# SUITABILITY CHECKER

How to utilise VIAGRA CONNECT's new customer tool in your pharmacy

# SUPPORT GUIDE

VIAGRA CONNECT (sildenafil 50mg) recently launched an online Suitability Checker to help make it easier for customers to purchase it from the pharmacy. The screening questions will allow men with erection problems (EPs)<sup>1</sup> to check whether VIAGRA CONNECT might be a suitable option for them, before visiting the pharmacy.



# HOW CAN THE **SUITABILITY CHECKER** HELP?

# Improved access

Up to 1 in 4 men\* in the UK have experienced some degree of EP, but difficulty accessing treatment via conventional primary care services, including GPs, can be a barrier.<sup>2</sup> The online Suitability Checker informs men whether VIAGRA CONNECT may be a suitable option for them. For these customers, obtaining VIAGRA CONNECT over the counter (OTC) at their local pharmacy may be easier than obtaining a prescription-only product.

# **Less daunting**

Some men may feel uncomfortable, ashamed or embarrassed about their EPs.<sup>3</sup> The idea of speaking to a healthcare professional may seem daunting and they may have concerns about the nature of the conversation. Using the Suitability Checker may put their mind at ease about the types of questions involved and allow them to consider their responses away from a healthcare setting. This may encourage them to take action on their EPs.

# More private

A concern about lack of privacy in the pharmacy may be off-putting for some men. However, the Suitability Checker can be completed in private, wherever they feel comfortable. A copy of the responses can be shown at the pharmacy counter, thereby subtly communicating their intention to purchase VIAGRA CONNECT without the need to explicitly ask for the product.

### More convenient

Customers can complete the Suitability Checker at a time and place that suits them. It may act as an information tool to potentially speed up the pharmacy consultation process, saving time for both the customer and the pharmacist/pharmacy team. The Suitability Checker can also indicate to customers when OTC treatment may not be suitable for them by suggesting that they make a GP appointment. This could enable timely investigation of potential underlying conditions.

## **VIAGRA CONNECT:**

- Is suitable for men aged 18 years and over with EPs¹
- Increases blood flow to the penis to help men achieve and maintain an erection for long enough to allow satisfactory sexual performance<sup>1.4</sup>
- Is considered one of the first-line drug treatments for EPs<sup>4.5</sup>
- Has been available
   OTC in UK pharmacies
   since 2018<sup>6</sup>
- Has helped over 1 million men with EPs\*\*



Sildenafil 50mg, F

Men reporting difficulty getting or keeping an erection in the past 12 months. Based upon Ipsos Healthcare, December 2022, VIAGRA CONNECT: EP in the UK 2022 KPI Tracking Study, in a survey of 3938 men.

<sup>\*\*</sup> Estimated from reported VIAGRA CONNECT use since launch (Kantar 2019) & UK male population 35+ years

# SUITABILITY CHECKER QUESTIONS

The Suitability Checker is an online questionnaire comprising of seven questions to help your customer determine whether VIAGRA CONNECT may be a suitable option for them. For your reference, the questions they will need to complete are included below:

1. In the last 6 months, have you had a heart attack or a stroke?		
Yes	No	Unsure
2. Do you feel very breathless or get chest pain with light to moderate exercise such as walking fast for 20 minutes or climbing 2 flights of stairs?		
Yes	No	Unsure
<ul><li>3. Are you taking any of these medicines or drugs?</li><li>3.1 Nitrate medicines for chest pain</li><li>3.2 Any recreational drugs such as poppers</li><li>3.3 Any other regular medication</li></ul>		
Yes	No	Unsure
<ul> <li>4. Do you have any of the following health conditions?</li> <li>4.1 Liver or kidney disease</li> <li>4.2 Blood diseases: leukaemia, sickle cell anaemia, multiple myeloma</li> <li>4.3 Bleeding issues: haemophilia or stomach ulcers</li> <li>4.4 A heart problem, uncontrolled high blood pressure, low blood pressure, unstable angina or heart failure</li> </ul>		
Yes	No	Unsure
5. Do you have Peyronie's disease or any other deformation of the penis?		
Yes	No	Unsure
<b>6.</b> Have you ever had loss of vision because of damage to the optic nerve (known as NAION) or have an inherited eye disease (e.g. retinitis pigmentosa)?		
. 5		
Yes	No	Unsure
	No ergies or intolerances (e.g.	51.00.0

Based on the responses, the following messages will be shown:

# If yes is selected to Question 3.3 and/or Question 7:

Thank you. Based on your responses, VIAGRA CONNECT may be suitable for you. Please download or take a screen shot of your responses to show the pharmacist. Please also bring along a list of your regular medication and/or allergies with you for the pharmacist to check your suitability.

# If yes is selected for any responses other than Questions 3.3 and 7:

Thank you. Based on your responses, VIAGRA CONNECT may not be suitable for you. Please speak to your GP.

### If no is answered for all of the responses or if unsure is answered for any of the responses:

Thank you. Based on your responses, VIAGRA CONNECT may be suitable for you. Please download or take a screen shot of your responses to show the pharmacist.



# POTENTIAL **OUTCOMES**

Based on their answers to the questionnaire. the customer will be informed of one of two possible outcomes.

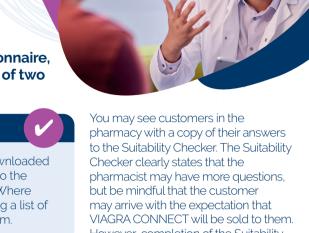


The customer is encouraged to take the downloaded answers or a screenshot of their responses to the pharmacy to aid a conversation about EPs. Where applicable, they may also be advised to bring a list of their regular medication or allergies with them.

VIAGRA CONNECT may not be suitable

The customer is advised to have a conversation with their GP for advice and to discuss next steps.

You may see customers in the pharmacy with a copy of their answers to the Suitability Checker. The Suitability Checker clearly states that the pharmacist may have more questions. but be mindful that the customer may arrive with the expectation that VIAGRA CONNECT will be sold to them. However, completion of the Suitability Checker doesn't mean that the product is definitely going to be supplied and it doesn't mean that it can be purchased without any consultation at all. Talk to your pharmacist about how to best approach these conversations and which process to follow in your pharmacy.



# Considerations for the pharmacist and the pharmacy team

"Can I just sell VIAGRA CONNECT when the customer shows their responses to the Suitability Checker?"

No. The Suitability Checker does not override a healthcare professional's judgement on whether to supply VIAGRA CONNECT, or inform customers that VIAGRA CONNECT is a suitable option for them. Depending on their responses, customers will be directed to either a pharmacist or GP to discuss whether supply would be appropriate. The Suitability Checker can aid this conversation. but the VIAGRA CONNECT Pharmacy Checklist remains available to support the healthcare professional's decision-making process.

"Has the Suitability Checker replaced the Pharmacy Checklist?"

No. The Suitability Checker contains seven simplified questions, but it does not capture the same level of detail as the Pharmacy Checklist.7

For example, it only specifically asks the customer whether they are taking nitrates or the recreational drug "poppers". A more extensive list of medicines that may interact with VIAGRA CONNECT can be found in the Pharmacy Checklist or Essential information for the supply of VIAGRA CONNECT.8 These documents are available to support conversations with customers.

"Is there other information that I need to share with my customer when VIAGRA CONNECT is supplied?"



Yes. You should encourage them to read the leaflet inside the pack to ensure that they know how to use VIAGRA CONNECT and when they should stop taking it to seek immediate medical advice. This level of information is not provided in the Suitability Checker. It is also important to advise customers to make an appointment with their GP within six months of taking VIAGRA CONNECT for the first time.

# ADDRESSING THE CAUSES OF EPS

Multiple underlying causes can contribute to EPs.9 Up to 80% of cases may be linked to an organic cause, the most common of which are those that affect blood supply.9.10 These EPs are usually associated with a gradual onset of symptoms,9 which could mean a delay in men seeking treatment. As a result, early detection (and treatment) of the primary cause may also be delayed. Remember to encourage men to have their blood pressure and cholesterol checked regularly as this may help to identify these risk factors early.

Availability of the Suitability Checker may motivate more men to take the initiative to investigate whether VIAGRA CONNECT may be suitable for them, but taking medication is only one part of the recommended approach to manage EPs; this should be

# Promoting a healthy lifestyle

Men are less likely to lead healthy lifestyles<sup>11</sup> and any additional advice that you can give to support healthy choices may also help with their EPs.<sup>12</sup>

#### Eat well

Eating a balanced, healthy diet can reduce the risk of heart disease and diabetes, both of which can lead to EPs. Men who eat lots of wholegrains, fruits and vegetables, and avoid processed foods and too much red meat. have fewer EPs.

#### Maintain a healthy weight

Obesity is associated with a range of health issues that may cause EPs. Men within a healthy body mass index (BMI) range have less likelihood of EPs.



#### **Keep active**

Regular exercise improves overall health and helps prevent physical issues, e.g. obesity, that can lead to EPs.



#### Limit alcohol

combined with

lifestyle

changes.4

Too many drinks can affect sexual performance in the short term, but alcohol can also lead to long-term EPs.



### Give up smoking

Smoking increases the risk of EPs. Non-smokers and ex-smokers are less likely to suffer from EPs than smokers.



#### Sleep well

Insufficient and disrupted sleep may increase the chances of having EPs. Making small changes, e.g. implementing good sleep hygiene, can help to encourage better sleep.



### **Reduce stress and anxiety**

Stress and anxiety can lead to a variety of physical symptoms, including EPs. Meditation or other mindfulness techniques may help to improve mood. However, if you are concerned about someone's mental wellbeing, encourage them to seek help.

#### References

Viagra Connect 50mg film-coated tablets. SmPC. 2023. Available at: https://www.medicines.org.uk/emc/product/8725/smpc/print
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 Online references last accessed April 2024.

#### Name of product: VIAGRA CONNECT® 50 mg Film-coated Tablets Active ingredient: 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 disorder and Lacrimation increased), Eye pain, Photophobia, Photopsia, Ocular hyperaemia, Visual brightness, Conjunctivitis, Vertigo, Tinnitus, Tachycardia, Palpitations, Hypertension, Hypotension, Epistaxis, Sinus congestion, Gastro Oesophagael reflux disease, Vomiting, Abdominal pain upper, Dry mouth, Rash, Myalgia, Pain in extremity, Haematuria, Chest pain, Fatigue, Feeling hot, Heart rate increased. Rare (≥ 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 postmarketing 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 nitrité) or nitrates in any form is therefore contraindicated. Co-administration of VIAGRA CONNECT with ritonavir (a highly potent P450 enzyme inhibitor) is contraindicated (see **Precautions**). The co-administration of phosphodiesterase type 5 (PDE5) inhibitors, including sildenafil, with guanylate cyclase stimulators, such as riociguat, is contraindicated as it may potentially lead to symptomatic hypotension (see Precautions). Agents for the treatment of erectile dysfunction, including sildenafil, should not be used by those men for whom sexual activity may be inadvisable, and these patients should be referred to their doctor. This includes patients with severe cardiovascular disorders such as a recent (6 months) acute myocardial infarction (AMI) or stroke, unstable angina or severe cardiac failure. Sildenafil should not be used in patients with severe hepatic impairment, hypotension (blood pressure < 90/50 mmHg) and known hereditary degenerative retinal disorders such as retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases). This is because the safety of sildenafil has not been studied in these sub-groups of patients, and its use is therefore contraindicated. Sildenafil is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure. VIAGRA CONNECT should not be used in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease). VIAGRA CONNECT is not indicated for use by women. The product is not intended for men without erectile dysfunction. This product is not intended for men under 18 years of age. Dosage and Method of use: For Oral Use: Adults: The recommended dose is one 50 mg tablet taken with water approximately one hour before sexual activity. The maximum recommended dosing frequency is once per day. If VIAGRA CONNECT is taken with food, the onset of activity may be delayed compared to the fasted state. Patients should be advised that they may need to take VIAGRA CONNECT a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If after several attempts on different dosing occasions patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor. Elderly: Dosage adjustments are not required in elderly patients (≥ 65 years old). Renal Impairment: No dosage adjustments are required for patients with mild to moderate renal impairment. However, since sildenafil clearance is reduced in individuals with severe renal impairment (creatinine clearance <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/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: pv.uk@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/SPCandPlLs/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