

The first P-medicine
for EPs in the UK



Take positive action for
men's health

Effective conversations about
VIAGRA CONNECT
in the pharmacy



VIAGRA
CONNECT®

Sildenafil

Date of preparation: June 2023
Job number: VIAC-2023-0370

Introduction

This training has been designed for the pharmacy team to support effective consultations when supplying VIAGRA CONNECT® to customers.



Sildenafil 50 mg | P

- For men over 18 affected by erectile dysfunction (ED)¹
- Recommended dose one 50 mg tablet taken with water approximately one hour before sexual activity
- Works to improve the blood flow in the penis
- Sexual stimulation is needed for it to work
- Available in packs of 2, 4 or 8 tablets

ASSESS YOUR KNOWLEDGE

How long has VIAGRA® (sildenafil) been established as a treatment for erection problems (EPs)?

Are you confident discussing the mental health implications associated with EPs and aware of signposting options available to support your customers?

How could customer consultations surrounding EPs and VIAGRA CONNECT supply opportunities present a gateway to unlock men's health services in your pharmacy?

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



Objectives

Learn about the heritage of VIAGRA

Look at ways to overcome potential barriers to purchase

Revisit important supply considerations of VIAGRA CONNECT

Support you to utilise consultations to address men's health issues

Promote the services available in your pharmacy

Be aware of services that you may need to signpost customers to

The story in numbers

With over 20 years of clinical experience, VIAGRA has established its heritage as the first treatment option for EPs.²

136



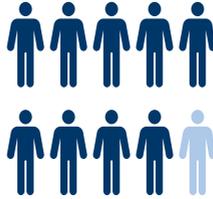
Over the years, more than **136 TRIALS** have been conducted involving more than 23,000 patients using sildenafil for the treatment of ED²

67 MILLION

Since launch, more than **67 MILLION PATIENTS** have used VIAGRA globally³

EPs are very common and are estimated to **affect about 6 million men** in the UK⁴

6 MILLION



9 OUT OF 10

9 OUT OF 10 CUSTOMERS in the UK choose VIAGRA CONNECT when buying an over the counter (OTC) treatment for EPs*

*90% of sales in the full year were VIAGRA CONNECT. Based on UK IRI unit sales data (2021)

25 & 54

YEARS OLD



Based on recent user analysis, **67%** of VIAGRA CONNECT users are aged between **25 AND 54 YEARS**⁴

Overcoming barriers

As a member of the pharmacy team, you are in an ideal position to help customers overcome any concerns they may have.

Raising awareness and destigmatising EPs⁵

A recent consumer panel survey has highlighted an improvement in customer perceptions of EPs compared to previous studies. **Key findings include:**

EPs are nothing to be embarrassed about:

63%
agree

37%
disagree

+ Neither agree or disagree/No response

It is easy for men to take action to treat their EPs

39%
agree

61%
disagree

+ Neither agree or disagree/No response

EPs are something that are talked about openly

18%
agree

82%
disagree

+ Neither agree or disagree/No response



Despite the positive trend, many customers still have concerns about discussing their EPs with others:

Over 1/3 of customers can't confidently say that EPs are nothing to be embarrassed about

More than 50% of customers may have concerns about how easy it is to take action

Over 80% of customers don't feel that EPs can be talked about openly



Remember, customers coming into your pharmacy to discuss their 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. Look out for customer behaviours and body language that may indicate nervousness and respond accordingly. Where available, let customers know that there is a consultation room in the pharmacy if they wish to discuss something in private.

Continuing to raise awareness of the high prevalence of EPs and highlighting that treatment is readily available will also help make it easier for potential customers to seek help.

Valuable source of support

When it comes to getting support from the pharmacy, research shows that men value pharmacist recommendation highly, especially when seeking information about the best types of medication to treat EPs.⁵

Leaflets and point of sale (POS) displays in the pharmacy can help raise awareness of EPs and showcase the OTC availability of VIAGRA CONNECT. Have some in your men's health section and put some at the counter, for example, so it's clear that men can come to you for further advice.



Impact on partners

Research shows that EPs can reduce quality of life for partners as a result of relationship difficulties and decreased sexual satisfaction and activity.⁶

However, while men associate only negative feelings with experiences of EPs, their partners tend to be more accepting of the situation. They want to be involved in the solution-seeking process so they can support their other half.⁵

This can be helpful to remember in your consultations. You can encourage men to open up and talk to their partner, who may be a useful source of support. This could also offer longer term benefits to both their relationship and overall mental health.

When speaking to customers, it is important to acknowledge the possible benefits of treatment for men with EPs and also their partners, who benefit from an intimate relationship.⁷

Treating EPs

Three key treatment factors

With its years of clinical experience, VIAGRA CONNECT performs strongly in all these areas, which will help you reassure customers. Evidence indicates **the three most important factors for customers seeking treatment for their EPs are:**⁵

2

EFFICACY²

VIAGRA CONNECT's efficacy is supported by substantial clinical evidence. The validated erection hardness scale (EHS) has objectively assessed the efficacy of EPs treatment with VIAGRA CONNECT.

1

TOLERABILITY⁸

Post-marketing studies have demonstrated sildenafil is well tolerated.

3

EASE OF PURCHASE

Many men may still not be getting treatment for their EPs. Raising awareness by using POS displays and promoting the availability of pharmacists and trained team members for consultations can help address this.

APPROPRIATE SUPPLY OF VIAGRA CONNECT⁹

Before a customer is supplied with VIAGRA CONNECT for the first time, the pharmacist must determine whether supply is appropriate. This includes checking to see if the customer has any underlying health conditions or is taking any prescription medicines that contraindicate use. They may use the Pharmacy Checklist to help assess suitability.

Some customers may be coming to your pharmacy having already purchased the product OTC in the past so it's important to know each team member's role in the sale and supply of VIAGRA CONNECT – check with your pharmacist if you are unsure. You should be familiar with the Pharmacy Checklist and, if applicable, any specific SOPs in your pharmacy.



Supply considerations in practice

Here are some scenarios that you may encounter when dealing with requests for VIAGRA CONNECT in your pharmacy:



SCENARIO 1:

A customer wishes to purchase VIAGRA CONNECT, explaining that he has run out of his prescribed sildenafil 50 mg tablets.

Men prescribed 50 mg of sildenafil **can** be supplied VIAGRA CONNECT if they meet the criteria for pharmacy supply, provided they do not take more than 50 mg daily. If the customer is using a different dose of sildenafil or another treatment, he should be referred to his GP.



SCENARIO 2:

A customer asks to make a repeat purchase of VIAGRA CONNECT. There has been a change to his blood pressure medicine dose since last supply.

As part of the repeat supply process, customers must be asked if anything has changed in their health or medicines usage. In this situation, it is important to flag the medication dose change to the pharmacist. The pharmacist will exercise their clinical and professional judgement to determine whether or not the customer's hypertension is controlled with the new dose and review for drug interactions. If satisfied that the customer is stabilised with respect to his hypertension, they can make a supply.

IMPORTANT REMINDER:^{10,11}

Customers supplied VIAGRA CONNECT for the first time should be advised how important it is to see a doctor within six months for a clinical review and to check for underlying conditions and risk factors associated with EPs.

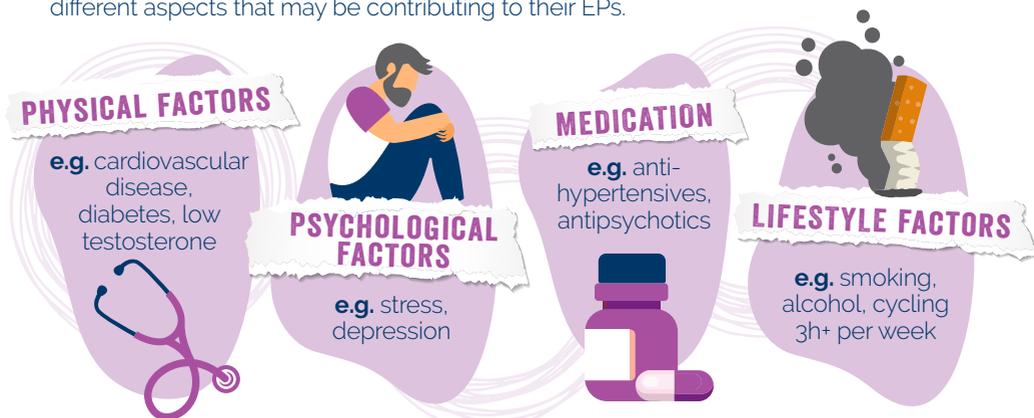


VIAGRA CONNECT: A gateway

Factors affecting EPs¹²

EPs are very common among men and usually nothing to worry about. Where EPs occur more frequently, there could be an underlying cause.⁹

Many factors are associated with EPs. Having an awareness and understanding of these can help you, in turn, improve your customer's understanding of the different aspects that may be contributing to their EPs.



Men's health in your pharmacy⁹

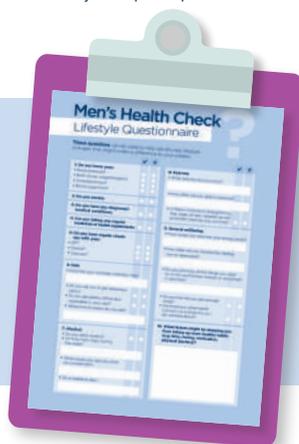
EPs can respond well to both treatment and lifestyle changes so it's important to think about the advice, support and services you provide to your customers.⁹

Conversations on EPs and VIAGRA CONNECT offer an ideal chance for the pharmacy team to identify lifestyle changes their customers can make or steps they can take to manage any underlying conditions, which may help improve their EPs and general wellbeing.

PROACTIVE CONVERSATIONS

The **Men's Health Check: Lifestyle Questionnaire** is a great tool to use to initiate conversations surrounding men's health with customers affected by EPs. The checklist can be used to:

- **Help identify and tailor lifestyle changes**
- **Offer pharmacy services (where available)**



to men's health

Services and signposting

Examples of further support that your pharmacy could offer to help customers with EPs include:

Discussing EPs may be an opportunity to assess **heart health**. Helpful measurements include cholesterol levels and blood pressure. You may offer services to measure these in your pharmacy or offer home testing kits.

Diabetes is a risk factor for men with EPs. Some men may not know they have diabetes so can benefit from urine or blood tests to check glucose levels. You may already offer a diabetes screening service in your pharmacy, or wish to consider offering one.

Obesity can be a risk factor for EPs. If your pharmacy offers a weight loss service, men with a high BMI affected by EPs could benefit from this. Additionally, encouraging affected individuals to follow a healthy diet and exercise daily is advised.

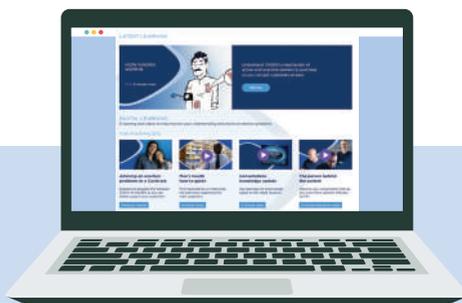
There is a link between **smoking** and EPs. Think about how you currently support customers looking to stop smoking in your pharmacy – if you don't already, you may want to consider offering a stop smoking service in the future.

The incidence of **depression** is up to three times higher in men with EPs.⁶ When discussing EPs, customers may appreciate having someone to listen to their concerns and give them an opportunity to work through their thoughts. You can also signpost customers to organisations who can help, including: Every Mind Matters; Mind; Relate; and Samaritans. Consider support groups local to your area and have their details available to share.

USEFUL RESOURCES

The Men's Health Services Toolkit training resource, which includes the Lifestyle Questionnaire, provides further details and ideas to help you have proactive conversations and improve access to healthcare advice for men. You can find all of these resources at:

pharmacymagazine.co.uk/viagraconnect-learning



References:

1. Viagra Connect 50 mg film-coated tablets (sildenafil): summary of product characteristics (Available at: <https://www.medicines.org.uk/emc/product/8725>)
2. Goldstein I. et al. *Sex Med Rev.* 2019 Jan; 7:115-128
3. Viatrix Pharmacy Academy: PP-VIA-GLB-0670 2021 Apr. (Data on file)
4. IPSOS Healthcare KPI Tracking study: February 2022 (Data on file)
5. Edelman DXi Survey data: February 2022 (Data on file)
6. Elterman D. et al. *Res Rep Urol.* 2021 Feb; 13:79-86
7. Douglas JM. et al. *Public Health Rep.* 2013; Supplement 1:1-4
8. Giuliano F. et al. *Int J Clin Pract.* 2010 Jan; 64:2:240–255
9. NHS UK: Erectile dysfunction (Available at: <https://www.nhs.uk/conditions/erection-problems-erectile-dysfunction/>)
10. Viagra Connect 50 mg film-coated tablets - Essential information for the supply of Viagra Connect (Available at: <https://www.medicines.org.uk/emc/mmm/1784/Document>)
11. Viagra Connect 50 mg film-coated tablets - Pharmacy Checklist (Available at: <https://www.medicines.org.uk/emc/mmm/1783/Document>)
12. NICE CKS: Erectile dysfunction (Available at: <https://cks.nice.org.uk/topics/erectile-dysfunction/>)

Online references last accessed January 2023.

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 (≥ 1/10): Headache. Common (≥ 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 (≥ 1/1,000 and <1/100): Rhinitis, Hypersensitivity; Somnolence; Hypoaesthesia, Lacrimation disorders (Dry eye, Lacrimal discharge 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 (≥ 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 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 <30ml/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**). Addition of a single dose of sildenafil to sacubitril/valsartan at steady state in patients with hypertension was associated with a significantly greater blood pressure reduction compared to administration of sacubitril/valsartan alone. Therefore, caution should be exercised when sildenafil is initiated in patients treated with sacubitril/valsartan. **C+D Trade Price (exc VAT)** 2 pack £8.82, 4 pack £16.17 and 8 pack £28.39 **Date of revision:** 04/2023

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystmOne/Version/MDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: p.vuk@viatris.com.

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: <http://www.mhra.gov.uk/SafetyInformation/MedicinesInformation/SPCandPILs/index.htm> and from Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

VIAGRA® 25 mg, 50 mg and 100 mg Tablets **PRESCRIBING INFORMATION - UK**

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

Indication: Erectile dysfunction. Sexual stimulation is required for efficacy. **Presentation:** Blue film-coated, rounded diamond-shaped ablets containing sildenafil citrate equivalent to 25 mg, 50 mg and 100 mg sildenafil. **Dosage and administration:** Adults: 50 mg approximately one hour before sexual activity. Adjust dose based on efficacy and toleration. Maximum dose is 100 mg. One dose per day is the maximum recommended. If taken with food, the onset of activity may be delayed. **Elderly:** Dosage adjustments are not required in the maximum recommended. If taken with food, the onset of activity may be delayed. **Elderly:** Dosage adjustments are not required in elderly patients. **Hepatic impairment, severe renal impairment:** 25 mg initial dose should be considered; adjust dose based on efficacy and toleration. **Children**

under 18 years: Not indicated. With CYP3A4 inhibitors: a starting dose of 2.5mg should be considered, except for ritonavir (see Warnings and precautions). With alpha-blockers: Patients should be stable on alpha-blocker therapy prior to initiating sildenafil treatment; starting dose of 25 mg should be considered. **Contraindications:** Co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form; coadministration of PDE5 inhibitors, including sildenafil, with guanylate cyclase stimulators, such as riociguat, as it may potentially lead to symptomatic hypotension; patients for whom sexual activity is inadvisable (e.g. patients with severe cardiovascular disorders); patients with vision loss in one eye due to non-arteritic anterior ischaemic optic neuropathy (NAION); severe hepatic impairment; hypotension; recent stroke or myocardial infarction; known hereditary degenerative retinal disorders; hypersensitivity to sildenafil or to any of the excipients. **Warning and precautions:** A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes. Cardiovascular status should be assessed, as sexual activity is associated with cardiac risk. Although their clinical relationship to Viagra has not been established, serious cardiovascular events have been reported (see Side-effects), mostly in patients with pre-existing cardiovascular risk factors and many occurring during or shortly after intercourse. Sildenafil has vasodilator properties, resulting in mild and transient decreases in blood pressure. Prior to prescribing sildenafil, physicians should carefully consider whether their patients with increased susceptibility to vasodilators could be adversely affected, especially in combination with sexual activity. Sildenafil potentiates the hypotensive effects of nitrates. Caution advised in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease) or predisposed to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia) and in patients with bleeding disorders or active peptic ulceration. Prolonged erections and priapism have been reported, if this persists for more than 4 hours immediate medical assistance should be sought by the patient. Not recommended in combination with PDE5 inhibitors or other treatments for erectile dysfunction. As with other PDE5 inhibitors, cases of visual defects have been reported. Cases of NAION have been reported spontaneously and in an observational study in connection with the intake of sildenafil and other PDE5 inhibitors. In case of sudden visual defect, the patient should stop taking Viagra and consult a physician immediately. Coadministration of sildenafil with ritonavir is not advised. Caution is advised when sildenafil is administered to patients taking an alpha-blocker, as coadministration may lead to symptomatic hypotension in a few susceptible individuals (see Drug Interactions). This is most likely to occur within 4 hours post sildenafil dosing. To minimise the potential for developing postural hypotension, patients should be hemodynamically stable on alpha-blocker therapy prior to initiating sildenafil treatment and a starting dose of 25 mg should be considered (see Dosage); physicians should advise patients what to do in the event of postural hypotensive symptoms. The film coating of the Viagra tablet contains lactose. Viagra should not be administered to men with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. This medicine contains less than 1 mmol (23 mg) per tablet, that is to say essentially 'sodium-free'. Not for use by women. **Interaction with other medicinal products:** In combination with inhibitors of CYP3A4 e.g. ketoconazole, erythromycin, cimetidine, a 25mg starting dose should be considered. Concomitant administration of strong CYP3A4 inducers, such as rifampin, is expected to cause greater decreases in plasma concentrations of sildenafil. Alpha-blockers - simultaneous co-administration may lead to symptomatic hypotension in a few susceptible individuals – See Dosage and Warnings and precautions. Ritonavir – see Warnings and precautions. Potentiates the hypotensive effects of nitrates (see Contraindications). Riociguat - see Contraindications. Nicorandil - Due to its nitrate component it has the potential to have serious interaction with sildenafil. No potentiation of the increase in bleeding time caused by acetyl salicylic acid (150mg) or the hypotensive effects of alcohol. No data on nonspecific phosphodiesterase inhibitors such as theophylline or dipyridamole. Sacubitril/valsartan - caution is advised. **Pregnancy and lactation:** There was no effect on sperm motility or morphology after single 100 mg oral doses of sildenafil in healthy volunteers. Not indicated for use by women. **Effects on ability to drive and use machines:** Caution if affected by dizziness or altered vision. **Undesirable effects:** Common and very common reported side-effects were flushing, hot flush, headache, dizziness, nausea, dyspepsia, altered vision (increased perception of light, blurred vision), rhinorrhoea (mild and transient, predominantly colour tinge to vision), nasal congestion. The following side effects have also been reported; rhinitis, hypersensitivity reactions, eye pain, red eyes/bloodshot eyes, lacrimation disorders, photophobia, photopsia, ocular hyperaemia, tachycardia, palpitation, ventricular arrhythmia, myocardial infarction, atrial fibrillation, unstable angina, sudden cardiac death, hypotension (see Warnings and precautions and Drug Interactions), hypertension, epistaxis, sinus congestion, nasal oedema, nasal dryness, throat tightness, syncope, cerebrovascular accident, transient ischaemic attack, gastro oesophageal reflux disease, vomiting, abdominal pain upper, hypoesthesia oral, rash, haematuria, haematopermia, penile haemorrhage, erection increased, priapism, NAION, retinal haemorrhage, arteriosclerotic retinopathy, retinal disorder, glaucoma, retinal vascular occlusion and 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, sudden decrease or loss of hearing, vertigo tinnitus seizure, seizure recurrence, somnolence, hypoesthesia, dry mouth, feeling hot, irritability, fatigue, myalgia, pain in extremity, chest pain, Steven Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). **Legal Category: POM Marketing Authorisation Number:** PLGB 50622/0089 - 25 mg Tablets; PLGB 50622/0090 - 50 mg Tablets; PLGB 50622/0088 - 100 mg Tablets **MAH:** Upjohn UK Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom NHS Price: 25 mg tablets, packs of 4 - £16.59; 25 mg tablets, packs of 8 - £33.19; 50 mg tablets, packs of 4 - £21.27; 50 mg tablets, packs of 8 - £42.54; 100 mg, packs of 4 - £23.50; 100 mg, packs of 8 - £46.99. **Date of Revision of Prescribing Information:** 05/2023

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card Scheme website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: p.v.uk@viatris.com

The SmPC for this product, including adverse reactions, precautions, contraindications, and method of use can be found at: <http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SP/CandPILLS/index.htm> and from Mylan Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

The history of VIAGRA® (sildenafil)

1983:

Research demonstrates that pharmacological agents can cause erections

1989-1992:

1989: Scientists synthesise sildenafil citrate as a potential treatment for angina

1992: Ongoing research reveals that erections are a side effect of using sildenafil



1997:

A drug application is submitted, supported by years of research including 21 clinical studies involving almost 4500 men with ED across 13 countries

1998:

Sildenafil (VIAGRA) becomes the first approved oral treatment option for ED



2017:

Classification of 50 mg dose of sildenafil from a prescription-only medicine to a pharmacy medicine for men >18 years of age with ED is approved

2018:

VIAGRA CONNECT® becomes available as an over the counter (OTC) treatment option in the UK



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