QUICK GUIDE TO ADVISING ON AVARANTE®

Feel confident incorporating the latest treatment for erectile dysfunction (ED) into your consultations

AVARANTE® (tadalafil 10mg) is a new* product licensed to treat ED.[1]

AVARANTE joins **VIAGRA CONNECT** to expand the Viatris range of pharmacy-only medicines licensed for ED in adult men (aged 18 years and over).[1,2]

*New from the makers of VIAGRA CONNECT

Tadalafil

Sildenafil

This training is not intended to replace the AVARANTE Risk Minimisation Materials (RMMs). To access the RMMS, visit www.medicines.org.uk/emc/product/100210/rmms

Tadalafil and sildenafil belong to the same drug class, namely phosphodiesterase type 5 (PDE5) inhibitors.[1,2] Oral PDE5 inhibitors are regarded as the first-line drug treatment for ED in men who don't have specific contraindications to their use.[3,4] There are no significant differences in the efficacy, safety or tolerability of different PDE5 inhibitors.[4] However, slight variations do exist and therefore, in specific circumstances, one product could be considered a more suitable choice than the other.

CONSIDERATIONS WHEN CHOOSING TREATMENT

The choice of PDE5 inhibitor mostly depends on the frequency of intercourse and the customer's preference.[5] The table below gives a pharmacokinetic comparison of tadalafil[1] and sildenafil[2] that may be useful in your decision-making process.

	Tadalafil	Sildenafil
Recommended time taken before sexual activity	At least 30 minutes	Approximately 1 hour
Time to reach maximum plasma concentration	Median 2 hours	Median 1 hour (fasted state)
Time to onset of effect	From 30 minutes	25 minutes (range 12-37 minutes) (fasted state)
Duration of action	Up to 36 hours	Up to 4 hours
Effect of food intake	Rate of absorption not affected by food	Rate of absorption reduced by mean of 60 minutes when taken with food, especially a high-fat meal

Other specific considerations may include:

Onset of action

VIAGRA CONNECT can start to work in as little as 25 minutes.[2] AVARANTE can lead to erections for successful intercourse in 30 minutes.[1] Customers who favour fast onset of action may benefit from using VIAGRA CONNECT as no pill works faster for ED.[2]

Duration of action

VIAGRA CONNECT is effective up to 4 hours after administration.[2] AVARANTE can work for up to 36 hours after taking it.[1] Customers may benefit from AVARANTE's longer window of opportunity on special occasions, such as a romantic getaway.

Frequency of use

AVARANTE is not recommended for continuous daily use. Those who use it frequently (i.e. at least twice weekly) should discuss with their GP whether a low daily dose of tadalafil on prescription would be more suitable.[1] VIAGRA CONNECT is suitable for daily use, if required.[2]

Food intake

Tadalafil's rate of absorption is not affected by food, whereas sildenafil's rate of absorption may be reduced/delayed by a mean of 60 minutes when taken with food, especially a high-fat meal.[2]

Efficacy

Most men will achieve an erection the first or second time they use a PDE5 inhibitor. However, they should be advised that it may need to be taken a number of times on different occasions before they can achieve an erection satisfactory for sexual activity. In the case of tadalafil, this should be no more than one tablet per day and no more than twice a week.[1] Two meta-analyses suggest that customers who prioritise high efficacy should use sildenafil 50mg (e.g. VIAGRA CONNECT).[5]

Tolerability and side effects

PDE5 inhibitors are generally well tolerated. The side effect profiles are slightly different. Tadalafil has been associated with a lower occurrence of flushing[6] and visual symptoms[7] compared with sildenafil,[2] but possibly a higher incidence of back and muscle pain.[1,2,3,6] Customers who are concerned about specific side effects may wish to bear this in mind.

SUPPLYING AVARANTE

ED may be referred to as erection problems (EPs) by your customers. Always ensure that you are clear on what they mean, regardless of the terminology they use, before supplying a product.

There are set criteria that must be met before an initial supply of AVARANTE can be made. The pharmacy checklist contains specific questions to check your customer's suitability in relation to their:[8]

- Cardiovascular health
- Medication and recreational drug use
- Other health conditions.

When a customer requests a repeat supply, you should determine whether AVARANTE remains suitable for them by checking that:[8,9]

- They have not experienced any problems relating to AVARANTE
- There are no changes in their health conditions or other medications since the last supply.

Refer to the ***Pharmacy Guide for AVARANTE 10mg film-coated tablets (tadalafil)*** and ***AVARANTE (tadalafil) Pharmacist Checklist Quick Guide*** for full details. If it is not appropriate to supply AVARANTE, refer the customer to their GP. When supply is deemed appropriate, discuss the key points below with your customer.

Key advice for AVARANTE:[1,8,9]

- The recommended dose is one 10mg tablet taken with or without food, at least 30 minutes prior to anticipated sexual activity
- The maximum dosing frequency is once per day; AVARANTE is not recommended for continuous daily use. Men who use this product frequently (i.e. at least twice a week) should be referred to their GP to discuss the suitability of a once-daily regimen with a lower dose, or consider an alternative treatment option
- Sexual stimulation is required for AVARANTE to work and its effects can last for up to 36 hours
- Do not take AVARANTE with grapefruit juice (this may increase the plasma levels of tadalafil)
- Do not take AVARANTE after excessive alcohol consumption
- AVARANTE works for most men on the first or second attempt, but if it does not work after several attempts, or if their ED worsens, they should be referred to their GP
- Must avoid nitrates, nitric oxide donors, amyl nitrite and nitrous oxide
- Common side effects include headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and dyspepsia
- Seek medical attention immediately if serious side effects occur
- Advise men to inform their doctor that they have started taking AVARANTE, especially if they are prescribed any new medication.

Please refer to the SmPC and Pharmacy Guide for AVARANTE 10mg film-coated tablets (tadalafil) for full details relating to contraindications, special warnings and precautions for use, interactions and side effects. Always advise your customer to read the Patient Information Leaflet and remember to refer anyone asking for treatment for EPs to their GP for a clinical review within six months,[1] regardless of whether OTC treatment has been supplied or not. Appropriate lifestyle advice should also be offered.[8,9]

Customer choice

The concomitant use of AVARANTE and other treatment for ED, including PDE5 inhibitors, is not recommended. A customer may switch from one oral PDE5 inhibitor to another, or from a prescription-only product to an OTC option.

Always ensure that they continue to meet the relevant criteria before supplying AVARANTE[8] or VIAGRA CONNECT.[10] Advise them to read the relevant Patient Information Leaflet and encourage them to inform their doctor that they are obtaining treatment for their EPs from the pharmacy.

- Customers switching from a prescription of tadalafil 10mg to AVARANTE should wait at least 36 hours after their last prescription dose before starting AVARANTE.[9]
- Customers switching from sildenafil 50mg on prescription, or from an OTC sildenafil 50mg product, should be advised to follow the correct dosing instructions.[9]

There may be instances when a customer could benefit from temporarily switching from one product to the other. For example, a customer using VIAGRA CONNECT as their usual go-to treatment may switch to AVARANTE when they plan a romantic weekend away.

NOTE: they should never be taken together at the same time, or on the same day.

The customer will need to wait at least 36 hours after their last AVARANTE dose before taking VIAGRA CONNECT on the next occasion. Customers taking VIAGRA CONNECT should wait 24 hours after their last dose before taking AVARANTE.

To find out more about AVARANTE and complete your training, visit https://www.pharmacymagazine.co.uk/introducing-avarante

References:
1. AVARANTE 10mg film-coated tablets. SmPC. 2024. Available at: https://www.medicines.org.uk/emc/product/100210/smpc/print. **2.** Viagra Connect 50 mg film-coated tablets. SmPC. 2024. Available at: https://www.medicines.org.uk/emc/product/8725 **3.** BNF. Erectile dysfunction. 2024. Available at: https://bnf.nice.org.uk/treatment-summaries/erectile-dysfunction/ **4.** Hatzimouratidis K, et al. Pharmacotherapy for erectile dysfunction: recommendations from the Fourth International Consultation for Sexual Medicine (ICSM 2015). J Sex Med. 2016; 13(4):465-488. **5.** Salonia A, et al. EAU Guidelines on sexual and reproductive health. 2024. Available at: https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Sexual-and-Reproductive-Health-2024_2024-05-23-101205_nmbi.pdf **6.** Gong B, et al. Direct comparison of tadalafil with sildenafil for the treatment of erectile dysfunction: a systematic review and meta analysis. Int Urol Nephrol. 2017; 49:1731–1740. **7.** Ahmed NS. Tadalafil: 15 years' journey in male erectile dysfunction and beyond. Drug Dev Res. 2019; 80:683–701. **8.** AVARANTE 10mg film-coated tablets (tadalafil) Pharmacist Checklist Quick Guide. 2024. Available at: https://www.medicines.org.uk/emc/rmm/101578/Document. **9.** Pharmacy Guide for AVARANTE 10mg film coated tablets (tadalafil). 2024. Available at: https://www.medicines.org.uk/emc/rmm/101574/Document. **10.** Essential information for the supply of VIAGRA CONNECT 50 mg film-coated tablets (sildenafil). 2023. Available at: https://www.medicines.org.uk/emc/rmm/1784/Document. **Online references last accessed December 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 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 <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/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

Content developed by Viatris working together with CIG Healthcare Partnership.

Job number: **UK-AVT-2025-00091**
Date of prep: **June 2025**