

Counter Guide to VIAGRA CONNECT®

YOUR CONSULTATION SUPPORT CARD

Erection problems (EPs) – when a man cannot get or sustain an erection long enough for sexual intercourse – are estimated to affect 5 million men in the UK.^{1,2} Men can access effective treatment from pharmacy. As well as being able to make a difference to someone's quality of life and relationships, there is also an opportunity to have a wider conversation about men's health and give appropriate lifestyle advice.

EPs can be caused by many factors, including physical causes, psychological causes and lifestyle factors. Sildenafil is a phosphodiesterase type-5 (PDE5) inhibitor. It works by blocking the action of PDE5, which helps to relax and widen the blood vessels, improving the flow of blood to the penis.



Contains sildenafil 50mg

For men aged 18 years and over

Dose:

One to be taken around an hour before sexual activity. Maximum once daily dosage



Consultation tips

- The VIAGRA CONNECT Pharmacy Checklist can be used to help give structure to consultations and identify where there may be contraindications for use, e.g. use of nitrates. Remember to offer the privacy of the consultation room.
- VIAGRA CONNECT should **not** be used by men who are not fit enough for sexual activity (e.g. recent stroke). Using the questions on the checklist can help to identify this.
- Common side-effects include: headache (if this persists, refer to the GP); flushing; nausea; indigestion and nasal congestion, which should resolve. Sometimes patients may be affected by dizziness or visual changes; if this occurs they should not drive until reactions have returned to normal. Loss of vision, priapism or chest pains need medical attention urgently.³
- If the product is not effective initially, the patient can be advised that it can take a few attempts to work. However, if they have tried on eight separate occasions, advise them that they can access an online pharmacy ED clinic or see their GP in order to discuss alternative options.

For additional learning and resources visit:

- www.p3pharmacy.co.uk/viagraconnect-learning
- hcp.viagraconnect.co.uk

Key advice

Advice to give when making a supply:

- See GP within 6 months of first use
- Needs sexual stimulation to work
- Avoid taking after a high fat meal; don't take with grapefruit/grapefruit juice
- Avoid drinking excess alcohol as that can impair the ability to have an erection
- Relevant lifestyle advice e.g. maintaining a healthy weight and diet; reducing stress; taking exercise; stopping smoking, and avoiding recreational drugs.

References:

- 1 Kantar TNS Omnibus Survey Dec 2010 – in a survey of 1,033 men (Data on file)
- 2 ONS Data 2019 (Data on file)
- 3 <https://patient.info/medicine/sildenafil-for-erectile-dysfunction-aronix-viagra-vizarsin>



VIATRIS

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 ($\geq 1/10$): Headache. Common ($\geq 1/100$ and $<1/10$): Dizziness, Visual colour distortions (Chloropsia, Chromatopsia, Cyanopsia, Erythroopsia and Xanthopsia), Visual disturbance, Vision blurred, Flushing, Hot flush, Nasal congestion, Nausea, Dyspepsia. Uncommon ($\geq 1/1,000$ and $<1/100$): Rhinitis, Hypersensitivity; Somnolence; Hypoaesthesia, Lacrimation disorders (Dry eye, Lacrimal disorder and Lacrimation increased), Eye pain, Photophobia, Photopsia, Ocular hyperaemia, Visual brightness, Conjunctivitis, Vertigo, Tinnitus, Tachycardia, Palpitations, Hypertension, Hypotension, Epistaxis, Sinus congestion, Gastro Oesophageal reflux disease, Vomiting, Abdominal pain upper, Dry mouth, Rash, Myalgia, Pain in extremity, Haematuria, Chest pain, Fatigue, Feeling hot, Heart rate increased. Rare ($\geq 1/10,000$ and $<1/1,000$): Cerebrovascular accident, Transient ischaemic attack, Seizure, Seizure recurrence, Syncope, Non-arteritic anterior ischaemic optic neuropathy (NAION), Retinal vascular occlusion, Retinal haemorrhage, Arteriosclerotic retinopathy, Retinal disorder, Glaucoma, Visual field defect, Diplopia, Visual acuity reduced, Myopia, Asthenopia, Vitreous floaters, Iris disorder, Mydriasis, Halo vision, Eye oedema, Eye swelling, Eye disorder, Conjunctival hyperaemia, Eye irritation, Abnormal sensation in eye, Eyelid oedema, Scleral discoloration, Deafness, Sudden cardiac death, Myocardial infarction, Ventricular arrhythmia, Atrial fibrillation, Unstable angina, Throat tightness, Nasal oedema, Nasal dryness, Hypoaesthesia oral, Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Penile haemorrhage, Priapism, Haematospermia, Erection increased, Irritability **Precautions:** Erectile dysfunction can be associated with a number of contributing conditions, e.g. hypertension, diabetes mellitus, hypercholesterolaemia or cardiovascular disease. As a result, all men with erectile dysfunction should be advised to consult their doctor within 6 months for a clinical review of potential underlying conditions and risk factors associated with erectile dysfunction (ED). If symptoms of ED have not improved after taking VIAGRA CONNECT on several consecutive occasions, or if their erectile dysfunction worsens, the patient should be advised to consult their doctor. Cardiovascular risk factors: Since there is a degree of cardiac risk associated with sexual activity, the cardiovascular status of men should be considered prior to initiation of therapy. Agents for the treatment of erectile dysfunction, including sildenafil, are not recommended to be used by those men who with light or moderate physical activity, such as walking briskly for 20 minutes or climbing 2 flights of stairs, feel very breathless or experience chest pain. The following patients are considered at low cardiovascular risk from sexual activity: patients who have been successfully revascularised (e.g. via coronary artery bypass grafting, stenting, or angioplasty), patients with asymptomatic controlled hypertension, and those with mild valvular disease. These patients may be suitable for treatment but should consult a doctor before resuming sexual activity. Patients previously diagnosed with the following must be advised to consult with their doctor before resuming sexual activity: uncontrolled hypertension, moderate to severe valvular disease, left ventricular dysfunction, hypertrophic obstructive and other cardiomyopathies, or significant arrhythmias. Sildenafil has vasodilator properties, resulting in mild and transient decreases in blood pressure. Patients with increased susceptibility to vasodilators include those with left ventricular outflow obstruction (e.g., aortic stenosis), or those with the rare syndrome of multiple system atrophy manifesting as severely impaired autonomic control of blood pressure. Men with these conditions must not use the product without consulting a doctor. Sildenafil potentiates the hypotensive effect of nitrates (see **Contra-indications**). Serious cardiovascular events, including myocardial infarction, unstable angina, sudden cardiac death, ventricular arrhythmia, cerebrovascular haemorrhage, transient ischaemic attack, hypertension and hypotension have been reported post-marketing in temporal association with the use of sildenafil. Most, but not all, of these patients had pre-existing cardiovascular risk factors. Many events were reported to occur during or shortly after sexual intercourse and a few were reported to occur shortly after the use of sildenafil without sexual activity. It is not possible to determine whether these events are related directly to these factors or to other factors. Priapism: Patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia), should consult a doctor before using agents for the treatment of erectile dysfunction, including sildenafil. Prolonged erections and priapism have been occasionally reported with sildenafil in post-marketing experience. In the event of an erection that persists longer than 4 hours, the patient should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result. Concomitant use with other treatments for erectile dysfunction: The safety and efficacy of combinations of sildenafil with other treatments for erectile dysfunction have not been studied. Therefore the use of such combinations is not recommended. Effects on vision: Cases of visual defects have been reported spontaneously in connection with the intake of sildenafil and other PDE5 inhibitors (see **Side Effects**). Cases of non-arteritic anterior ischaemic optic neuropathy, a rare condition, have been reported spontaneously and in an observational study in connection with the intake of sildenafil and other PDE5 inhibitors (see **Side Effects**). Patients should be advised that in the event of any sudden visual defect, they should stop taking VIAGRA CONNECT and consult a physician immediately (see **Contra-indications**). Concomitant use with CYP3A4 inhibitors: Pharmacokinetic analysis of clinical trial data indicated a reduction in sildenafil clearance when co-administered with CYP3A4 inhibitors (such as ketoconazole, itraconazole, erythromycin, cimetidine). Although, no increased incidence of adverse events was observed in these patients, they should be advised to consult a doctor before taking VIAGRA CONNECT as a 25 mg tablet may be more suitable for them (see **Precautions**). Concomitant use with alpha-blockers: Caution is advised when sildenafil is administered to patients taking an alpha-blocker, as the co-administration may lead to symptomatic hypotension in a few susceptible individuals (see **Precautions**). This is most likely to occur within 4 hours post sildenafil dosing. In order to minimise the potential for developing postural hypotension, patients should be hemodynamically stable on alpha-blocker therapy prior to initiating sildenafil treatment. Thus, patients taking alpha blockers should be advised to consult their doctor before taking VIAGRA CONNECT as a 25 mg tablet may be more suitable for them. Treatment should be stopped if symptoms of postural hypotension occur, and patients should seek advice from their doctor on what to do. Effect on bleeding: Studies with human platelets indicate that sildenafil potentiates the antiaggregatory effect of sodium nitroprusside in vitro. There is no safety information on the administration of sildenafil to patients with bleeding disorders or active peptic ulceration. Therefore the use of sildenafil is not recommended in those patients with history of bleeding disorders or active peptic ulceration, and should only be administered after consultation with a doctor. Hepatic impairment: Patients with hepatic impairment must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see **Dosage and Method of use**). Renal impairment: Patients with severe renal impairment (creatinine clearance <30 mL/min), must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see **Dosage and Method of use**). Lactose: The film coating of the tablet contains lactose. VIAGRA CONNECT should not be administered to men with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per tablet. Patients on low sodium diets can be informed that this medicinal product is essentially 'sodium-free'. Use with alcohol Drinking excessive alcohol can temporarily reduce a man's ability to get an erection. Men should be advised not to drink large amounts of alcohol before sexual activity. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Consistent with its known effects on the nitric oxide/cyclic guanosine monophosphate (cGMP) pathway, sildenafil was shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form is therefore contraindicated. Co-administration of VIAGRA CONNECT with ritonavir (a highly potent P450 enzyme inhibitor) is contraindicated (see **Precautions**). The co-administration of phosphodiesterase type 5 (PDE5) inhibitors, including sildenafil, with guanylate cyclase stimulators, such as riociguat, is contraindicated as it may potentially lead to symptomatic hypotension (see **Precautions**). Agents for the treatment of erectile dysfunction, including sildenafil, should not be used by those men for whom sexual activity may be inadvisable, and these patients should be referred to their doctor. This includes patients with severe cardiovascular disorders such as a recent (6 months) acute myocardial infarction (AMI) or stroke, unstable angina or severe cardiac failure. Sildenafil should not be used in patients with severe hepatic impairment, hypotension (blood pressure $<90/50$ mmHg) and known hereditary degenerative retinal disorders such as *retinitis pigmentosa* (a minority of these patients have genetic disorders of retinal phosphodiesterases). This is because the safety of sildenafil has not been studied in these sub-groups of patients, and its use is therefore contraindicated. Sildenafil is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure. VIAGRA CONNECT should not be used in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease). VIAGRA CONNECT is not indicated for use by women. The product is not intended for men without erectile dysfunction. This product is not intended for men under 18 years of age. **Dosage and Method of use:** For Oral Use: Adults: The recommended dose is one 50 mg tablet taken with water approximately one hour before sexual activity. The maximum recommended dosing frequency is once per day. If VIAGRA CONNECT is taken with food, the onset of activity may be delayed compared to the fasted state. Patients should be advised that they may need to take VIAGRA CONNECT a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If after several attempts on different dosing occasions patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor. Elderly: Dosage adjustments are not required in elderly patients (≥ 65 years old). Renal Impairment: No dosage adjustments are required for patients with mild to moderate renal impairment. However, since sildenafil clearance is reduced in individuals with severe renal impairment (creatinine clearance <30 mL/min), individuals previously diagnosed with severe renal impairment must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see **Precautions**). Hepatic Impairment: Sildenafil clearance is reduced in individuals with hepatic impairment (e.g. cirrhosis). Individuals previously diagnosed with mild to moderate hepatic impairment must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see **Precautions**). The safety of sildenafil has not been studied in patients with severe hepatic impairment, and its use is therefore contraindicated (see **Contra-indications**). Paediatric population: VIAGRA CONNECT is not indicated for individuals below 18 years of age. Use in patients taking other medicinal products: Pharmacokinetic analysis of clinical trial data indicated a reduction in sildenafil clearance when co-administered with CYP3A4 inhibitors (such as ritonavir, ketoconazole, itraconazole, erythromycin, cimetidine). With the exception of ritonavir, for which co-administration with sildenafil is contraindicated (see **Contra-indications**), individuals receiving concomitant treatment with CYP3A4 inhibitors must be advised to consult their doctor before taking VIAGRA CONNECT, since a 25 mg tablet may be more suitable for them (see **Precautions**). In order to minimise the potential of developing postural hypotension in patients receiving alpha blocker treatment (e.g. alfuzosin, doxazosin or tamsulosin), patients should be stabilised on alpha blocker therapy prior to initiating sildenafil treatment. Thus, patients taking alpha blockers must be advised to consult their doctor before taking VIAGRA CONNECT since a 25 mg tablet may be more suitable for them (see **Precautions**). **Cost:** 2 pack £9.16 (exc VAT), 4 pack £16.66 (exc VAT) and 8 pack £29.16 (exc VAT) Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161. **Date:** 12/2020

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