

**Cialis<sup>®</sup>**  
for men

# Pharmacy Guide

Cialis for men 10mg film-coated tablets  
(tadalafil).

**sanofi**

# About this guide and Cialis for men

Cialis for men 10mg film-coated tablets (tadalafil)

This guide, together with the **Cialis for men Checklist and Pharmacist Checklist Quick Guide** (which helps with the interpretation of patients’ answers), has been developed by Sanofi to support pharmacists and pharmacy assistants in **managing the risks** related to Cialis for men and enabling its **appropriate supply and use**.

It summarises key information to help you **identify patients to whom you can supply Cialis for men**, and the **advice you should give to help them use the product appropriately**. A series of situations that you might encounter with patients are included to highlight how the **advice in this guide can be applied in real-life situations**. Pharmacy training materials will be available in print and digitally.

Cialis for men is a film-coated tablet containing 10mg tadalafil for the **treatment of erectile dysfunction** (the inability to achieve and/or maintain a penile erection sufficient for satisfactory sexual performance) in adult men. It is taken **as needed at least 30 minutes before sexual activity** and no more than one tablet should be taken per day. Cialis for men has been shown to statistically **improve erectile function and the ability to have successful sexual intercourse for up to 36 hours**.

In some cases, patients will require **referral to their doctor to confirm suitability for Cialis for men** or for **advice or alternative treatment**. For full information, including all contraindications, warnings and possible side effects, please refer to the Summary of Product Characteristics and the Package Leaflet by searching for ‘Cialis for men’ on the Health Products Regulatory Authority website: [www.hpra.ie](http://www.hpra.ie).

Cialis  
for men

Checklist

Cialis for men is for the treatment of erectile dysfunction (ED) in adult men 18 years and older. If you are not a man 18 years or older you should not use this product. ED is the difficulty in achieving and/or maintaining an erection sufficient for sexual performance.

Please fill out this short checklist before speaking to a pharmacist. Your answers will help the pharmacist determine whether this product is right for you. It is important to answer all the questions and provide information that is as accurate as possible.

Tick the box that best applies; please answer all the questions.

QUESTION	ANSWER
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)?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Do you feel very breathless or get chest pain if you walk fast for 20 minutes or climb 2 flights of stairs?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Have you ever been prescribed any nitrate medicine used to treat or prevent chest pain (angina), heart attack or heart failure?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Are you using recreational drugs called "poppers" (e.g. amyl nitrate)?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Are you taking or using any medication?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Do you have any health conditions? For example: • Problems with your liver or kidneys • Blood disorders (e.g. haemophilia, sickle cell anaemia, multiple myeloma)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Have you ever had loss of vision because of damage to your optic nerve (known as NAION)?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE
Do you have Peyronie's disease or any other condition causing a change in the shape of your penis?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE

**IMPORTANT:** Erectile dysfunction may be an early sign of diseases such as heart disease or diabetes. You are advised to have a health check with your doctor within 6 months, to find out what could be causing your erectile dysfunction symptoms.

If you know you have any allergies or intolerances please check with the pharmacist.

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Cialis  
for men

Treatment for erectile dysfunction

Pharmacist  
Checklist  
Quick Guide

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# What is erectile dysfunction?

## PREVALENCE

Erectile dysfunction (ED) is the **inability to achieve and/or maintain an erection for satisfactory sexual performance**.<sup>14</sup> It is a common condition, **with 42.6% of men (aged ≥18 years) in the United Kingdom, and approximately 53.9 million men across the European Union** self-reporting difficulty in achieving or maintaining an erection during a 6-month period.<sup>12</sup> In Ireland, **49.6% of men (aged ≥18 years) reported at least one sexual dysfunction, and 15.4% of men (aged ≥18 years) reported erectile dysfunction**, which lasted for at least one month within the 5 years prior.<sup>28</sup>

## CAUSES

A number of things can cause or contribute to the development of ED, including **risk factors, underlying health conditions or certain medications**.

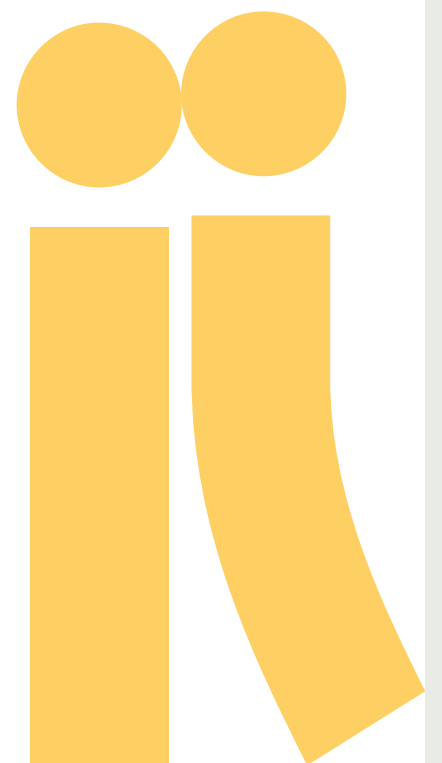
Risk factors of ED <sup>11,16,17,24</sup>	Underlying health conditions that can contribute to ED <sup>10,20,24,25,27</sup>	Medications that can cause ED as a side effect <sup>27</sup>
<ul style="list-style-type: none"><li>• Ageing</li><li>• Lack of exercise</li><li>• Obesity</li><li>• Smoking</li><li>• High cholesterol</li><li>• Metabolic syndrome</li></ul>	<ul style="list-style-type: none"><li>• Cardiovascular disease (CVD)</li><li>• Hypertension</li><li>• Diabetes</li><li>• Alcohol dependence</li><li>• Psychological issues (e.g. depression, performance-related issues, traumatic past experiences, low self-esteem and relationship problems)</li></ul>	<ul style="list-style-type: none"><li>• Hypertension (e.g. thiazide diuretics and beta-blockers)</li><li>• Prostate cancer (e.g. anti-androgens and luteinising hormone-releasing hormone agonists and antagonists)</li><li>• Pain (e.g. opiates)</li><li>• Psychological conditions (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors, benzodiazepines and antipsychotics)</li></ul>

## IMPACT OF ED ON QUALITY OF LIFE

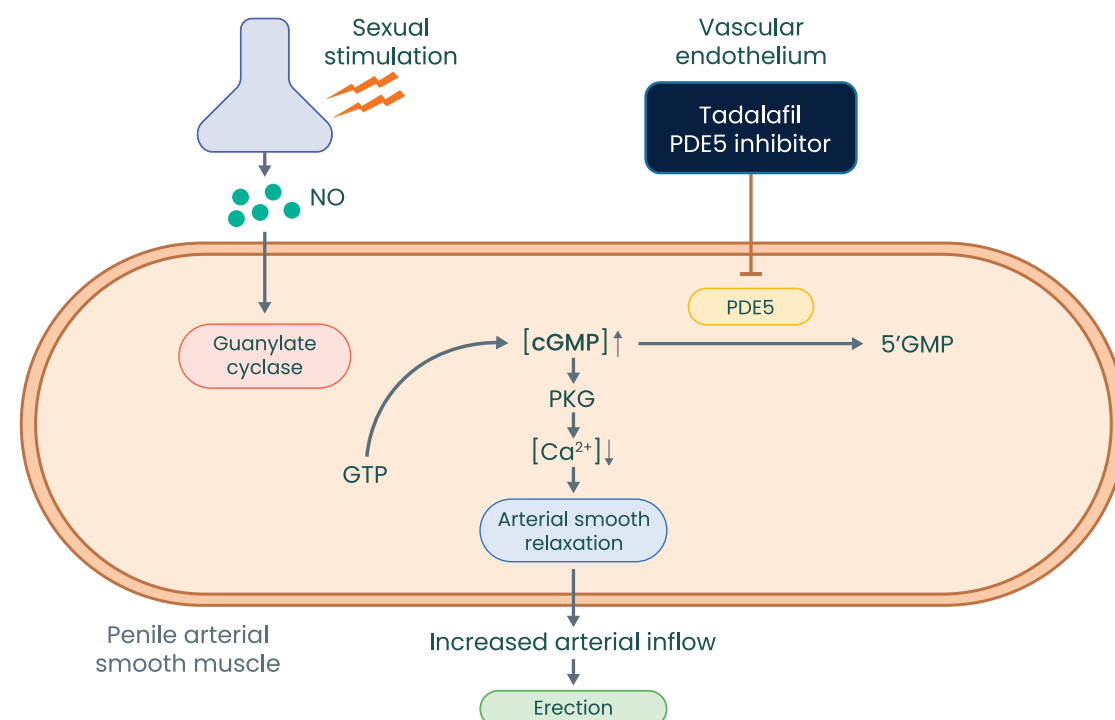
ED can have a **profound impact on the quality of life of men**, negatively affecting their emotional and psychological wellbeing and self-esteem, as well as their relationships.<sup>19</sup> The sexual and emotional lives of partners are also negatively impacted by ED, leading to significant relationship difficulties and distress.<sup>7,22</sup> Effective treatment for ED significantly improves sexual satisfaction for men and their partners<sup>2,4,8,15,26</sup> and increases sexual self-confidence,<sup>13</sup> resulting in better relationships<sup>5,15</sup> and a greatly enhanced quality of life.<sup>3,18</sup>

# What is Cialis for men and how does it work?

Cialis for men belongs to a class of medicines called **phosphodiesterase type 5 (PDE5) inhibitors**.<sup>23</sup> These are considered **first-line treatment for ED** by the European Association of Urology.<sup>9</sup>



## HOW CIALIS FOR MEN WORKS



Adapted from Cruz-Burgos M *et al.* 2021<sup>6</sup>

Ca<sup>2+</sup> = calcium ion; cGMP = cyclic guanosine monophosphate; 5'GMP = guanosine-5-monophosphate; GTP = guanosine triphosphate; NO = nitric oxide; PDE5 = phosphodiesterase type 5; PKG = protein kinase G.

Cialis for men is available as film-coated tablets containing **10mg of tadalafil**.<sup>23</sup> Tadalafil is a **selective, reversible PDE5 inhibitor**.<sup>23</sup> Similar to other PDE5 inhibitors, when **sexual stimulation** causes the local release of nitric oxide (NO), inhibition of PDE5 by tadalafil increases levels of cyclic guanosine monophosphate (cGMP) in the corpus cavernosum (smooth muscle within the penis). This leads to the relaxation of the smooth muscle and allows an inflow of blood into the penile tissues, thereby producing an erection.<sup>23</sup> In order for tadalafil to work, a **local release of NO is required**.<sup>23</sup>

**Cialis for men does not, therefore, work without sexual stimulation.**<sup>23</sup>

## THE EFFICACY OF CIALIS FOR MEN

Clinical studies have demonstrated that Cialis for men effectively treats ED at the recommended 10mg non-prescription dose. Studies in a **total of 706 men** of different ages **with ED**, who had ED of varying severity (mild to severe) and a range of concomitant diseases, observed that men were able to **achieve and maintain erections for successful intercourse** as early as **30 minutes after dosing** compared to placebo.<sup>23</sup> Cialis for men demonstrated **statistically significant improvement in erectile function and the ability to have successful intercourse up to 36 hours** following dosing.<sup>23</sup>

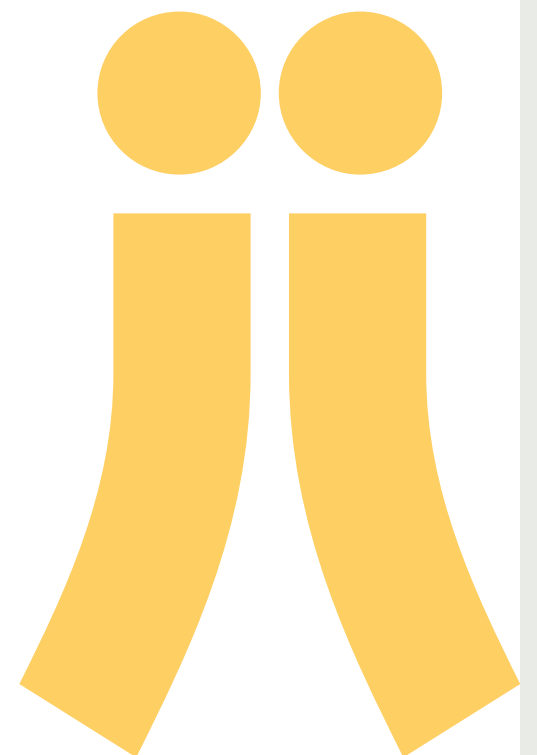
As with all PDE5 inhibitors, whilst many patients will find Cialis for men effective the first or the second time they use it, for others it may be necessary to make several attempts on different occasions before they experience the maximum benefit from treatment.<sup>23</sup>

Some patients may require a higher or more regular dose of Cialis for men and should be referred to their doctor for treatment.<sup>23</sup> In Ireland, the higher 20mg dose and the daily 5mg dose are only available on prescription.

# Who can use Cialis for men

Cialis for men is for adult men aged 18 years or over with ED, defined as the inability to achieve and/or maintain an erection sufficient for satisfactory sexual performance.<sup>14,23</sup> There are a number of contraindications and special warnings which mean that some patients cannot use Cialis for men, see the next page.<sup>23</sup>

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.**<sup>23</sup>



# Who must not use Cialis for men

**Cialis for men is not intended for men without ED and is not effective in this population.<sup>23</sup>**

Patients with any of the contraindications listed on the following pages must not use Cialis for men. These patients should be **referred to their doctor for advice and treatment.**<sup>23</sup>





All contraindications are listed in the table below, together with a brief explanation as to why each represents a contraindication.

CONTRAINDICATION	EXPLANATION
Health conditions	
<b>Severe or unstable CVD:</b> <ul style="list-style-type: none"><li>• <b>Heart attack</b> (myocardial infarction) in the last 3 months<sup>23</sup></li><li>• <b>Chest pain or breathlessness at rest</b> (unstable angina), or chest pain (angina) occurring during sexual intercourse<sup>23</sup></li><li>• <b>Heart failure</b> (New York Heart Association Class 2 or greater*) in the last 6 months<sup>23</sup></li><li>• <b>Irregular heartbeat</b> (arrhythmia), low blood pressure (hypotension; &lt;90/50 mmHg) symptoms of which include dizziness and blurred vision, or high blood pressure (hypertension) that is not well controlled with medication<sup>23</sup></li><li>• <b>Stroke</b> in the last 6 months<sup>23</sup></li></ul>	<p>Patients with these conditions were excluded from the clinical trials, so no safety data are available to assess the risk.<sup>23</sup></p> <p>Patients with <b>significant CVD</b>, for whom <b>sexual activity is considered by their doctor to be inadvisable</b>, are contraindicated because of the potentially higher risk of cardiovascular events during sex.<sup>23</sup></p> <p>Patients with cardiovascular symptoms suggesting unstable angina should be referred to their doctor as soon as possible for assessment and advice/treatment.</p>
<b>Loss of vision in one eye</b> due to non-arteritic anterior ischaemic optic neuropathy (NAION; loss of blood flow to the optic nerve) <sup>23</sup>	An <b>increased risk of NAION</b> has been suggested in men with ED taking tadalafil or other PDE5 inhibitors. Patients with pre-existing NAION must not use Cialis for men, regardless of whether their episode is related to previous PDE5 inhibitor use. <sup>23</sup>
<b>Anatomical deformation of the penis</b> <sup>23</sup>	This includes a bent or curved penis (angulation), scar tissue on or below the surface of the penis (cavernosal fibrosis) and Peyronie’s disease. <sup>23</sup>

\*New York Heart Association heart failure classification: Class 2 heart failure defined as slight limitation of physical activity; comfortable at rest; ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.<sup>1</sup>

CONTRAINDICATION		EXPLANATION
Allergy or intolerance		
Allergy or intolerance to the active substance or any of the excipients <sup>23</sup>		Patients who are allergic or intolerant to <b>tadalafil</b> or to any of the other <b>ingredients*</b> in Cialis for men, including lactose, must not use the product. <sup>23</sup>
Other medications		
Use of <b>NO donors or nitrates</b> <sup>23</sup> (such as amyl nitrite also known as “poppers”)	Concomitant use of either of these medications with Cialis for men may lead to an unsafe drop in blood pressure. <sup>23</sup>  Before taking any other medicines, patients should tell their doctor or pharmacist if they have taken Cialis for men within the last 48 hours, as the medicine may still be in their body.	
Use of <b>guanylate cyclase stimulators</b> (e.g. riociguat) <sup>23</sup>		
Indication		
Under 18 years of age <sup>23</sup>	Cialis for men is only indicated in <b>adult men</b> with erectile dysfunction. <sup>23</sup>	
Women <sup>23</sup>		

\*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<sup>23</sup>

WHEN TO REFER TO A DOCTOR

Many patients will be suitable for Cialis for men, however, there are situations in which patients need to be referred to their GP to check suitability for Cialis for men.<sup>23</sup>

These are situations where:

- A doctor needs to perform a benefit-risk assessment based on the patient’s medical history or comorbidities
- The patient is taking concomitant medication that interacts with Cialis for men. The doctor may be able to change the medication to reduce the risk of a drug-drug interaction to enable the patient to take Cialis for men
- A patient is unable to tolerate light or moderate physical activity

These situations are described in the table below, together with a brief explanation as to why each requires a benefit-risk assessment by a doctor before use of Cialis for men.

WARNING	EXPLANATION
Health conditions	
Severely impaired kidney function (severe renal impairment) <sup>23</sup>	This condition could cause patients to have increased plasma concentrations of Cialis for men which may increase the incidence of adverse reactions associated with the product. <sup>23</sup>
Severely impaired liver function (severe hepatic impairment) <sup>23</sup>	There are limited data on the safety of tadalafil in men with severe hepatic impairment (defined as Child-Pugh class C). <sup>23</sup>
Long-lasting erection (unrelated to sexual stimulation; priapism) <sup>23</sup>	Patients with erections lasting 4 hours or longer (whether painful or not) are at risk of damage to the penile tissue and permanent loss of potency if not treated immediately. <sup>23</sup>
Conditions that predispose to priapism (sick cell anaemia, multiple myeloma, leukaemia) <sup>23</sup>	
Pelvic surgery or radical non-nerve sparing prostatectomy <sup>23</sup>	The effectiveness of Cialis for men in these patients is unknown. <sup>23</sup>

WARNING	EXPLANATION
Health conditions	
Successful vascularisation (e.g. via coronary artery bypass grafting, stenting, or angioplasty), asymptomatic controlled hypertension, mild valvular disease <sup>21</sup>	These men are considered at low cardiovascular risk and may be suitable for treatment but they should consult a doctor before resuming sexual activity. <sup>21</sup>
Uncontrolled hypertension, moderate to severe valvular disease, left ventricular dysfunction, hypertrophic obstructive and other cardiomyopathies, or significant arrhythmias <sup>21</sup>	These men must be advised to consult a doctor before resuming sexual activity. <sup>21</sup>
Breathlessness or chest pain from light to moderate physical activity (e.g. walking briskly for 20 minutes or climbing 2 flights of stairs) <sup>21</sup>	This may indicate undiagnosed cardiovascular disease. Tadalafil is not recommended in these men. <sup>21</sup>
WARNING	EXPLANATION
Other medications	
Use of <b>alpha blockers</b> <sup>23</sup>	<p>Concomitant use in men receiving treatment for enlarged prostate (benign prostatic hypertrophy), or hypertension may lead to an unsafe drop in blood pressure.<sup>23</sup></p> <p>Concomitant use of Cialis for men and doxazosin is not recommended. Tadalafil and doxazosin appear to have a more pronounced hypotensive effect than other medicines in this class.<sup>23</sup></p> <p>Patients taking other alpha blockers should check with their doctor whether Cialis for men can be used.<sup>23</sup></p> <p>If patients experience symptoms of an unsafe drop in blood pressure, they should seek advice from their doctor.<sup>23</sup></p>
Use of <b>CYP1A2 substrates (e.g. theophylline)</b> <sup>23</sup>	Concomitant use of Cialis for men with theophylline may lead to a small increase in heart rate. <sup>23</sup> This may be used for COPD or asthma.

WARNING	EXPLANATION
Other medications	
Use of <b>CYP3A4 inhibitors</b> <sup>23</sup>	<p>Tadalafil is mainly metabolised by CYP3A4. Concomitant use of tadalafil with potent CYP3A4 inhibitors leads to increased plasma concentrations of tadalafil, which may increase the incidence of adverse reactions associated with the product.<sup>23</sup></p> <p>Potent CYP3A4 inhibitors include grapefruit juice, as well as treatments for:</p> <ul style="list-style-type: none"><li>• Human immunodeficiency virus (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>
Use of <b>CYP3A4 inducers</b> <sup>23</sup>	<p>Tadalafil is mainly metabolised by CYP3A4. Concomitant use of tadalafil with the CYP3A4 inducer, rifampicin, leads to reduced plasma concentrations of tadalafil, which may reduce its efficacy.<sup>23</sup></p> <p>Other CYP3A4 inducers that may also decrease plasma concentrations of tadalafil include treatments for epilepsy (e.g. phenobarbital, phenytoin and carbamazepine).<sup>23</sup></p>
Use of <b>5-<math>\alpha</math> reductase inhibitors</b> <sup>23</sup>	<p>There are no data regarding the effects of concomitant use of tadalafil with 5-<math>\alpha</math> reductase inhibitors.<sup>23</sup></p> <p>5-<math>\alpha</math> reductase inhibitors (e.g. finasteride) may be taken for enlarged prostate gland (benign prostatic hyperplasia)<sup>23</sup> or male pattern hair loss.</p>
Use of <b>other ED treatments</b> <sup>23</sup>	<p>The concomitant use of tadalafil and other PDE5 inhibitors or ED treatments is not recommended as this has not been studied.<sup>23</sup> However, patients may safely switch between different PDE5 inhibitors, including Cialis for men, as long as they take them as directed and not within 36 hours of their last Cialis for men dose.<sup>23</sup></p>



# How to supply Cialis for men

Before checking for any contraindications and warnings, including use of any interacting medications, **confirm that Cialis for men is indicated for the patient.** Cialis for men is for adult men aged 18 years or over with ED, and must **not be used by patients who do not have ED.**<sup>23</sup>

## FIRST-TIME USERS

If you establish that the patient has ED, follow steps 1–3 below to confirm suitability for Cialis for men.

### 1 Check that the patient does not have any contraindicated health conditions:<sup>21,23</sup>

- Myocardial infarction in the last 3 months
- Unstable angina or angina during sex
- Heart failure in the last 6 months of NYHA Class 2 or more
- Arrhythmia, hypotension (<90/50 mmHg; symptoms of which include dizziness and blurred vision), uncontrolled hypertension
- Stroke in the last 6 months
- NAION
- Allergy or intolerance to the active ingredient, tadalafil, or any of the excipients
- Anatomical deformations of the penis:
  - Bent or curved penis (angulation)
  - Scar tissue on or below the surface of the penis (cavernosal fibrosis)
  - Peyronie's disease

### 2 Check that the patient does not have any concomitant health conditions that represent warnings:<sup>21,23</sup>

- Severe renal impairment
- Severe hepatic impairment
- Priapism or conditions that predispose to priapism:
  - Sick cell anaemia
  - Multiple myeloma
  - Leukaemia
- Pelvic surgery or radical non-nerve sparing prostatectomy (the effectiveness of tadalafil is unknown in this group of patients)
- Increased susceptibility to vasodilators
- Successful vascularisation, asymptomatic controlled hypertension or mild valvular disease
- Uncontrolled hypertension, moderate to severe valvular disease, left ventricular dysfunction, hypertrophic obstructive and other cardiomyopathies, or significant arrhythmias
- Breathlessness or chest pain from light to moderate physical activity

**If the patient has any of these health conditions, Cialis for men may not be suitable and a benefit–risk assessment by a doctor is required before use. The patient should be referred to a doctor for assessment of suitability.**

### 3 Check that the patient is not taking any contraindicated medications, or medications that represent warnings:<sup>21,23</sup>

- NO donors or nitrates used:
  - For angina (e.g. molsidamine, nicorandil, glyceryl trinitrate, isosorbide dinitrate)
  - As the recreational drug “poppers” (amyl nitrite)
- Guanylate cyclase stimulators used for pulmonary hypertension (e.g. riociguat)
- Alpha blockers used for benign prostatic hypertrophy or hypertension (e.g. doxazosin)
- CYP1A2 substrates used for asthma or COPD (e.g. theophylline)
- CYP3A4 inhibitors used for:
  - HIV infections (e.g. ritonavir, saquinavir)
  - Fungal infections (e.g. ketoconazole, itraconazole)
  - Bacterial infections (e.g. clarithromycin, erythromycin)
  - Stomach ulcers or oesophageal reflux disease (e.g. cimetidine)
- CYP3A4 inducers used for bacterial infection (e.g. rifampicin) or for epilepsy (e.g. phenobarbital, phenytoin and carbamazepine)
- 5- $\alpha$  reductase inhibitors used for benign prostatic hyperplasia or male pattern hair loss (e.g. finasteride)

**If the patient is taking an interacting medication, refer the patient to a doctor for advice.**

**If the patient is taking a PDE5 inhibitor or other ED treatment, provide advice on how to take Cialis for men safely.**

**If the patient has any of the contraindicated health conditions, the supply of Cialis for men is not suitable. The patient should be referred to a doctor for advice and treatment.**

**Inform patients that erection problems can be a sign of another health condition such as heart disease, hypertension, diabetes or depression. Advise all patients who are supplied with Cialis for men to see their doctor at the earliest opportunity for a clinical review of potential underlying conditions and risk factors associated with ED.<sup>23</sup> It is recommended that this should occur within 6 months.**



## USING THE PHARMACIST CHECKLIST QUICK GUIDE, CIALIS FOR MEN CHECKLIST, REPEAT PURCHASE OR REFERRAL CARD WITH FIRST-TIME USERS

### Pharmacist Checklist Quick Guide

The Pharmacist Checklist Quick Guide is a (trifold) folder which contains guidance for the Pharmacist. It has been developed as a practical tool to guide you in your consultations with patients requesting Cialis for men in the pharmacy. The Pharmacist Checklist Quick Guide provides useful pharmacy supply information, including pharmacist actions and additional information and advice to give patients during consultations. The folder also contains the Cialis for men Checklist which is designed to be used in conjunction with the Pharmacist Checklist Quick Guide.

### Cialis for men Checklist

The Cialis for men Checklist can be provided to patients to complete themselves or alternatively you can use this in your consultation with the patient. The Cialis for men Checklist consists of a series of questions which can be answered 'yes', 'no' or 'unsure', covering the 3 steps outlined in the First-Time Users section of the Pharmacy Guide. It also includes a section where additional information can be added by the patient if necessary.

### Repeat Purchase or Referral Card

A Repeat Purchase or Referral Card is also available. This is a tear-off pad containing two pocket-sized cards, which can be supplied to the man depending on whether they are suitable for Cialis for men or require referral to their doctor.

The Repeat Purchase Card is to manage repeat supply. This is a card for patients to give to you or another pharmacist when they next request Cialis for men. It has space to record the date of first supply and a pharmacy stamp for verification, with a reminder to have a health check at the earliest opportunity and within 6 months of being supplied with Cialis for men.

The Referral Card is to manage doctor referrals. Patients can take this card to their doctor if their doctor needs to confirm suitability for Cialis for men.

You will have received printed copies of the Pharmacist Checklist Quick Guide, Cialis for men Checklist, and Repeat Purchase or Referral Card with this guide. Use of these materials is optional, and you are advised to use your professional judgement to decide when to use them. Pharmacy training materials will be available in print and digitally.

## REPEAT USERS

You do not need to repeat the same checks with patients requesting a repeat supply of Cialis for men in pharmacy as you make with a first-time user.

These patients should have a **Repeat Purchase Card**, with the pharmacy stamp indicating that a **pharmacist has previously questioned them and found them to be suitable** for Cialis for men.

If you establish that the patient has previously been supplied with Cialis for men in the pharmacy, follow the steps below to confirm continued suitability for the product.

### 1. 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 the patient to a doctor.

Lists of common as well as uncommon side effects are provided later in this guide and in the SmPC.

### 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 (refer to steps 1-3 outlined in the First-Time Users section of this guide). If the patient has developed a new health condition that is a contraindication or warning, or been prescribed any interacting medication, you will not be able to resupply Cialis for men and should refer the patient to a doctor for advice.

Remind patients that erection problems can be a sign of another health condition such as heart disease, hypertension, diabetes or depression.

Advise all patients whom you resupply with Cialis for men to see their doctor at the earliest opportunity for a clinical review of potential underlying conditions and risk factors associated with ED.<sup>23</sup> It is recommended that this should occur within 6 months.

# Advice for all patients taking Cialis for men

To ensure appropriate and beneficial use, it is important to give all patients taking Cialis for men advice on how and when to take it, what to expect, what to do if it does not work, and what medical advice and side effects to be aware of.



## HOW TO TAKE CIALIS FOR MEN

### How to take Cialis for men

- **One 10mg tablet as needed**<sup>23</sup>
- Can be taken **with or without food**.<sup>23</sup> The rate and extent of absorption of Cialis for men is not influenced by food

### When to take Cialis for men

- Should be taken at least **30 minutes before anticipated sexual activity**<sup>23</sup>
- Maximum recommended dose of one tablet a day<sup>23</sup>
- Not recommended for daily use – patients using the product at least twice weekly should consult their doctor to discuss whether a once daily regimen with a lower dose of tadalafil would be more appropriate<sup>23</sup>

### What to expect

- **Sexual stimulation is required** for Cialis for men to be effective<sup>23</sup>
- Starts working **30 minutes** after taking<sup>23</sup>
- Effects last for **up to 36 hours** (1.5 days)<sup>23</sup>
- 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 before they are successful<sup>23</sup>

### What to do if Cialis for men does not work

- 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<sup>23</sup>
- Patients whose ED worsens after using Cialis for men should see their doctor<sup>23</sup>

Remind every patient to read the PIL carefully before taking Cialis for men.

Before taking any other medicines, patients should tell their doctor or pharmacist if they have taken Cialis for men within the last 48 hours, as the medicine may still be in their body.

## WHEN TO SEEK MEDICAL ADVICE

There are some uncommon but serious side effects that you should make patients aware of when supplying Cialis for men. If patients experience any of these symptoms, they should be advised to **STOP taking Cialis for men and seek immediate medical attention**, and inform the doctor that they have taken Cialis for men.

SYMPTOM	EXPLANATION
<b>Long-lasting (more than 4 hours) erection</b> <sup>23</sup>	Men with <b>priapism</b> are at risk of <b>damage to the penile tissue and permanent loss of potency</b> if not treated immediately. <sup>23</sup>
<b>Sudden vision defect or loss</b> <sup>23</sup>	Vision defects and cases of NAION have been reported in men with ED after Cialis for men and other PDE5 inhibitor use. <sup>23</sup>
<b>Sudden decrease or loss of hearing</b> <sup>23</sup>	Cases of sudden hearing loss have been reported after Cialis for men use. <sup>23</sup>
<b>Chest pain</b> within 48 hours (2 days) of taking Cialis for men; <b>dizziness or nausea</b> during or after sex <sup>21,23</sup>	Indicators of extra strain on the heart and circulation. <sup>23</sup> <ul style="list-style-type: none"><li>• <b>Nitrates must <u>not</u> be used to treat</b> chest pain, as concomitant use with Cialis for men may lead to an unsafe drop in blood pressure<sup>23</sup></li><li>• If chest pain occurs before, during or after intercourse, get in a semi-sitting position and try to relax. Seek immediate medical help</li></ul>



### WHAT SIDE EFFECTS TO BE AWARE OF

Cialis for men is **generally well-tolerated** and **serious side effects are rare**.<sup>23</sup>

The most commonly reported side effects with Cialis for men are **headache, flushing, nasal congestion, dyspepsia, back pain and myalgia**. Side effects are **transient, and generally mild or moderate**.<sup>23</sup>

Below are lists of the commonly (occurring in at least 1 man per 100) and uncommonly reported (at least 1 man per 1000) side effects with Cialis for men. **Please read the SmPC for full details of side effects.**

COMMON <sup>23</sup>	UNCOMMON <sup>23</sup>
Headache	Hypersensitivity reactions
Flushing	Dizziness
Nasal congestion	Blurred vision, sensations described as eye pain
Dyspepsia	Tinnitus
Back pain, myalgia, pain in extremity	Tachycardia, palpitations
	Hypotension,* hypertension (symptoms include dizziness and blurred vision)
	Dyspnoea, epistaxis
	Abdominal pain, vomiting, nausea, gastro-oesophageal reflux
	Rash
	Haematuria
	Prolonged erections
	Chest pain,† peripheral oedema, fatigue

### THE IMPORTANCE OF REGULAR HEALTH CHECKS

Advise patients using Cialis for men to see their doctor for a **health check at the earliest opportunity**.<sup>23</sup> **It is recommended that this should occur within 6 months.** Patients should also see their doctor if symptoms of ED do not improve after taking Cialis for men on several consecutive occasions, or if they worsen.<sup>23</sup>

Erection problems can be a **sign of an underlying health condition** such as heart disease, hypertension, diabetes or depression.<sup>23</sup> Health checks can **identify these conditions** in a timely manner, so that they can be managed appropriately.

\*More commonly reported when Cialis for men is given to patients who are already taking antihypertensive medicinal products.<sup>23</sup>

†Most men had pre-existing cardiovascular risk factors.<sup>23</sup>

### ADVICE FOR ALL PATIENTS

All patients presenting in pharmacy with erection problems, whether or not they are suitable for Cialis for men, will benefit from information and advice about the possible causes of ED and lifestyle advice that can help them change behaviours that might be affecting their erections.

**All patients should be advised to see their doctor at the earliest opportunity and no later than 6 months after being supplied Cialis for men to check that they do not have important underlying health conditions such as cardiovascular disease or diabetes, that might be causing their ED symptoms.**

In addition, they can help their erection problems as well as improving their overall health by managing the following lifestyle factors that are risk factors for ED.<sup>14</sup>



Stop smoking



Limit alcohol intake to small or moderate amounts



Avoid recreational drugs



Lose or manage their weight (men who are overweight are more at risk of ED)



Eat healthily



Take regular exercise



Reduce stress

# Supply situations

In most situations, the decision about whether or not Cialis for men can be supplied to a patient will be clear and uncomplicated. However, there are a few situations where the decision may be less obvious. This section outlines a selection of supply situations representing some of these more complicated scenarios. Consider for each of the situations whether you would supply Cialis for men to the patient. Suggested actions and advice are provided for each of the supply situations.



### SITUATION 1

#### Cialis for men and benign prostatic hyperplasia

Mr Y (62 years old) has benign prostatic hyperplasia for which he has been taking finasteride for the last 3 years. Over the last 12 months he has experienced problems with erections and sometimes has difficulty maintaining the erection. This is causing some stress in his relationship with his wife, and he is keen to see whether Cialis for men can help.

#### Suggested actions

Mr Y may be suitable for Cialis for men but should be referred to his doctor to confirm suitability before use.

No drug-drug interaction studies have been performed for concomitant use of 5-alpha reductase inhibitors like finasteride so a medical benefit-risk assessment should be conducted before use.

### SITUATION 2

#### Symptoms suggestive of underlying cardiovascular disease

Mr M (50 years old) works long hours with a major corporation. He is aware that his lifestyle could be healthier and thinks that his difficulty getting an erection could be a symptom of his working pattern and lifestyle, but he cannot change this at the moment and would like to try Cialis for men to see if it helps.

He sometimes experiences chest pain when he runs for the train, but puts it down to not being very fit.

#### Suggested actions

Do not supply Cialis for men. Refer Mr M to his doctor for assessment of his cardiovascular symptom (chest pain on exertion) and to confirm his suitability, before supplying him with Cialis for men.

Explain to him that the chest pain he experiences when he runs could be a sign of a cardiovascular condition, therefore he needs to see his doctor for advice and to assess his suitability for taking Cialis for men.

### SITUATION 3

#### Concomitant use of Cialis for men and theophylline

Recently divorced, Mr O (53 years old) is about to begin dating again and is worried that the occasional problem he had maintaining an erection might still be an issue. He would like to have something to use should he need it. He keeps himself very fit with regular exercise and has never smoked. His only problem is asthma which has worsened with age and he has been prescribed theophylline to manage it.

#### Suggested actions

Do not supply Cialis for men. Refer Mr O, to his doctor for advice and confirmation that he can take Cialis for men.

Although there are no health concerns that would mean Mr O could not take Cialis for men, taking Cialis for men and theophylline at the same time could increase his heart rate so he should check with his doctor that it is suitable for him to use Cialis for men.

### SITUATION 4

#### Taking Cialis for men with another PDE5 inhibitor

Mr Z (62 years old) experienced frequent erection problems for a number of years until he was prescribed sildenafil. He ran out of his current prescription last night and is going on holiday with his partner tomorrow, so has come into the pharmacy for help as he wants to ensure his sexual performance will not be affected.

#### Suggested actions

Cialis for men can be supplied to Mr Z. Advise him that he must not take Cialis for men and sildenafil at the same time or on the same day and that he should let his doctor know that he is taking Cialis for men.

### SITUATION 5

#### Heavy alcohol use and Cialis for men

Mr A (45 years old) is a chef working long hours in a busy restaurant in town. He tends to socialise late after his shift, and drinks heavily. He noticed that he sometimes has difficulty maintaining his erection, but is confident it can be resolved with medication and would like to try Cialis for men. He is otherwise fit and healthy, with no cardiovascular disease or other contraindications and is not taking any medication.

#### Suggested actions

Cialis for men can be supplied to Mr A, but he should be advised not to drink heavily whilst taking Cialis for men. This is because the combination of large volumes of alcohol and Cialis for men could cause a drop in his blood pressure when standing up, leading to dizziness. Explain that alcohol can be a cause of erection problems, especially in large quantities and provide lifestyle advice to help him manage his ED.

## SITUATION 6

### Use of Cialis for men after heart attack

Mr J (67 years old) is a retired teacher who had a mild heart attack 15 months ago. He is now fully recovered and starting to enjoy life again. Since his heart attack, however, he sometimes experiences problems getting an erection. He has come to the pharmacy to see if he can buy something to help.

He has no cardiovascular symptoms and is able to exercise without chest pain or breathlessness. He is taking aspirin, an ACE inhibitor and a statin.

#### Suggested actions

Cialis for men can be supplied to Mr J. His heart attack was more than 3 months ago and his cardiovascular disease is stable and well managed on his current medication. It is important to check whether he has been given a short-acting nitrate (GTN) as a 'rescue medication' should he experience chest pain and to ensure he understands that he **must not use** nitrates if he is taking Cialis for men because of the risk of a dangerous drop in blood pressure.

Advise him to tell his doctor that he is taking Cialis for men and to seek immediate medical help should he experience **chest pain** within 48 hours (2 days) of taking Cialis for men or **dizziness or nausea** during or after sex.

## SITUATION 7

### Use of Cialis for men for performance enhancement

Mr C (32 years old) works hard and plays hard. He is about to go on a holiday with his friends to Ibiza and is looking for a "performance enhancer" to take with him.

#### Suggested actions

Do not supply Cialis for men.

Cialis for men is only indicated for men who have ED, not for use as a performance enhancer.

## SITUATION 8

### Cardiovascular risk factors

Mr D (57 years old) is an accountant, who is overweight due to his lack of time to exercise. He is also a heavy smoker. He has been married for 25 years. For a long time, there have been periods in which he occasionally has difficulty getting an erection. In the last 18 months it has become noticeably worse. He has been too embarrassed to speak to his doctor about it, but has come to a pharmacy in a different part of the town to get some medication to help. He does not have any cardiovascular symptoms and is not taking any medication.

#### Suggested actions

Cialis for men can be supplied to Mr D, providing he does not have any contraindications or other conditions that would require referral to his doctor. Explain that erection problems can be a sign of underlying cardiovascular disease and that it is therefore **very important for Mr D to see his doctor to have his health checked at the earliest opportunity**, especially since he has other risk factors for heart disease.

## SITUATION 9

### Controlled hypertension

Mr L (67 years old), has recently met someone having been alone for the last 5 years following his wife's death. He has not had sex during the last 5 years and is very nervous about what will happen in this new relationship because the last few times he had sex with his wife, he had problems maintaining his erection. He has seen the adverts for Cialis for men and thinks that this might be the solution.

He is generally fit and well, but has high blood pressure which has been difficult to manage. However, his current medication; a combination of an angiotensin-II receptor antagonist and a thiazide diuretic, which he has been taking for the last 6 months, seem to be working and his doctor is happy that his blood pressure is sufficiently controlled on this treatment.

#### Suggested actions

Cialis for men can be supplied to Mr L. His hypertension has been well controlled on medication for the last 6 months and he is not taking any contraindicated medication.

Explain to Mr L that he should tell his doctor that he is taking Cialis for men, especially if his blood pressure medication needs to be changed again.

## SITUATION 10

### ED and depression

Mr B (38 years old) has been experiencing difficulty maintaining erections long enough to have sexual intercourse with his husband. This has been happening regularly over the last 9 months and even going on holiday did not help. His husband has strongly encouraged him to see whether Cialis for men could help.

He volunteers that this has really affected his confidence and he is feeling stressed and very down about it. In fact, he thinks he has been feeling really low for a long time now. Work is extremely stressful, and he is very unhappy with his job.

He is well, with no physical health problems and is not taking any medication.

#### Suggested actions

Cialis for men can be supplied to Mr B. He has no contraindications and is not taking any medication.

He should be advised to see his doctor about his persistent low mood. Depression can be a cause of ED and it is important that he is properly assessed in case any treatment is necessary. He should also let his doctor know that he is taking Cialis for men.



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# 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 ( $\geq 1/100$  and  $< 1/10$ ): Headache, flushing, nasal congestion, dyspepsia, back pain, myalgia, pain in extremity. Uncommon ( $\geq 1/1,000$  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 ( $\geq 1/10,000$  and  $< 1/1,000$ ): 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 infarction, unstable angina pectoris, ventricular arrhythmia, urticaria, Stevens-Johnson syndrome, exfoliative dermatitis, hyperhidrosis, 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, Brüningsstraße 50, 65929, Frankfurt am Main, Germany.

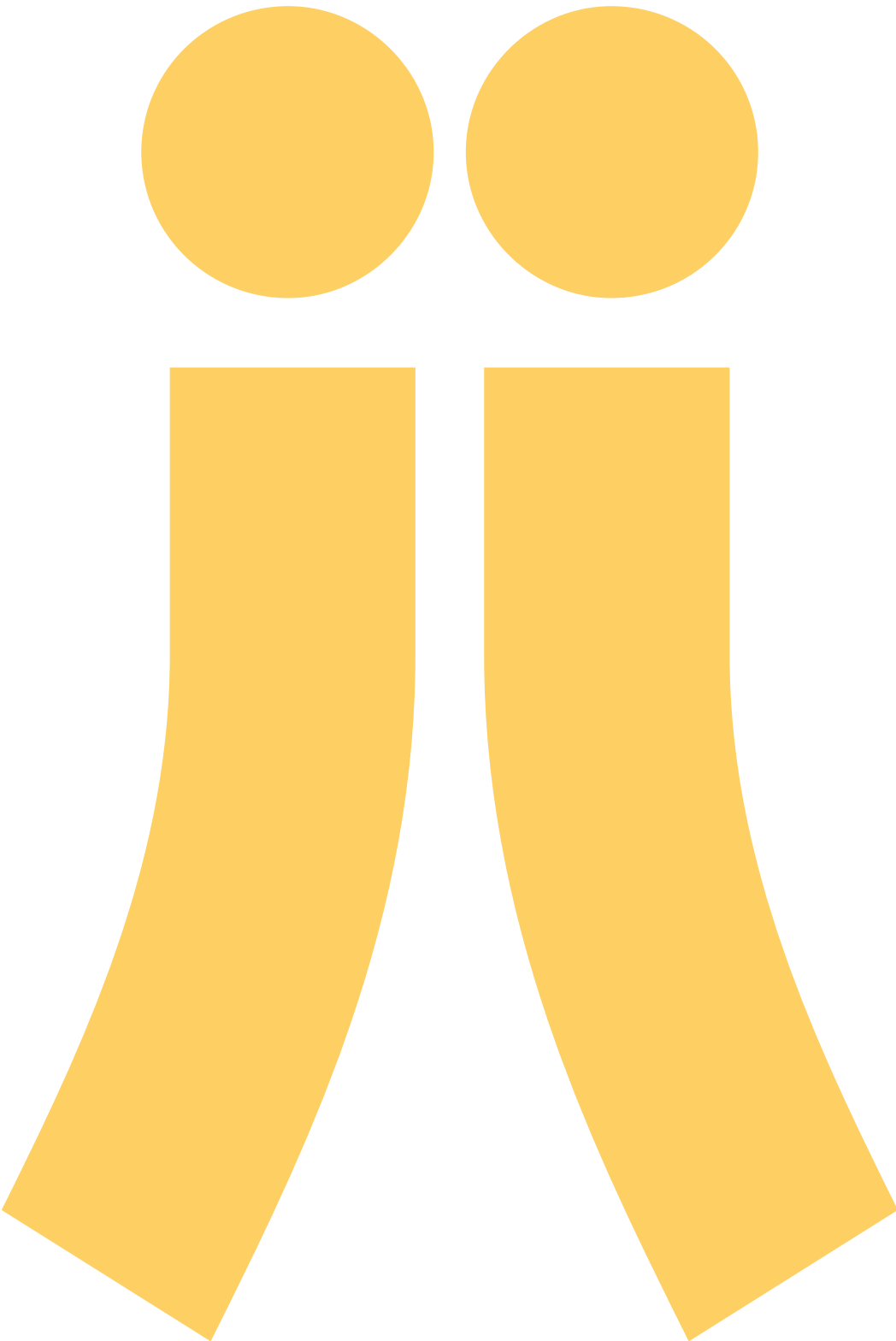
**Further information is available from the distributor:** Clonmel Healthcare Ltd. Pharmacovigilance, Waterford Road, Clonmel, Co. Tipperary, E91 D768.

**Email:** [medicalinformation@clonmel-health.ie](mailto:medicalinformation@clonmel-health.ie).

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Adverse events should be reported: Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to the Clonmel Healthcare Medical Information department on (052) 617 7777.





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