



Sildenafil

THE PSYCHOLOGY OF ERECTION PROBLEMS

This training is for pharmacy professionals to support them to advise men affected by erection problems (EPs) and recognise opportunities for engaging with men about their general health.

Objectives:

- Understand the potential psychological causes of EPs
- Appreciate how both younger and older men may be affected by EPs
- Understand the wider physical and mental health aspects of EPs

REFLECTION: Are you confident to signpost men to other services when having conversations about EPs? Do you know what other services are available in your area to support men's health?

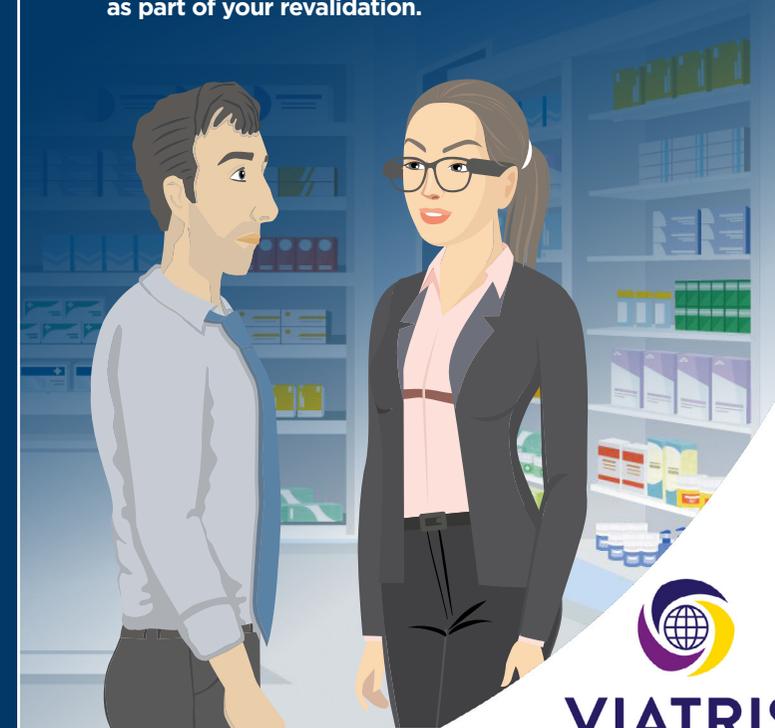
Introduction

EPs are complex and can affect men at any age. They often have both psychological and physical components. Careful questioning will help to ensure that the advice is tailored to each patient.

Giving men the opportunity to discuss any medical concerns and issues may highlight opportunities for signposting to other services to improve their overall health.

Men are often reticent to speak to healthcare professionals about their health. Every consultation for EPs gives an opportunity to discuss lifestyle changes, medication use, health monitoring, mental wellbeing and general health concerns, and support male patients to improve their overall wellbeing.

Remember that you can record any learning and how you use this information in your consultations as part of your revalidation.



VIATRIS



Depression

Depression can affect how men feel about themselves and others, and sufferers are less likely to seek help.¹ EPs may either contribute to, or result from, depression.

Advising on EPs

Having difficulty getting or sustaining an erection hard enough for sex (called erectile dysfunction, or erection problems) is common and can be treated in many cases. Although it's not unusual, some men may feel uncomfortable admitting to the issue or discussing it. As there are many factors that can contribute to EPs, your health discussions with male patients might open up opportunities for further health intervention - whether that relates to physical or mental health.



Stress

Stress can result from many areas, including lack of sleep and worries about work, money or relationships

A complex issue

Lifestyle factors such as diet, smoking, lack of sleep or excess weight may have a role within EPs. In addition, EPs could either be a contributing factor to psychological issues, or be a result of psychological issues. As you read through this booklet, you should gain a deeper understanding of some of the issues that might be impacting on a patient's erection and how this can improve your consultations.



Self-esteem

Self-esteem issues can cause EPs, or conversely can happen as a result of EPs and may be a sign of depression



Anxiety

Anxiety can be specifically related to performance or be more generalised



Relationships

Relationship issues can affect a man's ability to have an erection but, equally, erection difficulties can impact on relationships



UNDERSTANDING ERECTIONS

There are three different types of erections – psychogenic, reflexogenic and nocturnal. Psychogenic erection is a result of audiovisual stimuli or fantasy. Reflexogenic erection is produced by tactile stimuli to the genital organs. Nocturnal erection occurs mostly during rapid-eye-movement (REM) sleep.²

For an erection to happen, sexual stimulation triggers neurotransmitter release from the cavernous nerve terminal, causing relaxation of the smooth muscle and changes to blood flow in the penis. The process of an erection involves psychological, neurological and vascular pathways.³ Any changes to these pathways can result in EPs.

EPs can have psychological causes and an effect on a man's psychosocial wellbeing. EPs can also be due to physical causes, which can affect the blood flow (vasculogenic), the nerve impulses (neurogenic), hormones or anatomy (the structure of the penis, such as Peyronie's disease). These physical causes include potential undiagnosed conditions such as CVD, diabetes, hypertension or hypercholesterolemia.

Age is a contributing factor to EPs, and incidence does increase with age; however, men under 40 are also affected, due to both physical and psychological causes. Moreover, evidence indicates that incidence is increasing in this younger age group.^{3,4} Psychogenic causes tend to result in a sudden onset of symptoms, whereas physical causes may lead to a gradual onset of symptoms, with no effect on libido. If a man can achieve an erection for masturbation, it is more likely that EPs within a relationship are psychogenic. Many EPs involve a combination of psychological and physical components.³

Psychological causes

Some of the factors that contribute to EPs may be assumed to be short-lived, such as performance anxiety; however, many psychological causes can affect men on a long-term basis, and some men may find themselves in a cycle where worry about EPs compounds the problem.⁵ Lifestyle factors can also have an impact on EPs, and these may again be compounded by psychological issues, such as smoking or drinking when stressed.



Stress/money

Life stresses such as work pressures, worry about money or job security (areas that men have traditionally been seen as responsible for) can result in EPs. These can affect men of any age. Signs of stress include: headaches, dizziness, heart palpitations, difficulty concentrating or making decisions, feeling overwhelmed, changes to appetite/sleep and irritability.⁶ When stressed, the blood level of the hormone cortisol is increased. Cortisol can affect the ability to have an erection, and long-term raised cortisol levels can affect testosterone production.⁷

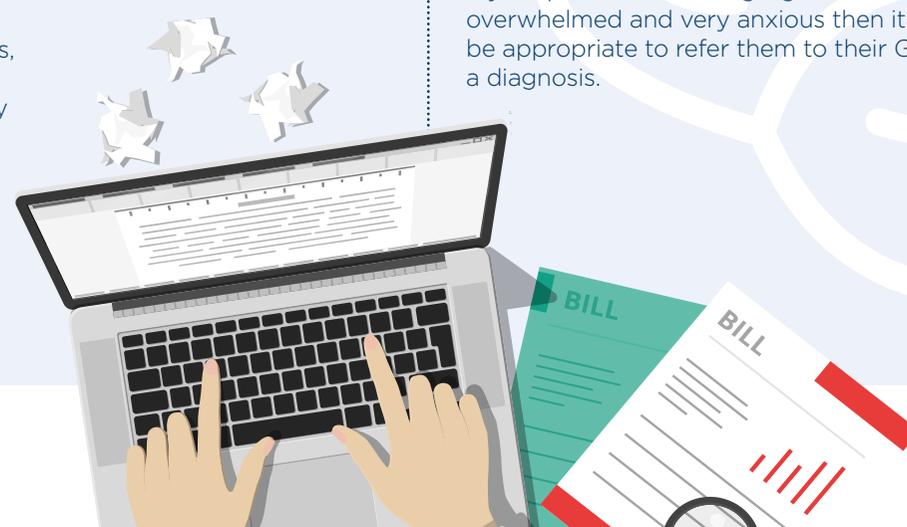
When discussing medication for EPs, you may be in a position to identify what some of the underlying issues may be and whether referral to other services is appropriate.



Anxiety

Anxiety is a feeling of unease, such as worry or fear, that can be mild or severe.⁸ General anxiety and medicines used to treat anxiety can contribute to EPs. Generalized anxiety disorder (GAD) is a long-term condition, and those affected feel anxious about a wide range of issues and events. GAD can cause both psychological (mental) and physical symptoms including feeling restless or worried, having difficulty concentrating, having trouble sleeping and dizziness or heart palpitations.⁹

If your patient is showing signs of feeling overwhelmed and very anxious then it may be appropriate to refer them to their GP for a diagnosis.





DID YOU KNOW?
 The prevalence of EPs in younger men (aged under 40) may be as high as

25%⁴



Performance anxiety

Performance anxiety may be an issue for some men, particularly early in their sexual life as they may be overly focused on their erection. This can then impact on arousal and the quality of the erection. Men may also be worried about their sexual performance or their body image. Any previous sexual failure can then affect future sexual confidence.¹⁰



Depression

There is thought to be a link between EPs and depression, and there may be changes to libido or sexual function as a result of taking anti-depressants.¹⁰ One of the biggest causes of depression in men is loss, such as a job, a relationship or sense of security. Men affected by depression may feel angry, irritable and stressed. They may lose interest in what they used to enjoy (including sex and normal routines) and withdraw from those around them. They may drink excessively or use drugs, and find their sleep and appetite is affected.¹¹

Listening out for changes to someone's routine and what may have led to these changes may help you to identify someone potentially affected by depression.



Self-esteem

Men may associate their ability to have an erection with their masculinity. Having EPs can therefore impact self-esteem.¹² Long-term low self-esteem can, in turn, have an impact on mental health.



Relationship issues

How a man feels about his partner can impact on his ability to have an erection. If he feels pressure to perform, or is no longer happy in the relationship, or has a sense of guilt about his ability to satisfy his partner, he might not be able to achieve an erection.⁵



Pharmacy support

During discussions about EPs you may identify occasions where patients need additional support. Some patients might need to be referred to their GP for appropriate counselling, sex therapy or mental health support.

Some advice you can give includes:¹³

- Offer suggestions of how they can take time out to relax and exercise
- Suggest tips to encourage them to eat well, while limiting their use of alcohol, cigarettes or drugs
- Providing details of mental health charities that can offer support may be appropriate.



Signposting and further reading

For a list of mental health charities visit:
www.nhs.uk/conditions/stress-anxiety-depression/mental-health-helplines/

To find out more about the sexual wellbeing of men, visit:
<https://sexualadviceassociation.co.uk/>

Lifestyle and EPs

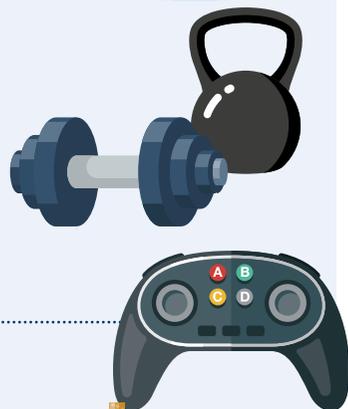
A number of lifestyle factors can contribute to EPs. These include:

Diet and being overweight – obesity may cause damage to blood vessels, and a diet high in saturated fats may increase blood cholesterol levels, contributing to EPs¹⁵



Alcohol consumption – alcohol can damage the nerves and affect hormone levels

Recreational drug use such as taking cocaine or cannabis can result in EPs, and may particularly affect younger men who may be using these substances.⁴ Anabolic steroids are sometimes taken without medical advice to increase muscle mass and improve athletic performance; these can also cause EPs¹⁶



Not exercising enough – a lack of exercise is linked to hypertension and obesity. Exercise has been shown to improve erectile function in men affected by vascular EPs¹⁷

Smoking – this causes blood vessel constriction^{13,18}



Men who cycle for more than three hours per week may have an increased risk of developing EPs. They may be advised to stop cycling for a while to see if there is any improvement.¹³



Disease and EPs

There are many health conditions associated with EPs and you can help patients manage their condition or discuss with them further health checks that may be appropriate.

● Cardiovascular

The most common physical cause of EPs is atherosclerosis, which affects the supply of blood to the penis. Penile blood vessels are narrow, and EPs can be an early indicator of future heart problems, occurring around three to five years before a heart complaint (e.g. myocardial infarction).^{10,18}

High blood pressure, diabetes and high cholesterol are also possible causes, as they too affect blood supply to the penis. In younger men, the role of EPs as a marker for cardiovascular risk is an opportunity to identify subtle and subclinical conditions in apparently healthy men.¹⁰

● Lower urinary tract symptoms (LUTS)

The prostate gland increases in size from the age of 40, narrowing the urethra and causing problems passing urine (straining to pass urine, an increased need to urinate and a feeling that the bladder doesn't empty fully). Prostate enlargement, also called benign prostatic hyperplasia (BPH), and prostate cancer (the most common cancer in men in the UK) have similar symptoms, so men affected should be advised to speak to their GP.¹⁹

There may be an opportunity to discuss the link in men prescribed treatment for BPH. Conversely, you could also question men with EPs to see if they additionally have signs of BPH.²⁰

● Endocrine conditions

Conditions such as diabetes, thyroid dysfunction, Klinefelter syndrome (where men have an extra X chromosome) and hypogonadism (when there is reduced testicular function) are linked with EPs. Testosterone deficiency is a more common cause of EPs in older men.³ Patients with diabetes can be advised to control their blood sugar levels and blood pressure to help manage EPs.²¹

● Neurogenic

Multiple sclerosis, Parkinson's disease, stroke, diabetes and spinal injury or disorder can affect the nerves and result in EPs.¹⁸

EPs may be a side-effect of medication such as finasteride (used for male pattern baldness), antidepressants, NSAIDs, neuroleptics or antiepileptics.³ It may be appropriate to discuss the potential side-effects with the patient and identify when they should consider discussing medication changes with their GP.



Treating EPs

Phosphodiesterase-5 inhibitors such as sildenafil can be taken orally to treat EPs. VIAGRA CONNECT (sildenafil) is available to purchase from the pharmacy. If treatment with sildenafil doesn't help, there are other options and patients can be referred to their GP to discuss injection treatment, testosterone replacement and vacuum devices. As EPs can have a considerable effect on men's mental wellbeing and relationships, finding the right treatment can make a real difference.

GP checks

As we have seen, EPs can be linked with other medical conditions, so men purchasing VIAGRA CONNECT should be advised to see their GP within six months of first taking it. **A GP may assess him by:**¹⁸

- Checking heart and lung function
- Taking blood pressure and cholesterol measurements
- Diabetes screening
- Physical examination of the genitals
- Checking testosterone levels.

You may offer some of these services in your pharmacy to support health monitoring, or this might be something to consider in the future.



Men's health: the stats¹⁴

75%
of premature
deaths from heart
disease are male



67%
of men are
overweight or obese



4 out of 5
suicides are male



Middle aged men are **twice** as likely to have diabetes as women

Men are more likely to smoke and drink to dangerous levels, eat too much salt and red meat and not enough fruit and vegetables.



Contains: Sildenafil 50mg

- For men 18 and over with EPs
- One tablet to be taken around an hour before sexual activity
- Sexual stimulation is required for it to work
- Maximum dose is one tablet daily

See product information on the back page.

References: **1.** <https://www.rcpsych.ac.uk/mental-health/problems-disorders/depression-and-men> **2.** <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1351051/#:~:text=In%20summary%2C%20the%20structures%20above,to%20activate%20the%20erectile%20process> **3.** Nguyen HMT, Gabrielson AT, Hellstrom WJG. Erectile Dysfunction in Young Men-A Review of the Prevalence and Risk Factors. *Sex Med Rev.* 2017;5(4):508-520. doi:10.1016/j.sxmr.2017.05.004 **4.** Capogrosso, P., Colicchia, M., Ventimiglia, E., Castagna, G., Clementi, M.C., Suardi, N., Castiglione, F., Briganti, A., Cantiello, F., Damiano, R., Montorsi, F. and Salonia, A. (2013), One Patient Out of Four with Newly Diagnosed ED Is a Young Man. *J Sex Med.* 10: 1833-1841. doi:10.1111/jsm.12179 **5.** <https://www.webmd.com/erectile-dysfunction/guide/ed-psychological-causes> **6.** <https://www.nhs.uk/conditions/stress-anxiety-depression/understanding-stress/> **7.** <https://www.apa.org/helpcenter/stress/effects-male-reproductive> **8.** <https://www.nhsinform.scot/illnesses-and-conditions/mental-health/anxiety> **9.** <https://www.nhs.uk/conditions/generalised-anxiety-disorder/> **10.** Rastrelli G, Maggi M. Erectile dysfunction in fit and healthy young men: psychological or pathological? *Transl Androl Urol.* 2017;6(1):79-90. doi:10.21037/tau.2016.09.06 **11.** <https://www.mensmindsmatter.org/depression-in-men.html> **12.** <https://www.issm.info/sexual-health-qa/how-does-erectile-dysfunction-ed-affect-a-mans-self-esteem/#:~:text=Many%20men%20associate%20erectile%20dysfunction%20with%20abilities%20to%20please%20their%20partner> **13.** <https://cks.nice.org.uk/topics/erectile-dysfunction/management/management/> **14.** <https://www.menshealthforum.org.uk/statistics> **15.** <https://www.obesityaction.org/community/article-library/men-is-obesity-affecting-your-sex-life/> **16.** <https://www.nhs.uk/conditions/anabolic-steroid-misuse/> **17.** Gerbild H, Larsen CM, Graugaard C, Areskoug Josefsson K. Physical Activity to Improve Erectile Function: A Systematic Review of Intervention Studies. *Sex Med.* 2018;6(2):75-89. doi:10.1016/j.esxm.2018.02.001 **18.** <https://sexualadviceassociation.co.uk/erectile-dysfunction/> **19.** <https://www.nhs.uk/conditions/prostate-cancer/> **20.** [https://www.europeanurology.com/article/S0302-2838\(03\)00464-0/fulltext](https://www.europeanurology.com/article/S0302-2838(03)00464-0/fulltext) **21.** Diabetes and Erectile Dysfunction, Neelima V. Chu, Steven V. Edelman *Clinical Diabetes* Jan 2001, 19 (1) 45-47; DOI: 10.2337/diaclin.19.1.45 **22.** <https://www.menshealthforum.org.uk/erectile-dysfunction-faqs>

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, Erythroptosis 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, Haemospermia, 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 (\geq 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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