

Developing your consultations on erection problems



Sildenafil

Since the successful 2018 introduction of **VIAGRA CONNECT**[®] into pharmacy, post-launch research into its supply and use has identified some key areas for a knowledge update. Wider research has also shown that a broader spectrum of men come into the pharmacy asking about VIAGRA CONNECT than originally expected.

Assess your knowledge

Would you supply VIAGRA CONNECT to an otherwise eligible man who had a heart attack eight months ago?



Would you refer a man to his GP if he has come to you reporting of a headache since taking VIAGRA CONNECT?



You will find the answers to these questions within this training.

Objectives

- **Explain** some of the key learnings from the post-authorisation safety study (PASS) research
- **Provide** a refresher about the types of patients coming to the pharmacy seeking advice
- **Support** you to train the team to handle requests with confidence
- **Revisit** key product features

Erection problems

VIAGRA CONNECT may be used by men over 18 who have difficulty getting or keeping an erection for satisfactory sexual intercourse. It may be an occasional incident, or something that occurs more frequently. Erection problems (EPs) are estimated to affect 4.3 million men in the UK*¹ but not all men will seek treatment. So bear in mind that many of your male patients may be suffering in silence and possibly either too embarrassed to seek help or unaware of the treatment options.

Causes include:

- Physical (co-existing conditions include hypertension, diabetes, hypercholesterolaemia or cardiovascular disease)
- Psychological (e.g. work-related stress, performance anxiety, depression)
- Medication side-effect (e.g. beta-blockers, ACE inhibitors, anti-depressants, anti-epileptics).

Most men occasionally fail to get or keep an erection – contributing lifestyle factors include stress, anxiety, lack of sleep, unhealthy diet, drinking too much alcohol or recreational drug use. Other causes are smoking, a lack of physical activity and obesity.²⁻⁴

The perception of erection problems just being something that affects older men is not true, although it is more common with increasing age.⁴ For many men, they may feel embarrassed to admit that they have occasional or regular erection problems, and may then purchase products online instead of seeking medical advice from a pharmacist or their GP. Purchasing medicines online opens up the potential risk of using counterfeit medicines, or men not getting the most appropriate healthcare advice.

*Men reporting occasional and frequent difficulty getting or maintaining an erection



Knowledge refresher



Outcomes from the PASS research showed the following areas where there were gaps in the knowledge or practical application of the guidance for some pharmacists. You can use this information to refresh your knowledge and to reinforce any training with your team as appropriate. Remember to record any CPD that you can use as part of your revalidation.

Patients using other medication

Men using a different dose of sildenafil or another erectile dysfunction (ED) treatment cannot be supplied VIAGRA CONNECT.



Riociguat should not be used concomitantly with VIAGRA CONNECT. Riociguat is a guanylate cyclase stimulator, used for pulmonary hypertension. It is predicted to increase the risk of hypotension if taken with sildenafil.

Patients taking beta blockers can use VIAGRA CONNECT, assuming their blood pressure is stable and they are otherwise suitable for supply.

Patients with medical conditions

Men who have had a heart attack or stroke more than six months ago can be supplied with VIAGRA CONNECT as appropriate.



Hypertension and hypercholesterolaemia may cause ED – consider this when assessing a patient for VIAGRA CONNECT. Check when they last had a BP check or cholesterol level test, for example, and remind them to see their GP within six months of first purchase.

Other medical conditions such as diabetes and cardiovascular disease may also cause erection problems, so listen out for other symptoms such as thirst, tiredness, chest pain or breathlessness.

Side effects

Headaches and nausea are common side-effects of VIAGRA CONNECT. If these persist, men should seek medical advice.



Conversations about **erection problems**

Talking about erection problems or VIAGRA CONNECT may not be embarrassing for you as a healthcare professional, but this may not be the case for some men – so sensitivity and empathy are required.

DID YOU KNOW?

Pharmacy has already helped over 1 million men to take action through the supply of VIAGRA CONNECT,⁵ showing its vital role in supporting men's health and wellbeing.



Co-existing conditions that may be undiagnosed due to lack of symptoms (such as hypertension) should always be considered in men affected by erection problems. This is why it is essential that anyone purchasing VIAGRA CONNECT should see their GP for a follow-up within six months of first purchase. The penile artery is smaller in diameter than other arteries, and any changes in blood flow (e.g. narrowing due to fatty deposits/hardened arteries) will be seen in those smaller arteries. Diabetes may affect blood vessels and nerves.

NOTE: As a result of this PASS study, changes have been made to the VIAGRA CONNECT Pharmacy Checklist and the Essential Information for the supply of VIAGRA CONNECT booklet.

Top tips

- Reflect back the type of language the patient uses (e.g. 'problems in the bedroom department', 'not being able to get it up', erectile dysfunction, ED, 'brewer's droop')
- Give all patients the opportunity for a private consultation in the consultation room
- Be aware of any sensitivities in terms of who they may know in the team and how to protect their confidentiality
- Allow initial time in the consultation for the patient to feel at ease. For example, explain what will happen and ask if they have any questions at the beginning
- Display leaflets or tokens that customers can pick up and hand to the team to reduce the need to ask out loud about erection problems at the counter

Reflection



- What impact do you think erection problems may have on relationships and personal confidence of your patients?
- What difference might effective treatment make?
- What barriers might there be to men seeking help from the pharmacy?
- How do you and your team try to make the pharmacy experience less intimidating?
- How do you feel personally about having such sensitive conversations?

Initiating conversations about men's health

As well as patients coming in to ask for VIAGRA CONNECT, remember to use other interactions such as medicines reviews or smoking cessation services to ask if they have any concerns about erection problems. These may be linked to prescribed medication or other underlying medical issues.

Obviously, this can be a sensitive topic to broach, but phrases such as the following may help:

“ Did you know that hypertension can also cause problems in other arteries? Some of my patients find that it affects their erections and we have been able to help by recommending medication or discussing potential medication changes. ”

“ I notice that you are taking an SSRI – common side effects include erection problems. If you are affected by this, I may be able to suggest how to minimise them. ”

It may be helpful to have product information readily available to give to potential patients (e.g. product leaflet). You could also train the team to be confident to identify and approach patients who are browsing the men's healthcare section.

Training your team

Depending on the level of experience of your pharmacy team, a tailored training approach is suitable. Below are some approaches to consider, plus details of the different resources available.



New team members, or those new to VIAGRA CONNECT consultations:

- Go to pharmacymagazine.co.uk/viagraconnect-learning for additional e-learning and other resources
- Read and review the questions on the Pharmacy Checklist
- Practise scenarios to improve confidence
- Discuss the approach that can be taken with different patients

Team members who are experienced in recommending VIAGRA CONNECT or have completed the launch training materials:

- Give refresher training on the outcomes from the PASS research
- Remind them that although they may be more confident, they should still offer the privacy of a consultation room if patients would prefer
- Encourage self-reflection on their consultation skills and experience so far



Contains sildenafil 50mg.

For men over 18 years of age with erectile dysfunction (ED).

Dose: ONE tablet to be taken approximately one hour before sexual activity. Sexual stimulation is needed for it to work.

If the patient has not had intercourse for a while due to erection problems, it may take a few times for it to work. They may want to consider masturbation initially.

Maximum dose: One 50mg tablet once daily.

Additional advice

As well as supplying VIAGRA CONNECT if appropriate, you can give the following advice:

- Remind men to see their GP within six months of first supply
- Lifestyle changes such as losing weight (if overweight), stopping smoking, eating healthily, daily exercise and reducing stress can help
- Keep intake of alcohol to within the recommended guidance of 14 units per week
- Some men may want to consider relationship therapy, sex therapists or counselling

Self-test questions

1. With which of the following side-effects would you advise the patient to stop taking the medication and consult their GP? **(Tick all that apply)**

- a. Flushing
- b. Dyspepsia
- c. Headache
- d. Sudden decrease in vision
- e. Chest pains during intercourse

2. Which of the following should NOT be taken concomitantly with VIAGRA CONNECT? **(Tick all that apply)**

- a. Propranolol
- b. Isosorbide dinitrate
- c. Erythromycin
- d. Riociguat
- e. Doxazosin

Further resources



With a **big new consumer campaign** planned for this summer, this training will help make sure you and your team are ready to handle increased requests for VIAGRA CONNECT.

Updating your knowledge on VIAGRA CONNECT could count towards one of your CPD entries as part of your revalidation (mygphc.org). Take a look online for a whole host of additional support materials from VIAGRA CONNECT.

pharmacymagazine.co.uk/viagraconnect-learning
hcp.viagraconnect.co.uk

References

1. Kantar TNS Omnibus Survey Dec 2010 – in a survey of 1,033 men (Data on file)
2. <https://www.nhs.uk/conditions/erection-problems-erectile-dysfunction/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4291878/>
4. <https://patient.info/mens-health/erectile-dysfunction-impotence>
5. Kantar 2019, VIAGRA CONNECT Omnibus Survey, 1,499 men 35+ yrs & UK male population 35+ yrs (data on file)

Online references last accessed May 2020.



PRODUCT INFORMATION

VIAGRA CONNECT 50mg Film Coated Tablets

Active ingredient(s): Sildenafil **Product licence number:** PL 00165/0392 **Name and address of the product licence holder:** Pfizer Consumer Healthcare Ltd, 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 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, Haematopermia, 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 (see section 5.1). 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 section 4.3). 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 section 4.8). 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 section 4.8). 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 section 4.3). 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 section 4.5 for further information). 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 section 4.5). 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 section 4.2 and 5.2 for further information). 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 section 4.2 and 5.2 for further information). Lactose: The film coating of the tablet contains lactose. VIAGRA CONNECT should not be administered to men with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. 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 (see section 5.1), 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 section 4.5). 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 section 4.5). 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 (see section 4.4). 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 (see section 5.2). 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 section 4.4 for further information). 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 section 4.4 for further information). The safety of sildenafil has not been studied in patients with severe hepatic impairment, and its use is therefore contraindicated (see section 4.3). 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 section 4.3), 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 section 4.4 for further information). 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 sections 4.4 and 4.5). **Cost:** 4 pack £16.66 (exc VAT) and 8 pack £29.16 (exc Vat) **Date:** November 2017