



Sildenafil

TUNE INTO MEN'S WORRIES

Understanding your male customers



VIATRIS



OVER A QUARTER
OF MEN WITH
EPs HAVE NOT
SPOKEN TO
ANYBODY ABOUT
THEIR ISSUES



INTRODUCTION

ERECTION PROBLEMS (EPs) ARE VERY COMMON AND ARE ESTIMATED TO AFFECT 5 MILLION MEN IN THE UK.^{1,2}

EPs can have a huge impact on relationships as well as having an emotional impact on both the man and their partner. In a recent survey of 5,007 adults in the UK, 64% said that regular intimacy with a partner makes them feel loved, 49% that it makes them feel more like a man/woman and over half of adults agreed that physical intimacy is one of the most important aspects of a relationship.³

Despite being common, over a quarter of men with EPs have not spoken to anybody about their issues and just 46% of men have discussed them with their partner. Embarrassment is the main reason for men not speaking about EPs while more than one in ten men don't want to acknowledge their EPs.³

You may also feel embarrassed or uncomfortable talking about EPs with your male customers as these conversations can be sensitive and a bit tricky. This booklet aims to help you get under the skin of your male customers experiencing EPs, tackle some of the myths that surround them, as well as increasing your confidence in having conversations about EPs. It looks at some typical concerns or questions that customers might have and some explanations that you might find useful. Always remember to approach these conversations with sensitivity and offer the option of using the consultation room or moving to a quiet corner of the pharmacy.



IS IT SAFE
FOR ME
TO TAKE?



OVER 1 MILLION MEN HAVE USED VIAGRA CONNECT AS A TREATMENT FOR THEIR EPs.⁴

VIAGRA CONNECT is an effective treatment for EPs in men aged 18 years and over. It helps men to get an erection, stay hard enough for sex and keep an erection for the duration of sex.⁵

While VIAGRA CONNECT is suitable for most men with EPs, it isn't suitable for everyone. You can reassure customers that before supplying VIAGRA CONNECT, the pharmacist will ask them a few questions to make sure they don't have any underlying health conditions and aren't taking any medicines that would indicate that VIAGRA CONNECT wouldn't be suitable for them to take.

Customers should be advised to see their GP within six months of first receiving VIAGRA CONNECT.

Your customers may ask if VIAGRA CONNECT has any side effects. All medicines can cause side effects, although not everybody gets them.

The most common side effect of VIAGRA CONNECT is a headache.⁵ Advise them to read the Patient Information Leaflet inside the pack to find out more about possible side effects.

Men should be advised to only purchase VIAGRA CONNECT from a pharmacy or online from a regulated website to ensure they are purchasing a genuine licensed medicine and not a counterfeit medicine. Treatments for EPs are among the most commonly counterfeited medicines. They might be ineffective or contain potentially dangerous ingredients.



SURELY I'M TOO YOUNG TO
NEED VIAGRA CONNECT?



WHILE THE INCIDENCE OF EPs DOES INCREASE AS MEN GET OLDER, IT IS ESTIMATED THAT BY THE AGE OF 40, 40% OF MEN WILL HAVE EXPERIENCED THEM AT SOME STAGE.⁶

Most men will have times when they just can't get or keep an erection and there are many different factors that can cause this:

- Physical factors or having an underlying medical condition such as diabetes or heart disease
- Psychological factors such as stress, depression or being worried about not being able to get or keep an erection (performance anxiety)
- Side effects from prescribed medicines.



Lifestyle factors that can cause EPs include:

- Smoking
- Drinking too much alcohol
- Recreational drug use
- Unhealthy diet
- Lack of physical activity
- Obesity
- Lack of sleep.

In younger men, EPs could be an early indication of heart disease, undiagnosed high blood pressure, diabetes or high cholesterol, when they appear otherwise healthy.

This is why the pharmacist will ask particular questions to ascertain all the facts and give lifestyle advice or refer to the GP where appropriate.

Customers should be advised to see their GP within six months of first receiving VIAGRA CONNECT.

I ONLY HAVE
PROBLEMS
OCCASIONALLY –
IS IT WORTH TRYING
VIAGRA CONNECT?



MANY MEN ARE UNAWARE THAT STRESS AND LIFESTYLE FACTORS CAN CAUSE EPs.

EPs can happen with varying frequency; 20% of men surveyed said they struggled to be intimate due to not being able to get or maintain an erection every time they have sex, while an additional 30% of men said they suffered over half the times they tried to be intimate with their partner. Other men find it only happens occasionally.³

It is worth exploring factors that could be causing occasional EPs, such as stress, drinking a lot of alcohol before trying to have sex or other lifestyle factors. Many men are unaware that stress and lifestyle factors can cause EPs. Only half of UK adults surveyed linked EPs to stress and drinking too much alcohol, while just over a third mentioned that being overweight could have an effect.³

Performance anxiety may be an issue for some men; they may be anxious about their body image or worried about their sexual performance. This can impact on their arousal and ability to get and maintain an erection.

VIAGRA CONNECT can be recommended for occasional EPs. Customers should be advised that VIAGRA CONNECT alone won't give them an erection; they also need sexual stimulation and need to be aroused for it to work.

You could recommend the VIAGRA CONNECT 2-pack as it is designed for trial purchases.



A young woman with voluminous, curly brown hair is the central focus, looking off to the side with a thoughtful expression. In the background, a man with a beard and short hair is visible, looking away. The scene is set in a dimly lit room, possibly a living area, with a blue and white plaid shirt visible on the man. The overall mood is contemplative and intimate.

COULD VIAGRA
CONNECT HELP
BRING ME CLOSER
TOGETHER WITH
MY PARTNER?



ON AVERAGE, UK ADULTS ARE SEXUALLY INTIMATE SIX TIMES A MONTH. 46% OF ADULTS SAY THEY WOULD LIKE TO BE INTIMATE MORE FREQUENTLY THAN THEY CURRENTLY ARE.³

EPs can have a significant impact on intimacy and relationships as well as self-esteem and mental health. A man experiencing EPs may feel inadequate, depressed, frustrated or angry with himself and may become withdrawn from his partner. His partner may feel that they have done something wrong, think he doesn't find them attractive anymore or that he has found someone else.

There are lots of different factors that can cause EPs and it is important that couples are open and honest with each other. For adults surveyed who said they would like to be more intimate in their relationship, the most common solution

was to ignore the issue and carry on regardless, and only a quarter were considering talking to their partner about the issue.³

Talking to each other and exploring the factors that could be causing EPs may help to find ways to overcome them. Using VIAGRA CONNECT to help a man get and keep an erection to have sex may also help him to reconnect with his partner and once again have an intimate relationship with them.



A man with short dark hair, wearing a blue patterned button-down shirt, is shown in profile from the chest up. He is looking at a tablet computer held in his left hand, with his right hand resting on his chin in a thoughtful pose. The background is a softly lit room with a lamp and a couch. A large, semi-transparent question mark is overlaid on the bottom right of the image, enclosed in a dotted circular border. The text 'WILL I HAVE AN ERECTION FOR FOUR HOURS?' is written in white, uppercase letters on the bottom left.

WILL I HAVE
AN ERECTION
FOR FOUR HOURS?

VIAGRA CONNECT CAN START TO WORK WITHIN 30 MINUTES IN RESPONSE TO SEXUAL STIMULATION AND AROUSAL. MEN CAN STILL GET AN ERECTION IN RESPONSE TO SEXUAL STIMULATION AND AROUSAL FOR UP TO FOUR HOURS AFTER THEY TAKE VIAGRA CONNECT.⁵

While men can still get an erection for up to four hours after taking VIAGRA CONNECT, it won't be constant; it will subside after sex.

It is unlikely that a man will have an erection for longer than this after taking VIAGRA CONNECT. However, prolonged erections lasting for more than four hours (or priapism) have been occasionally reported.

If a customer does get an erection that won't go down for more than four hours after taking VIAGRA CONNECT, he should be advised to seek immediate medical attention; if not treated, this can lead to tissue damage in the penis and impotence.





WHAT IF I TRY IT
AND IT DOESN'T
WORK?

FOR MOST MEN, VIAGRA CONNECT WILL WORK THE FIRST OR SECOND TIME THEY TRY IT. FOR MEN WHO HAVE NOT BEEN ABLE TO HAVE SEX FOR A WHILE, IT MAY TAKE ADDITIONAL ATTEMPTS TO OBTAIN MAXIMUM BENEFIT.

Customers should be reminded that the maximum recommended dose for VIAGRA CONNECT is one tablet daily and that they shouldn't exceed this.

You can advise customers that VIAGRA CONNECT won't give them an erection if they aren't sexually aroused; they and their partner should engage in intimate foreplay just as they would if he wasn't taking VIAGRA CONNECT.

74% OF MEN REPORTED THAT VIAGRA CONNECT IMPROVED THEIR ERECTIONS.⁵

If after several attempts on different occasions a customer is still unable to get an erection for sex, they should be advised to consult their GP. There are other treatment options available for erection problems.

If your customer doesn't want to commit to purchasing the standard 4-pack, the VIAGRA CONNECT 2-pack would be an appropriate alternative, as it is designed for trial purchases.



Conversation tips

Conversations about EPs can be a bit tricky. Here are some tips that may help you when discussing EPs with your male customers:

- Make the most of leaflets and point of sale materials that men can use to start a conversation. Perhaps put some in the men's health section in your pharmacy
- Run men's health campaigns to encourage men to talk about their health
- When having conversations about EPs, look for visual signs of them feeling awkward, listen and reflect back the language they are using
- Remind them that there is a consultation room available if they would like to have a conversation in private.

Reflection

- Can you list three learnings that you will take away from this booklet to use when having conversations with customers about EPs and VIAGRA CONNECT?
- Think about what else you could do in your pharmacy to help men feel more comfortable asking for advice about EPs and VIAGRA CONNECT.

Further resources



Take a look online for our full set of training materials, including our foundation learning e-module, videos, case studies and a copy of the Pharmacy Checklist.

Explore now at tmmagazine.co.uk/viagraconnect-learning

Additional pharmacy resources can be found at hcp.viagraconnect.co.uk

References: **1.** Kantar TNS Omnibus Survey Dec 2010 - in a survey of 1,033 men (Data on file) **2.** ONS Data 2019 (Data on file) **3.** Opinium Research June 2020. The research was conducted by Opinium among a nationally representative sample of 5,007 UK adults. The Report was commissioned/funded by Upjohn **4.** <https://www.viagraconnect.co.uk> **5.** <https://www.medicines.org.uk/emc/product/8725/smpc> **6.** <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5313305/>

FULL ESSENTIAL 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, Erythrospia 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 Oesophageal 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, Haematospermia, 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 guanylate 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

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December 2020
PP-VUJ-GBR-0339