



Advising on erection problems in a covid era

Helping customers love life again

Coronavirus has affected us all in many ways. From coping with increased levels of stress to dealing with multiple lockdowns, it has been a challenge. One example is men's health, where research has associated a link between COVID-19 and erection problems (EPs).¹

Objectives:



Explore the links between COVID-19 and EPs



Refresh your knowledge on EPs



Build product knowledge of VIAGRA CONNECT[®] (sildenafil 50mg)



Understand the benefits of good sexual health



Increase your confidence to discuss EPs with customers



VIAGRA CONNECT (sildenafil 50mg) P

- For men over 18 affected by erectile dysfunction
- Maximum dose one tablet per day, taken with water about one hour before sexual activity
- Available in packs of 2, 4 or 8 tablets

COVID-19 and EPs

Taking account of the pandemic, lockdowns and general changes to day-to-day routines and lifestyles - with the accompanying impact on mental health - it should come as no surprise that EPs have been associated with COVID-19.¹

Both personal and work lives have been impacted; this may have contributed towards increased pressure on relationships and more stress and anxiety amongst the population.

We are continuously learning about COVID-19 and its potential impact on EPs. Current documented symptoms of COVID-19 may potentially have an impact on a customer's sex life - for example, feeling exhausted, breathlessness and low mood. People suffering with long COVID (those who experience prolonged symptoms after catching the virus) are very likely to experience extreme tiredness, which may result in a lack of physical energy to have sex. We also need to remember that those with long COVID are likely to feel anxious and experience low mood,² which may reduce a person's sex drive.

Background to EPs

EPs (also referred to as erectile dysfunction) are very common in men and usually nothing to worry about.³ The factors contributing to EPs can be split into four main areas: lifestyle, medication, physical and psychological. Where EPs happen more frequently, an underlying cause may exist.³ Having an awareness and understanding of the contributing factors can help support your discussions with customers.

EPs affect around 5 million men in the UK^{6,7} and it is hoped that seeking treatment advice becomes normal and accepted for affected customers.

With this in mind, you might notice an increase in customers coming in to seek advice and purchase VIAGRA CONNECT in the coming months.



Who are your customers?

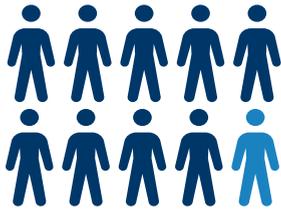
Although EPs tend to increase with age, this doesn't mean that younger men are not affected. Modern lives are stressful and with worries over COVID-19, health, finances and/or work, for example, EPs can occur in adult men at any age. It is estimated that by the time a man is in his 40s, he has a 40% chance of having some form of EP and this increases about 10% every decade thereafter.⁴

Benefits of good sexual health

Good sexual health is key to a state of physical, emotional, mental and social wellbeing.⁸ Data from a survey of almost 4,000 men and women has shown that a fulfilling and enjoyable sex life is one of the most important life priorities and is associated with a positive overall outlook on life.⁹



Treatment goals



In a study, **nine in 10 men** stated the two most important attributes of their EP medication were:

1

Providing a rigid erection

2

A low level of side effects¹²

Erection hardness score

Erection hardness (a rigid erection) is a key component of sexual performance, improved wellbeing and quality of life.¹³ **The erection hardness score (EHS)** is a simple tool that can be used to measure this.¹⁴ The EHS scoring system classifies erection hardness into **the following four grades**:



Why does erection hardness matter?

Research has shown that sildenafil citrate treatment can result in grade 4 erection hardness.¹⁵ The greatest sexual satisfaction has been reported at grade 4 erection hardness, which is the recognised treatment aim for customers with EPs.¹⁵

Erection hardness is linked with improvements in:

- Relationship and sexual satisfaction (for customers and their partners)
- Confidence
- Self-esteem^{13,15}



Maintaining an erection and achieving successful sexual intercourse is **24 times more likely** with an EHS grade of 4 compared to a grade of 3,¹⁶ showcasing a key benefit of VIAGRA CONNECT treatment when resulting in an EHS grade of 4.

24x

Results from the Global Better Sex Survey involving 12,653 participants across 27 countries reported that, for **88% of women** and **95% of men**, it was important to be able to achieve and maintain an erection.¹⁷



Supplying VIAGRA CONNECT

Before first supply, the pharmacist will assess whether treatment is appropriate. The VIAGRA CONNECT Pharmacy Checklist can help in this initial assessment.

Some customers may come to your pharmacy having already purchased the product in the past, so it is important to check nothing has changed in their health or if they have started any new medications, including over-the-counter medicines, since initial purchase.

The 2-pack is a good option to consider for first time customers who wish to trial the product.

Taking VIAGRA CONNECT¹⁸

- **Max dose:** one tablet per day (swallowed whole with water, one hour before planned sexual activity)
- **It can start to work within 30 minutes,** but men can still get an erection in response to sexual stimulation for up to 4 hours after taking the dose
- **Can be taken with or without food** but it may take longer to work after a high fat meal
- **Sexual stimulation is needed** for VIAGRA CONNECT to work.



Supply note

EPs can be associated with a number of contributing conditions, e.g. hypertension, diabetes mellitus, hypercholesterolaemia and/or cardiovascular disease, so it is important that customers are advised to see their GP within six months of first supply for a clinical review and to check for underlying conditions and risk factors associated with EPs.¹⁸

Additional advice for customers

- **Customers must see their GP** within six months of first supply
- **Lifestyle changes** such as losing weight, eating healthily, quitting smoking, regularly exercising and reducing stress can help customers manage their EPs
- **Alcohol intake** should be kept within the recommended guidance of 14 units per week
- **Refer to the patient information leaflet (PIL)** for details on possible side effects
- **Remind customers** they should only purchase VIAGRA CONNECT from a pharmacy or regulated website to ensure they are purchasing a genuine licensed medicine and not a counterfeit product.





Top tips for consultations

Customers coming into the pharmacy to discuss EPs or purchase VIAGRA CONNECT may feel embarrassed or self-conscious, so you should always try to make them feel welcome and put them at ease.

Remember to let customers know at the start of any conversation that there is a private consultation room available in the pharmacy if they wish to discuss something in confidence.

You should be aware of the behaviors and body language that customers may show in your pharmacy suggestive of needing help and support. Signs to look out for include:

- **Glancing** at the VIAGRA CONNECT product/display repeatedly
- **Appearing embarrassed** and/or asking about other related products/services
- **Leaving a queue** or avoiding the till when the pharmacy is busy
- **Browsing** the sexual health products available in your pharmacy for long periods of time.

References

1. Sansone A. et al. *Andrology*. 2021; 9: 1053-1059. 2. <https://www.nhs.uk/conditions/coronavirus-covid-19/long-term-effects-of-coronavirus-long-covid/> 3. <https://www.nhs.uk/conditions/erection-problems-erectile-dysfunction/> 4. Ferrini M. et al. *Transl Androl Urol*. 2007; 6: 20-27 5. Ipsos Omnibus Consumer Online Panel; October 2021 (Data on file) 6. Kantar TNS Omnibus. December 2010 (Data on file) 7. ONS data 2019 (Data on file) 8. Douglas J. et al. *Public Health Reports*. 2013; 128: 1-4 9. Dean J. et al. *J Int Med Res*. 2013; 41: 482 10. Brody S. et al. *J Sex Med*. 2010; 7: 1336-1361 11. Klapilova K. et al. *J Sex Med*. 2015; 12: 667-675 12. Mulhall JP. et al. *J Urol*. 2016; 195: e951 13. Claes H. et al. *Int J Impot. Res*. 2008;20: 418-424 14. Mulhall JP. et al. *J. Sex Med*. 2007; 4: 1626-1634 15. King R. et al. *Int J Impot. Res*. 2007;19: 398-406 16. Goldstein I. et al. *J Sex Med*. 2008; 5:2374-2380 17. Mulhall JP. Et al. *J. Sex Med*. 2008; 5: 788-795 18. Viagra Connect 50 mg film-coated tablets (sildenafil): summary of product characteristics. Online references last accessed November 2021.

Further support

Supplying men with VIAGRA CONNECT presents an opportunity to extend your pharmacy's men's health offering. During supply consultations, pharmacists can use the opportunity to address other health queries or try to improve their patient's understanding of all the varied factors that may be contributing to their EPs.

We want to do all we can to help bring back that loving feeling for couples having problems with EPs. Encouraging men to open up and talk to their partner, who may be a useful source of support, may offer longer term benefits to both their relationship and overall mental health.

Additional resources:

Visit pharmacymagazine.co.uk/viagra-connect for additional e-learning resources, including videos and a detailed e-module for those new to pharmacy or who need a refresher.



PRODUCT INFORMATION

Name of product: VIAGRA CONNECT 50 mg film-coated tablets. **Active ingredient(s):** Sildenafil. **Product licence number:** PL 50622/0063. **Name and address of the product licence holder:** Upjohn UK Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **Supply classification:** P. **Indications:** For erectile dysfunction in adult men. **Side Effects:** The safety profile of VIAGRA is based on > 9,000 patients in > 70 double-blind placebo controlled clinical studies. The most commonly reported adverse reactions in clinical studies among sildenafil treated patients were headache, flushing, dyspepsia, nasal congestion, dizziness, nausea, hot flush, visual disturbance, cyanopsia and vision blurred. Adverse reactions from post marketing surveillance has been gathered covering an estimated period >10 years. Because not all adverse reactions are reported to the Marketing Authorisation Holder and included in the safety database, the frequencies of these reactions cannot be reliably determined. Very Common ($\geq 1/10$): Headache. Common ($\geq 1/100$ and $< 1/10$): Dizziness, Visual colour distortions (Chloropsia, Chromatopsia, Cyanopsia, Erythropsia and Xanthopsia), Visual disturbance, Vision blurred, Flushing, Hot flush, Nasal congestion, Nausea, Dyspepsia. Uncommon ($\geq 1/1,000$ and $< 1/100$): Rhinitis, Hypersensitivity; Somnolence; Hypoaesthesia, Lacrimation disorders (Dry eye, Lacrimal disorder and Lacrimation increased), Eye pain, Photophobia, Photopsia, Ocular hyperaemia, Visual brightness, Conjunctivitis, Vertigo, Tinnitus, Tachycardia, Palpitations, Hypertension, Hypotension, Epistaxis, Sinus congestion, Gastro Oesophagael reflux disease, Vomiting, Abdominal pain upper, Dry mouth, Rash, Myalgia, Pain in extremity, Haematuria, Chest pain, Fatigue, Feeling hot, Heart rate increased. Rare ($\geq 1/10,000$ and $< 1/1,000$): Cerebrovascular accident, Transient ischaemic attack, Seizure, Seizure recurrence, Syncope, Non-arteritic anterior ischaemic optic neuropathy (NAION), Retinal vascular occlusion, Retinal haemorrhage, Arteriosclerotic retinopathy, Retinal disorder, Glaucoma, Visual field defect, Diplopia, Visual acuity reduced, Myopia, Asthenopia, Vitreous floaters, Iris disorder, Mydriasis, Halo vision, Eye oedema, Eye swelling, Eye disorder, Conjunctival hyperaemia, Eye irritation, Abnormal sensation in eye, Eyelid oedema, Scleral discoloration, Deafness, Sudden cardiac death, Myocardial infarction, Ventricular arrhythmia, Atrial fibrillation, Unstable angina, Throat tightness, Nasal oedema, Nasal dryness, Hypoaesthesia oral, Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Penile haemorrhage, Priapism, Haematospemia, Erection increased, Irritability. **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. The following patients are considered at low cardiovascular risk from sexual activity: patients who have been successfully revascularised (e.g. via coronary artery bypass grafting, stenting, or angioplasty), patients with asymptomatic controlled hypertension, and those with mild valvular disease. These patients may be suitable for treatment but should consult a doctor before resuming sexual activity. 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. Men with these conditions must not use the product without consulting a doctor. Sildenafil potentiates the hypotensive effect of nitrates (see Contra-indications). Serious cardiovascular events, including myocardial infarction, unstable angina, sudden cardiac death, ventricular arrhythmia, cerebrovascular haemorrhage, transient ischaemic attack, hypertension and hypotension have been reported post-marketing in temporal association with the use of sildenafil. Most, but not all, of these patients had pre-existing cardiovascular risk factors. Many events were reported to occur during or shortly after sexual intercourse and a few were reported to occur shortly after the use of sildenafil without sexual activity. It is not possible to determine whether these events are related directly to these factors or to other factors. 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. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result. Concomitant use with other treatments for erectile dysfunction: The safety and efficacy of combinations of sildenafil with other treatments for erectile dysfunction have not been studied. Therefore the use of such combinations is not recommended. Effects on vision: Cases of visual defects have been reported spontaneously in connection with the intake of sildenafil and other PDE5 inhibitors (see Side Effects). Cases of non-arteritic anterior ischaemic optic neuropathy, a rare condition, have been reported spontaneously and in an observational study in connection with the intake of sildenafil and other PDE5 inhibitors (see Side Effects). Patients should be advised that in the event of any sudden visual defect, they should stop taking VIAGRA CONNECT and consult a physician immediately (see Contra-indications). Concomitant use with CYP3A4 inhibitors: Pharmacokinetic analysis of clinical trial data indicated a reduction in sildenafil clearance when co-administered with CYP3A4 inhibitors (such as ketoconazole, itraconazole, erythromycin, cimetidine). Although, no increased incidence of adverse events was observed in these patients, they should be advised to consult a doctor before taking VIAGRA CONNECT as a 25 mg tablet may be more suitable for them (see Precautions). 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 (see Precautions). 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 as a 25 mg tablet may be more suitable for them. 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: Studies with human platelets indicate that sildenafil potentiates the antiaggregatory effect of sodium nitroprusside in vitro. There is no safety information on the administration of sildenafil to patients with bleeding disorders or active peptic ulceration. Therefore 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 impairment must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see Dosage and Method of use). Renal impairment: Patients with severe renal impairment (creatinine clearance < 30 mL/min), must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see Dosage and Method of use). 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. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Consistent with its known effects on the nitric oxide/cyclic guanosine monophosphate (cGMP) pathway, sildenafil was shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form is therefore contraindicated. Co-administration of VIAGRA CONNECT with ritonavir (a highly potent P450 enzyme inhibitor) is contraindicated (see Precautions). The co-administration of phosphodiesterase type 5 (PDE5) inhibitors, including sildenafil, with guanlylate cyclase stimulators, such as riociguat, is contraindicated as it may potentially lead to symptomatic hypotension (see Precautions). 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). This is because the safety of sildenafil has not been studied in these sub-groups of patients, and its use is therefore contraindicated. 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. **Dosage and Method of use:** For Oral Use: Adults: 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. Elderly: Dosage adjustments are not required in elderly patients (≥ 65 years old). Renal Impairment: No dosage adjustments are required for patients with mild to moderate renal impairment. However, since sildenafil clearance is reduced in individuals with severe renal impairment (creatinine clearance < 30 mL/min), individuals previously diagnosed with severe renal impairment must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see Precautions). Hepatic Impairment: Sildenafil clearance is reduced in individuals with hepatic impairment (e.g. cirrhosis). Individuals previously diagnosed with mild to moderate hepatic impairment must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see Precautions). The safety of sildenafil has not been studied in patients with severe hepatic impairment, and its use is therefore contraindicated (see Contra-indications). Paediatric population: VIAGRA CONNECT is not indicated for individuals below 18 years of age. Use in patients taking other medicinal products: Pharmacokinetic analysis of clinical trial data indicated a reduction in sildenafil clearance when co-administered with CYP3A4 inhibitors (such as ritonavir, ketoconazole, itraconazole, erythromycin, cimetidine). With the exception of ritonavir, for which co-administration with sildenafil is contraindicated (see Contra-indications), individuals receiving concomitant treatment with CYP3A4 inhibitors must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see Precautions). In order to minimise the potential of developing postural hypotension in patients receiving alpha blocker treatment (e.g. alfuzosin, doxazosin or tamsulosin), patients should be stabilised on alpha blocker therapy prior to initiating sildenafil treatment. Thus, patients taking alpha blockers must be advised to consult their doctor before taking VIAGRA CONNECT since a 25 mg tablet may be more suitable for them (see Precautions).

Cost: 2 pack £9.16 (exc VAT), 4 pack £16.66 (exc VAT) and 8 pack £29.16 (exc VAT)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161. **Date:** 12/2020