

VIAGRA CONNECT® (Sildenafil)

Patient supply scenario cards for Pharmacists



PP-VCO-IRL-0117

VIAGRA
CONNECT®

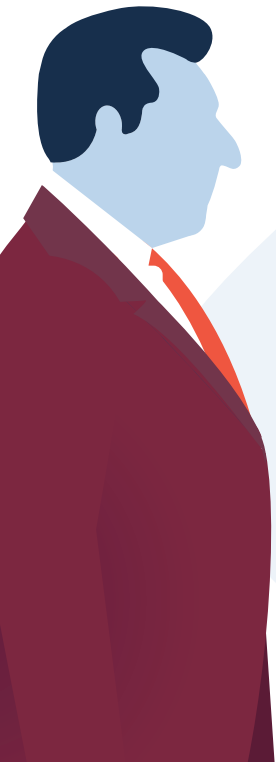
How to use this item

These scenario cards provide some of the most useful and frequently seen patient scenarios for VIAGRA connect.

They can be used in conjunction with the Pharmacy Consultation Guide¹ to help you accurately assess patients' suitability for treatment with VIAGRA connect. You can use it to help you:

- Determine if any of the customer's medications are contraindicated with VIAGRA CONNECT
- Determine a customer's fitness for physical activity
- Counsel customers on correct usage of the product

Remember: Always advise your customer that he should see his GP as soon as possible within 6 months of his first VIAGRA CONNECT supply.



Mr. S has been under a lot of stress

Age: 51

Situation: Widowed 3 years ago and has just found a new partner. Has had problems with erectile function for the last 8 months and is anxious for it not to affect his new relationship.

Upon following the Pharmacy Consultation Guide¹, you find the following:

Health: Relatively good, with nothing untoward in last check-up 5 months ago.

Medication and lifestyle:

- Ibuprofen for osteoarthritis
- Prior smoker, stopped 8 years ago
- No contraindicated medical conditions

Should you supply VIAGRA CONNECT[®] to Mr. S?

Should you supply VIAGRA CONNECT[®] to Mr. S?

VIAGRA CONNECT can be supplied to Mr. S. The Pharmacy Consultation Guide¹ and your professional judgement indicate that he has low cardiovascular risk, is in good health and is fit for physical activity.

What should you do next?

- Reassure Mr. S that VIAGRA CONNECT usually works the first or second time – but for maximum benefit it can take up to 8 separate doses with maximum one dose per day, especially in men who have not had sexual intercourse for some time²
- Advise him that if he doesn't respond after 8 doses, he should consult his GP²
- Ask him to tell his GP as soon as possible within the next 6 months that he is using VIAGRA CONNECT²



A stylized illustration of a man's profile, facing right. He has dark, curly hair and is wearing a dark blue suit jacket, a white shirt, and a pink tie. The background behind him is a light blue shape that overlaps with the text area.

Mr. T has high blood pressure

Age: 55

Situation: Difficulties sustaining an erection and wonders if VIAGRA CONNECT® would help.

Upon following the Pharmacy Consultation Guide¹, you find the following:

Health: High blood pressure, which has been stable for the last 3 months after a year of difficult control.

Medication and lifestyle:

- Combination of two different blood pressure medications which are not contraindicated with Viagra CONNECT
- Recent weight loss and diet changes to help with high blood pressure
- No contraindicated medical conditions and BP is stable.

Should you supply VIAGRA CONNECT to Mr. T?

Should you supply VIAGRA CONNECT[®] to Mr. T?

VIAGRA CONNECT can be supplied to Mr. T, because his hypertension is now controlled and he is not taking any contraindicated medications^{1,2}. He appears fit for physical activity.

What should you do next?

- Advise Mr. T of the likely side effects with VIAGRA CONNECT²
- Advise him on the dosing and to tell his GP as soon as possible within the next 6 months that he is using VIAGRA CONNECT²
- Advise him to come back if he has any problems, or if there are any changes to his health or medication





Mr. F is struggling to keep up with his girlfriend

Age: 36

Situation: Has recently found a new girlfriend, who is hard to satisfy. He is finding his recovery period longer than usual and wants something to 'pep him up'.

Upon following the Pharmacy Consultation Guide¹, you find the following:

Health: Good; no medical issues and no issues with getting an erection or sexual intercourse.

Medication and lifestyle:

- No medications
- Follows good diet and exercise regime
- No contraindicated medical conditions

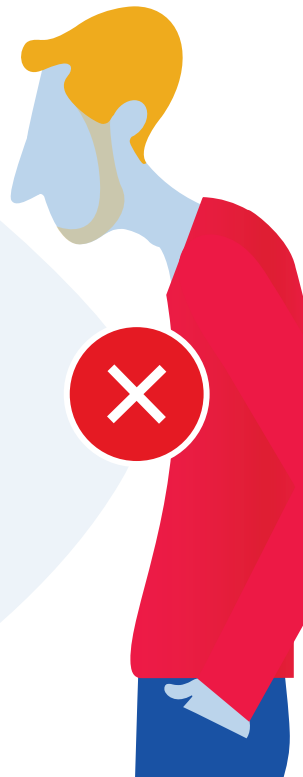
Should you supply VIAGRA CONNECT[®] to Mr. F?

Should you supply VIAGRA CONNECT[®] to Mr. F?

VIAGRA CONNECT cannot be supplied to Mr. F, because it will not enhance performance in men without ED².

What should you do next?

- Explain that VIAGRA CONNECT is only indicated for men who have erectile dysfunction
- Explain to patient what erectile dysfunction is and why he does not have erectile dysfunction
- Complete the 'no supply' tear-off slip at the bottom of the Pharmacy Consultation Guide and provide it to Mr F. Advise him to visit his GP for further advice





Mr. K would like repeat supply

Age: 48

Situation: Mr. K came into your pharmacy last week. After taking him through the Pharmacy Consultation Guide¹, you supplied an 8-tablet pack of VIAGRA CONNECT. He is back this week and has asked for a further supply of 8 tablets.

Health: No concerns that might limit the ability to re-supply.

Medication and lifestyle:

- VIAGRA CONNECT at recommended dose
- Follows sensible diet and exercise regime

Should you supply VIAGRA CONNECT to Mr. K?

Should you supply VIAGRA CONNECT[®] to Mr. K?

Checks

- Check that the patient has a slip for resupply
- Check that the drug is working for him and that he is getting the benefit he needs

What should you do next?

- Provided there has been no change since Mr. K completed the Pharmacy Consultation Guide, you can provide a further supply of VIAGRA CONNECT.
- Remind Mr. K that the maximum dose is 1 tablet per day²
- Remind him to see his GP as soon as possible within 6 months from first supply of VIAGRA CONNECT²





Mr. J has unidentified heart conditions

Age: 65

Situation: Mr. J is a regular customer. He has now enquired about VIAGRA CONNECT® for the first time, as he is worried that his erectile function has recently declined and is affecting his relationship with his wife.

Upon following the Pharmacy Consultation Guide¹, you find the following:

Health: Mr. J has some problems with his heart. He tells you he suffers from angina and he occasionally gets out of breath, but is closely monitored by his doctor.

As this is Mr. J's regular pharmacy you check his medication records, he is taking beta blockers and another cardiovascular medication which are not contraindicated with VIAGRA CONNECT®

Medication and lifestyle:

- Combination of three different medications, which could be used for various cardiovascular diseases

Should you supply VIAGRA CONNECT to Mr. J?

Should you supply VIAGRA CONNECT® to Mr. J?

Viagra Connect may be supplied to Mr. J. Mr. J's medications are not contraindicated with VIAGRA CONNECT, but could be causing erectile dysfunction as a side effect¹.

He may also be using a nitrate medication to treat or prevent angina symptoms when needed. It is important to inform Mr. J that nitrates must not be used at the same time as VIAGRA CONNECT².

What should you do next?

If you determine that VIAGRA CONNECT is suitable for Mr. J:

- Advise Mr. J of the common side effects with VIAGRA CONNECT
- Advise him on the dosing and to tell his GP as soon as possible within the next 6 months that he is using VIAGRA CONNECT²
- Advise him to come back if he has any problems, or if there are any changes to his health or medication.



References

1. Viagra Connect Pharmacy Consultation Guide. Available at: <https://www.medicines.ie/medicines/viagra-connect-50-mg-film-coated-tablets-35041/educational-material-hcp>.
2. Viagra Connect Summary of Product Characteristics. Available at <https://www.medicines.ie/medicines/viagra-connect-50-mg-film-coated-tablets-35041/spc>.

Full Essential Information

Name of product: VIAGRA CONNECT 50 mg film-coated tablets **Active ingredient:** sildenafil

Further information is available in the SmPC.

Supply classification: Pharmacy only.

Indications: For erectile dysfunction in adult men.

Dosage and Method of 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 Warnings and 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 Warnings and Precautions). The safety of sildenafil has not been studied in patients with severe hepatic impairment, and its use is therefore contraindicated (see Contra-indications). **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 Warnings and 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 Warnings and Precautions). **Side Effects:** 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, Haemospermia, Erection increased, Irritability.

Warnings and 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 Contraindications). 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. 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. 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. 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. 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. 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. 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. 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. 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.

Legal Category: Product not subject to medical prescription Marketing Authorisation Number:

PA023055/016/001 Marketing Authorisation Holder: Upjohn EESV, Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Netherlands. **For further information on this medicine please contact:** Medical Information on 1800 633 363. For queries regarding product availability please contact: Viatris, NewenhamCourt, Northern Cross, Malahide Road, Dublin 17. Phone number: +353 1 871 1600.

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