take several attempts on different occasions before they are able to achieve an erection</li> </ul>
What to do if Cialis for men does not work	<ul> <li>Patients who are not able to achieve a sufficient erection for satisfactory sexual activity even after several attempts on different occasions should see their doctor</li> <li>Patients whose ED worsens after using Cialis for men should see their doctor</li> </ul>
When to have a health check	Patients should see their doctor at the earliest opportunity after being supplied     Cialis for men to check for underlying conditions that could be causing their ED. It is     recommended that this should occur within 6 months
When to seek medical help	<ul> <li>Patients should be advised to STOP taking Cialis for men and seek immediate medical help if they experience any of the following side effects:         <ul> <li>Long-lasting (more than 4 hours) erection</li> <li>Sudden vision defect or loss</li> <li>Sudden decrease or loss of hearing</li> <li>Chest pain within 48 hours (2 days) of taking Cialis for men; dizziness or nausea during or after sex. If this occurs, patients should be advised to get into a semi-sitting position and try to relax. DO NOT TAKE NITRATES to treat chest pain</li> </ul> </li> </ul>
Read the PIL	Remind every patient to read the PIL carefully before taking Cialis for men

# Advice for patients who have not been supplied Cialis for men

See your doctor for advice and treatment

 Patients should see their doctor for assessment of suitability for Cialis for men or for alternative treatment for their ED

# General health advice for all patients

ED can be a sign or symptom of another underlying health problem, e.g. cardiovascular disease, hypertension, diabetes mellitus, hypercholesterolaemia or alcohol dependence. All patients with ED should therefore be advised to consult their doctor within 6 months for a clinical review of potential underlying conditions and risk factors associated with ED.

Provide appropriate advice on lifestyle factors and general healthy living, including losing weight, giving up smoking, cutting back on alcohol/recreational drugs, exercising regularly, reducing stress.

Please read the SmPC for full details of contraindications, warnings and precautions. Remind every patient to read the PIL carefully before taking Cialis for men.

# Cialis for men 10mg tablets Product Information

Cialis for men 10mg tablets Product Information

**Presentation**: Cialis for men 10mg film-coated tablets containing 10mg of tadalafil. **Indications**: Treatment of erectile dysfunction in adult males. **Dose and administration**: Men (including the elderly) 18 years of age or over: The recommended dose is one 10mg tablet taken at least 30 minutes prior to anticipated sexual activity. The maximum dosing frequency is once per day. Cialis for men is not recommended for continuous daily use. Contraindications: Hypersensitivity to the active substance or to any of the excipients, co-administration with nitric oxide donors or nitrates, cardiac disease in patients where sexual activity is inadvisable, myocardial infarction within the last 90 days, unstable angina or angina during sexual intercourse, New York Heart Association Class 2 or heart failure within 6 months, uncontrolled arrhythmia, hypotension (<90/50mmHg), uncontrolled hypertension, stroke within 6 months, non-arteritic anterior ischaemic optic neuropathy (NAION) causing loss of vision in one eye, co-administration with guanylate cyclase stimulators (e.g. riociguat), women, those without erectile dysfunction, and men under 18 years of age. **Warnings and precautions**: All men with erectile dysfunction should be advised to consult their doctor at the earliest opportunity for a clinical review of potential underlying conditions and risk factors associated with erectile dysfunction. Patients should consult their physician if symptoms of erectile dysfunction have not improved after taking Cialis for men on several consecutive occasions, or if their erectile dysfunction worsens. Patients who experience erections lasting longer than 4 hours should seek immediate medical assistance. Patients should consult their doctor before taking Cialis for men if they have: An anatomical deformation of the penis (such as angulation, cavernosal fibrosis, or Peyronie's disease), or conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma, or leukaemia), undergone pelvic surgery or radical non-nerve sparing prostatectomy, severe renal impairment, severe hepatic impairment, or in the event of sudden decrease or loss of hearing. Patients with pre-existing cardiovascular disease and/or risk factors should be advised of the potential cardiac risk associated with sexual activity. Cialis for men is not recommended for patients who experience chest pain or breathlessness after light or moderate activity. Concomitant administration of Cialis for men and alpha 1 adrenergic blockers may lead to symptomatic hypotension in some patients. Cialis for men contains lactose; Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take Cialis for men. Visual defects, including central serous chorioretinopathy (CSCR) and cases of NAION have been reported in connection with treatment. In the case of sudden visual defect, visual acuity impairment and/or visual distortion, the patient should stop taking Cialis for men and consult a physician immediately. **Interactions**: Nitrates, nitric oxide donors (nicorandil, molsidomine), doxazosin and other alpha 1 adrenergic blockers, antihypertensives, riociguat, 5-alpha reductase inhibitors (e.g. finasteride), theophylline, ethinylestradiol, terbutaline, alcohol, CYP3A4 inhibitors such as ketoconazole, itraconazole, erythromycin, clarithromycin, and grapefruit juice should be administered with caution as they may increase the incidence of adverse reactions. Inducers of CYP3A4 such as rifampicin, phenobarbital, phenytoin and carbamazepine may decrease plasma concentrations of tadalafil and decrease efficacy. **Pregnancy and breastfeeding**: Cialis for men is not indicated for use in women, **Adverse Reactions**: Adverse events observed from spontaneous reporting and clinical trials: Common (≥1/100 and <1/10): Headache, flushing, nasal congestion, dyspepsia, back pain, myalgia, pain in extremity. Uncommon (≥1/1,000 and <1/100): Hypersensitivity reactions, dizziness, blurred vision, sensations described as eye pain, tinnitus, tachycardia, palpitations, hypotension, hypertension, dyspnoea, epistaxis, abdominal pain, vomiting, nausea, gastro-oesophageal reflux, rash, haematuria, prolonged erections, chest pain, peripheral oedema, fatigue. Rare (21/10,000 and <1/1000): Angioedema, stroke (including haemorrhagic events), syncope, transient ischaemic attacks, migraines, seizures, transient amnesia, visual field defect, swelling of eyelids, conjunctival hyperaemia, NAION, retinal vascular, occlusion, sudden hearing loss, myocardial instruction, unstable angina pectoris, ventricular arrhythmia, varicaria, Stevens-Johnson syndrome, exfoliative dermatitis, hyperhydrosis, priapism, penile haemorrhage, haematospermia, facial oedema, sudden cardiac death.

Legal status: Product not subject to medical prescription.

Marketing Authorisation Number: PA25208/001/001

Product licence holder: A. Nattermann & Cie. GmBH, Brüningstraße 50, 65929, Frankfurt am Main, Germany.

Further information is available from the distributor: Clonmel Healthcare Ltd. Pharmacovigilance, Waterford Road, Clonmel, Co. Tipperary, E91 D768.

Email: medicalinformation@clonmel-health.ie.

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Adverse events should be reported: Reporting forms and information can be found at <a href="https://www.hpra.ie">www.hpra.ie</a>. Adverse events should also be reported to the Clonmel Healthcare Medical Information department on (052) 617 7777.

#### References:

1. American Heart Association. Classes of Heart Failure [Internet]. 2017 [cited January 2024]. Available from: <a href="https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure.">https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure.</a>



Treatment for erectile dysfunction

# Pharmacist Checklist Quick Guide

Marketing Authorisation Holder: A. Nattermann & Cie. GmBH, Brüningstraße 50, 65929, Frankfurt am Main, Germany.

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#### Guidance on use

This Pharmacist Checklist Quick Guide is provided to assist you in your assessment of a **patient's suitability for Cialis for men**. It is designed to be used in conjunction with the Cialis for men Checklist. The Cialis for men Checklist can be provided to the patient to complete before consultation with you or it can be used as part of your consultation with the patient.

Use of this material is optional and pharmacists should use their professional judgement to decide when and how to use it.

Cialis for men is for adult men aged 18 years or over with erectile dysfunction (ED), and should not be used by men who do not have ED.

CHECKLIST QUESTION	PHARMACIST ACTION	
Cardiovascular health		
Do you, or have you ever had a problem with your heart or blood vessels (e.g. heart attack, stroke, low or high blood pressure or feeling dizzy)?	Patients with stable cardiovascular disease or those with low cardiovascular risk may be suitable for Cialis for men, as long as their doctor has advised they can resume sexual activity and they do not have any other contraindications.	
	<ul> <li>Do not supply Cialis for men to patients with any of the following conditions:</li> <li>Myocardial infarction in the last 3 months</li> <li>Unstable angina or angina during sex</li> <li>Heart failure in the last 6 months of New York Heart Association (NYHA) Class 2 or more<sup>1</sup></li> <li>Arrhythmia, hypotension (&lt;90/50 mmHg; symptoms of which include dizziness and blurred vision), uncontrolled hypertension</li> <li>Stroke in the last 6 months</li> </ul>	
	These patients should be referred to their doctor.	
Do you feel very breathless or get chest pain if you walk fast for 20 minutes or climb 2 flights of stairs?	Do not supply Cialis for men to patients who experience cardiovascular symptoms on light/moderate physical activity.	
	Advise them to see their doctor as soon as possible for assessment and advice/treatment for their cardiovascular symptoms.	
Medication		
Have you ever been prescribed any nitrate medicine used to treat or prevent chest pain (angina), heart attack or heart failure?	Do not supply Cialis for men to patients who have been prescribed a nitrate medication.  Refer them to their doctor for advice about treatment for their ED.	
Are you using recreational drugs called "poppers" (e.g. amyl nitrite)?	Do not supply Cialis for men to patients who are using recreational drugs called "poppers" (e.g. amyl nitrite).	
	Advise patients not to use Cialis for men with nitrates as this may lead to a drop in blood pressure.	
Are you taking or using any medication?	<ul> <li>Do not supply Cialis for men to patients taking any of the following medications:</li> <li>Guanylate cyclase stimulators used for pulmonary hypertension (e.g. riociguat)</li> <li>Alpha blockers used for benign prostatic hypertrophy or hypertension (e.g. doxazosin, alfuzosin or tamsulosin)</li> <li>CYP1A2 substrates used for asthma or COPD (e.g theophylline)</li> <li>CYP3A4 inhibitors used for: <ul> <li>HIV infections (e.g. ritonavir, saquinavir)</li> <li>Fungal infections (e.g. ketoconazole, itraconazole)</li> <li>Bacterial infections (e.g. clarithromycin, erythromycin)</li> <li>Stomach ulcers or oesophageal reflux disease (e.g. cimetidine)</li> </ul> </li> <li>5-alpha reductase inhibitors used for benign prostatic hyperplasia or male pattern hair loss (e.g. finasteride)</li> </ul>	

CHECKLIST QUESTION	PHARMACIST ACTION	
Medication		
Are you taking or using any medication?	Refer them to their doctor for advice about treatment for their ED. The doctor may be able to change the concomitant medication to reduce the risk of a drug-drug interaction in order to enable the patient to take Cialis for men.	
	While CYP3A4 inducers (e.g. rifampicin) are not contraindicated, they may reduce the efficacy of Cialis for men.	
	Patients taking another PDE5 inhibitor can switch to Cialis for men as long as they take it as indicated.	
Other health conditions		
Do you have any health conditions?	Do not supply Cialis for men to patients who report any of the following health conditions representing warnings for use of Cialis for men:	
For example:  Problems with your liver or kidneys  Blood diseases (e.g leukaemia, sickle cell anaemia, multiple myeloma)	<ul> <li>Severe renal impairment (including dialysis)</li> <li>Severe hepatic impairment (Child-Pugh class C)</li> <li>Conditions that predispose to priapism: <ul> <li>Sickle cell anaemia</li> <li>Multiple myeloma</li> <li>Leukaemia</li> </ul> </li> <li>Refer them to their doctor for advice about treatment.</li> </ul>	
Have you ever had loss of vision because of damage to your optic nerve (known as NAION)?	Do not supply Cialis for men to patients who report non-arteritic anterior ischaemic optic neuropathy (NAION). Refer them to their doctor for advice about treatment.	
Do you have Peyronie's disease or any other condition causing a change in the shape of your penis?	Do not supply Cialis for men to patients with anatomical deformations of the penis that predispose to priapism:  Bent or curved penis (angulation)  Scar tissue on or below the surface of the penis (cavernosal fibrosis)  Peyronie's disease  Refer them to their doctor for advice about treatment.	

For patients who are allergic or intolerant to **tadalafil** or to any of the other **ingredients** in Cialis for men, including patients who have a lactose intolerance, should not use the product.

#### Ingredients in Cialis for men

Tablet core: lactose monohydrate, croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurilsulfate, magnesium stearate.

Film coat: lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), iron oxide yellow (E172), talc.

#### REPEAT SUPPLY

- Check that the patient has not experienced any problems related to Cialis for men
   Check for any side effects and provide advice on managing common side effects or refer to a doctor.
- 2. Check that there are no changes in the patient's health conditions or other medications since the last supply of Cialis for men
- Check for any changes that are contraindications or warnings and advise the patient to see a doctor for advice.
- 3. Check when the last supply of Cialis for men was and that the patient is not using Cialis for men on a continuous daily basis

Cialis for men is not recommended for continuous daily use. If the patient requires frequent use (i.e. at least twice weekly), they should be advised to see a doctor.

