SUPPORTING MEN WITH ERECTILE DYSFUNCTION

This guide is to help pharmacists understand how they can advise men on the use of VIAGRA CONNECT[®] (sildenafil) 50 mg film-coated tablets.

Objectives:

- Understand how common erectle problems (ED) is and its potential impact
- Understand the range of causes of ED
- Know what advice to give to customers who are using VIAGRA CONNECT[®]

Please see Abbreviated Prescribing Information at the end of this piece. For more information please contact Viatris or refer to the SmPC for full prescribing information.



Viatris, Newenham Court, Malahide Rd, Northern Cross, Dublin 17 VIAC-2024-0034. Date of preparation: February 2024



INTRODUCTION TO ED

ED can affect men throughout their lives.¹ In Ireland, 1 in 3 men have experienced ED and 1 in 5 men experience ED regularly.²

One in five

men experience erectile dysfunction (ED) regularly.²



There are many different causes of ED.³ Erectile dysfunction can affect men differently. Some cannot achieve an erection. Others may achieve an erection, but not firm enough for having sex or they may lose the erection before or during sex.⁴

Causes include:

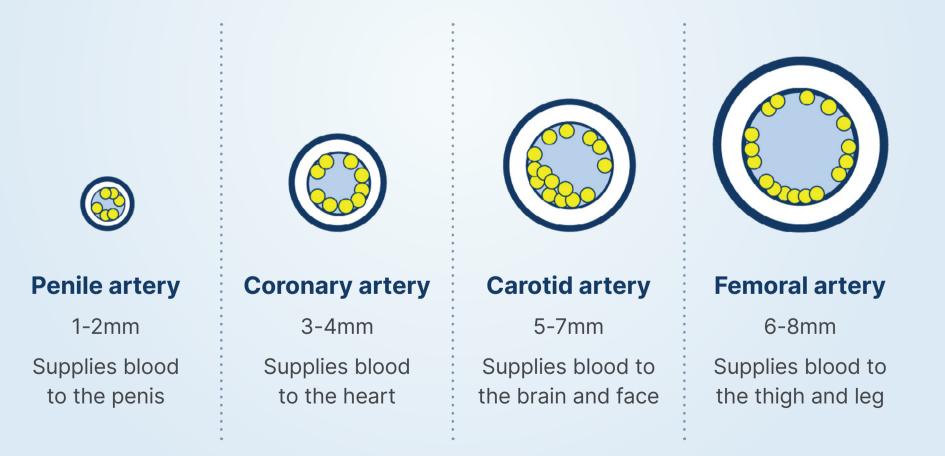


Physical

Reduction in blood flow to the penis can cause ED which may be a predictor of coronary artery disease.⁵ There is also close relationship between ED and cardiovascular damage. Hypertension, diabetes, obesity and obstructive sleep apnea are also associated with ED.⁶

ED AND ASSOCIATION WITH CARDIOVASCULAR DISEASE.⁷

There is a growing body of evidence that ED is a vascular disorder. Risk factors for atherosclerosis are often found in ED. Given the systemic nature of atherosclerosis, all major vascular beds should be affected to the same extent. However, the larger vessels are able to tolerate the burden better than the smaller ones such as the penile artery. Therefore, they can become blocked more quickly.⁷





Psychological

Purely psychological causes account for only 1 in 10 cases.⁸

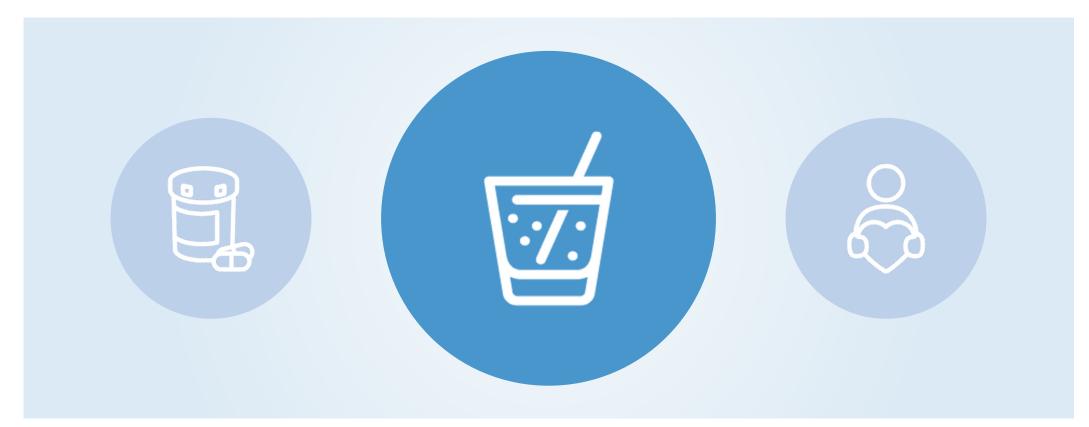
The brain is involved in initiating the series of physical events that lead to an erection, starting with sexual excitement. However, a number of things can interfere with these feelings and may cause or worsen erectile dysfunction. These include:⁹

- Depression, feeling anxious or experiencing other mental health conditions
- Stress
- Relationship issues perhaps due to poor communication



Medicine side-effect

Some prescription medicines, such as antihypertensives, diuretics and antidepressants, are associated with ED.¹⁰

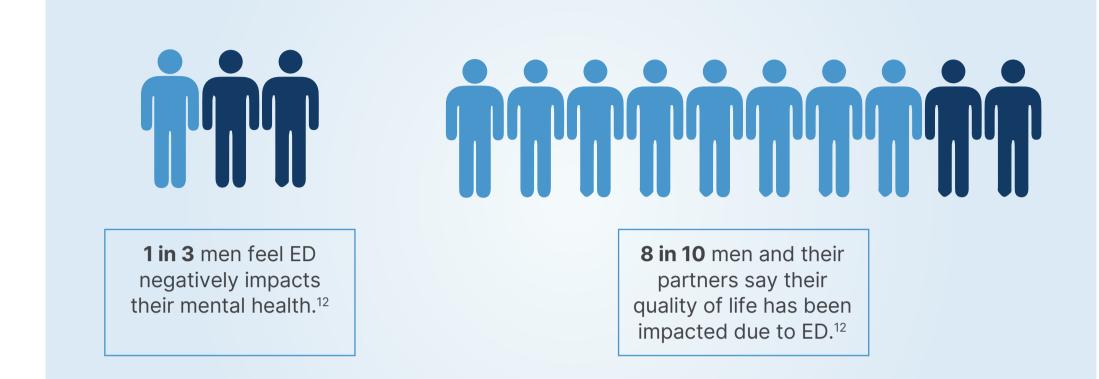


Lifestyle factors

Recreational drug use, excess alcohol consumption, long distance cycling and smoking may contribute to ED.¹¹

IMPACT OF ED

Results from a survey carried out in Ireland with over 500 men and their partners¹²



The survey also highlighted that 58% of men and 54% of their partners avoid sex because of erectile dysfunction.¹²



Conversation tips

- Remember it may be the first time your patient has spoken to someone about the issue
- Offer the use of the consultation room to have a conversation in private
- Show empathy
- Use the same language that your patient uses
- Making eye contact, smiling and mirroring your patient's body language can all help create rapport



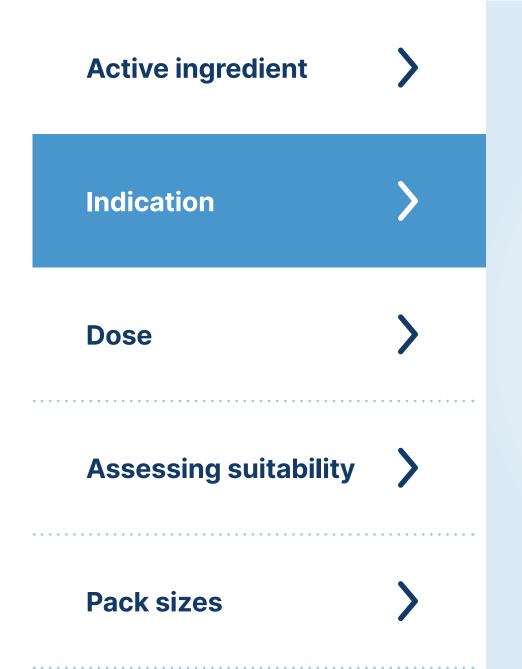
Contains:

Sildenafil 50 mg, a phosphodiesterase type 5 inhibitor.

Sildenafil is an oral therapy for erectile dysfunction. In the natural setting, i.e. with sexual stimulation, it restores impaired erectile function by increasing blood flow to the penis.¹³







VIAGRA CONNECT[®] is indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for VIAGRA CONNECT[®] to be effective, sexual stimulation is required.¹³





One tablet to be taken around an hour before sexual activity (maximum dose: 1 daily).

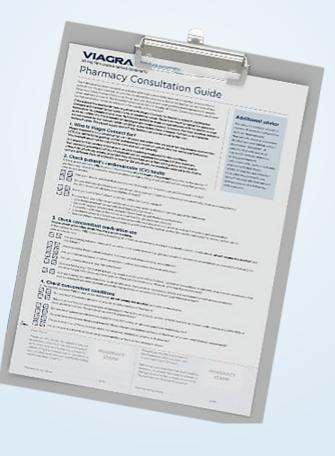
The recommended dose is one 50 mg tablet taken with water approximately one hour before sexual activity. The maximum recommended dosing frequency is once per day. If VIAGRA CONNECT[®] is taken with food, the onset of activity may be delayed compared to the fasted state.

Patients should be advised that they may need to take VIAGRA CONNECT[®] a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If after several attempts on different dosing occasions patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor.¹³ For more information read the SmPC available at <u>www.medicines.ie</u>



The **Consultation Guide** will help you to assess if VIAGRA CONNECT[®] is suitable for your patient.

Available to download on <u>www.medicines.ie</u>

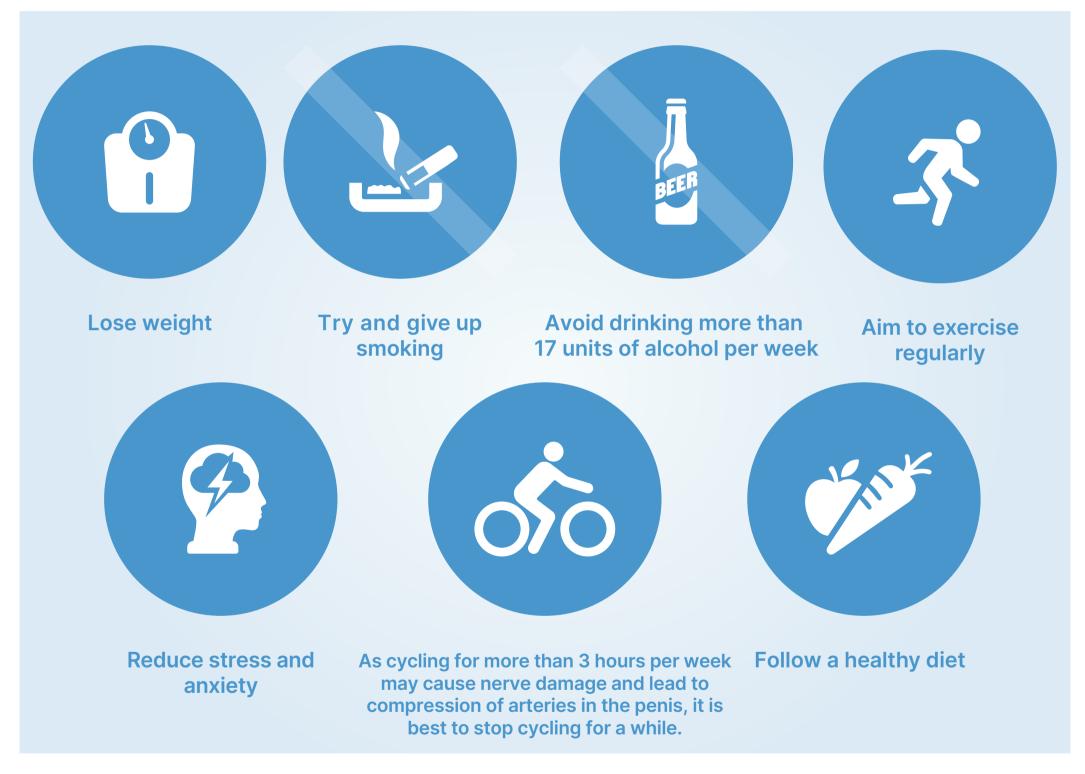




LIFESTYLE ADVICE

Remind all patients who purchase VIAGRA CONNECT[®] that they should see their GP within 6 months of first supply.¹³

You can also advise customers to:14



What if a patient finds it doesn't work?

Patients should be advised that they may need to take VIAGRA CONNECT[®] a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If after several attempts on different dosing occasions patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor.¹³

HOW TO HELP ENCOURAGE MEN TO VISIT YOUR PHARMACY

Placing point of sale material in the window or near men's toiletries shows men that your pharmacy stocks VIAGRA CONNECT[®].



Be aware of patients who are browsing, appearing to be waiting for the pharmacist to be free and be proactive in approaching them



Have a specific men's health/grooming section – e.g. include food supplements, skincare, shaving accessories and healthcare designed for men



Make the most of leaflets and point of sale materials supplied by VIAGRA CONNECT[®] that men can use to start a conversation. Have some in your men's health section and put some at the counter, for example



Run men's health campaigns – these could tie in with national events or other health campaigns, such as men's health week in June or Movember in November

MCQS(CORRECT ANSWER HIGHLIGHTED IN RED)

1. How does VIAGRA CONNECT[®] (sildenafil) work in simple terms?

- a. It allows muscles in the penis to relax so that blood flows in more easily
- b. It increases the level of testosterone in the body
- c. It causes contraction of the muscles in the penis
- d. It acts on the brain to stimulate an erection

2. Which one of the following should NOT be taken with VIAGRA CONNECT[®]?

- a. Orange juice
- b. Kale
- c. Grapefruit juice
- d. Dairy products
- 3. Which of the following could cause ED?
- a. Cardiovascular disease
- b. Stress
- c. Excess alcohol consumption
- d. Diabetes

4. How should VIAGRA CONNECT[®] be taken?

- a. Around an hour before sexual activity. Maximum dose of one daily
- b. Three hours before sexual activity. Maximum dose of one daily
- c. Once daily in the morning
- d. Immediately before sexual activity. The dose can be repeated as needed

References

- 1. Capogrosso P, et al. One patient out of four with newly diagnosed erectile dysfunction is a young man--worrisome picture from the everyday clinical practice. J Sex Med. 2013 Jul;10(7):1833-41.
- 2. Behaviour & Attitudes Market Research Erectile Dysfunction. March 2020. This research was undertaken for Upjohn/Pfizer. Survey participants were male, aged between 35 and 75 and living in Ireland. Viatris Data on file.
- 3. https://www.nhs.uk/conditions/erection-problems-erectile-dysfunction/ Accessed November 2023
- 4. Viagra Connect Product Information Leaflet. Accessed November 2023.
- 5. Kirby M, Jackson G. Erectile dysfunction as a predictor of coronary artery disease. Cardiovascular medicine. July/August 2011.
- 6. Artom, Nathan & Pinna, Giuliano. (2014). The erectile dysfunction as a cardiovascular risk factor. Italian Journal of Medicine. 8. 10.4081/itjm.2014.500.
- 7. Montorsi P, et al. The Artery Size Hypothesis: A Macrovascular Link Between Erectile Dysfunction and Coronary Artery Disease. Am J Cardiol 2005;96[suppl]:19M–23M).
- 8. The British Association of Urological Surgeons. Erectile dysfunction. Frequently asked questions. Available at: https://www.baus.org.uk/patients/conditions/3/erectile_dysfunction_impotence. Accessed November 2023
- 9. https://www.mayoclinic.orgdiseases-conditionserectile-dysfunctionsymptoms-causes. Accessed November 2023
- 10. https://my.clevelandclinic.org/health/diseases/10035-erectile-dysfunction Assessed August 2023
- 11. https://www.medic8.com/healthguide/impotence/other-causes.html. Accessed November 2023
- 12. Viagra Connect Men & Partners Research. Survey in the United Kingdom, Ireland, Poland and Norway. February 2022. Viatris Data on file.
- 13. Viagra Connect SmPC available on www.medicines.ie
- 14. https://www2.hse.ie/conditions/erectile-dysfunction/. Accessed November 2023

For more information, please contact Viatris or refer to the SmPC for full prescribing information.

ABBREVIATED PRESCRIBING INFORMATION

Viagra Connect (sildenafil) 50 mg film-coated tablets

Please refer to Summary of Product Characteristics (SmPC) before prescribing

Indications, Dosage and Administration: Indications: For erectile dysfunction in adult men. Dosage and Method of use: Adults: one 50 mg tablet taken with water approx. one hour before sexual activity. The maximum dosing frequency is once per day. The onset of activity may be delayed if taken with food. Patients should be advised that they may need to take Viagra Connect a number of times on different occasions (max of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If patients are still not able to achieve a sufficient penile erection they should be advised to consult a doctor. Elderly: no dosage adjustments required (> 65 years old). Renal Impairment: No dosage adjustments for patients with mild to moderate renal impairment. Dosage adjustments required for those with severe renal impairment, see SmPC. Hepatic Impairment: Dosage adjustments required for those with mild-moderate hepatic impairment, see SmPC. Viagra Connect is contraindicated for patients with severe hepatic impairment (see contraindications). Presentation: Film-coated tablets containing sildenafil citrate equivalent to 50 mg of sildenafil. Contraindications: Hypersensitivity to the active substance or to any of the excipients. Co-administration with nitric oxide donors (such as amyl nitrite), nitrates, ritonavir, guanylate cyclase stimulators (such as riociguat) is contraindicated. Agents for the treatment of erectile dysfunction, including sildenafil, should not be used by those men for whom sexual activity may be inadvisable, and these patients should be referred to their doctor. This includes patients with severe cardiovascular disorders such as a recent (6 months) acute myocardial infarction (AMI) or stroke, unstable angina or severe cardiac failure. Sildenafil should not be used in patients with severe hepatic impairment, hypotension (blood pressure < 90/50 mmHg) and known hereditary degenerative retinal disorders such as retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases). Sildenafil is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure. Viagra Connect should not be used in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease). Viagra Connect is not indicated for use by women. The product is not intended for men without erectile dysfunction. This product is not intended for men under 18 years of age. Warnings and precautions: Erectile dysfunction can be associated with a number of contributing conditions, e.g. hypertension, diabetes mellitus, hypercholesterolaemia or cardiovascular disease. As a result, all men with erectile dysfunction should be advised to consult their doctor within 6 months for a clinical review of potential underlying conditions and risk factors associated with erectile dysfunction (ED). If symptoms of ED have not improved after taking Viagra Connect on several consecutive occasions, or if their erectile dysfunction worsens, the patient should be advised to consult their doctor. Cardiovascular risk factors: Since there is a degree of cardiac risk associated with sexual activity, the cardiovascular status of men should be considered prior to initiation of therapy. Agents for the treatment of erectile dysfunction, including sildenafil, are not recommended to be used by those men who with light or moderate physical activity, such as walking briskly for 20 minutes or climbing 2 flights of stairs, feel very breathless or experience chest pain. For a list of patients who are considered at low cardiovascular risk from sexual activity see SmPC. Patients previously diagnosed with the following must be advised to consult with their doctor before resuming sexual activity: uncontrolled hypertension, moderate to severe valvular disease, left ventricular dysfunction, hypertrophic obstructive and other cardiomyopathies, or significant arrhythmias. Sildenafil has vasodilator properties, resulting in mild and transient decreases in blood pressure. Patients with increased susceptibility to vasodilators include those with left ventricular outflow obstruction (e.g. aortic stenosis), or those with the rare syndrome of multiple system atrophy manifesting as severely impaired autonomic control of blood pressure. Priapism: Patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia), should consult a doctor before using agents for the treatment of erectile dysfunction, including sildenafil. Prolonged erections and priapism have been occasionally reported with sildenafil in post-marketing experience. In the event of an erection that persists longer than 4 hours, the patient should seek immediate medical assistance. Concomitant use with other treatments for erectile dysfunction is not recommended. Effects on vision: Patients should be advised that in the event of any sudden visual defect, they should stop taking Viagra Connect and consult a physician immediately. Concomitant use with CYP3A4 inhibitors: patients should be advised to consult a doctor before taking Viagra Connect as a 25 mg tablet may be more suitable for them. Concomitant use with alpha-blockers: Caution is advised when sildenafil is administered to patients taking an alpha-blocker, as the co-administration may lead to symptomatic hypotension in a few susceptible individuals. This is most likely to occur within 4 hours post sildenafil dosing. In order to minimise the potential for developing postural hypotension, patients should be hemodynamically stable on alpha-blocker therapy prior to initiating sildenafil treatment. Thus, patients taking alpha blockers should be advised to consult their doctor before taking Viagra Connect. Treatment should be stopped if symptoms of postural hypotension occur, and patients should seek advice from their doctor on what to do. Effect on bleeding: the use of sildenafil is not recommended in those patients with history of bleeding disorders or active peptic ulceration, and should only be administered after consultation with a doctor. Hepatic impairment: Patients with hepatic or renal impairment must be advised to consult their doctor before taking Viagra Connect, since a 25 mg tablet may be more suitable for them. Lactose: The film coating of the tablet contains lactose. Viagra Connect should not be administered to men with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per tablet. Patients on low sodium diets can be informed that this medicinal product is essentially 'sodium-free'. Use with alcohol: Drinking excessive alcohol can temporarily reduce a man's ability to get an erection. Men should be advised not to drink large amounts of alcohol before sexual activity. Interactions with other medicinal products and other forms of interaction: Individuals receiving concomitant treatment with CYP3A4 inhibitors must be advised to consult their doctor before taking Viagra Connect, dosing adjustments may be required, see SmPC. Patients receiving alpha blocker treatment should be stabilised on therapy prior to initiating sildenafil treatment and must be advised to consult their doctor before taking Viagra Connect as dosing adjustments may be required, see SmPC. Caution when sildenafil is initiated in patients treated with sacubitril/valsartan, see SmPC. Fertility, pregnancy and lactation: There was no effect on sperm motility or morphology after single 100 mg oral doses of sildenafil in healthy volunteers. Viagra Connectis not indicated for use by women. **Undesirable effects:** Very common (\geq 1/10): headache. Common (>1/100, <1/10): dizziness, visual colour distortions, visual disturbance, vison blurred, flushing, hot flush, nasal congestion, nausea, dyspepsia. For details of uncommon, rare and very rarely reported adverse events and those of unknown frequency, see SmPC.

Reporting of adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/ risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse reactions/events should also be reported to the marketing autorisation holder at the email address: pv.ireland@viatris.com or phone 0044(0)8001218267.

Legal Category: Not subject to medical prescription. Supply through pharmacies only.

Marketing Authorisation Number: PA23055/016/001

Marketing Authorisation Holder: Upjohn EESV, Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Netherlands.

Full prescribing information available on request from: Viatris, Dublin 17. Phone 01 8322250

Date of Revision of Abbreviated Prescribing Information: 01 Feb 2024

Reference Number: IE-AbPI-ViagraConnect-v004

