

WHAT EPs CAN MEAN FOR PARTNERS

Dealing with sexual partners' queries about VIAGRA CONNECT

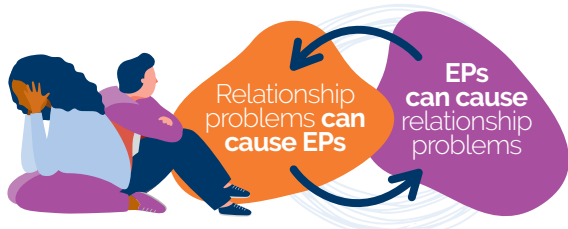
This training explores how erection problems (EPs) can be considered a shared health problem for both men and their sexual partners.¹ Understanding how EPs may affect partners can help you tailor your advice to those seeking information or treatment to support the men in their lives.



It takes two...

According to the British Association of Urological Surgeons, an EP is defined as an inability to obtain or maintain an erection sufficient for penetration and **for the satisfaction of both sexual partners.**²

Much has been written about how EPs can impact the male sufferer, including how feelings of upset and embarrassment as well as worry and stress can negatively affect their quality of life.^{2,3} However, this may extend to their partner's sexual experience and the couple's relationship. EPs can be the cause or the result of relationship problems in a detrimental cycle.



Research has shown that partners can also struggle with negative thoughts, fears and insecurities, and some may feel responsible for their partner's EPs.⁴ This may impact their own mental and sexual health and they may also be in need of support as a result.⁴

(Not) having a conversation

Research suggests that less than half of men with EPs speak to their partner about it. Embarrassment is the main reason they keep the issue to themselves.⁵

Partners may also be reluctant to bring up the issue with the sufferer, because:⁵

- 28% don't want to put pressure on them
- 27% don't want to make the situation worse
- 11% are concerned that they would be blamed.

Research found that 31% of sufferers and 22% of partners thought that being "worried about not being able to maintain an erection" was the cause of EPs.⁵ However, there are multiple factors that can contribute to EPs.^{6,7} Understanding the condition, and the interplay of various factors causing it, may help partners recognise ways in which they can support or approach a conversation with the sufferer.



“ Sexual health is a state of physical, emotional, mental and social well-being in relation to sexuality ”

World Health Organization, 2006



Building understanding

One way to provide some reassurance to partners is to let them know that they are not alone. EPs are common; they affect up to 1 in 4 men in the UK.*

Various factors can lead to EPs, including:^{6,7}

● Organic causes

- Vascular (e.g. cardiovascular disease, hypertension, obesity, diabetes mellitus)
- Endocrine (e.g. low testosterone, overactive or underactive thyroid)
- Neurogenic (e.g. multiple sclerosis)
- Anatomical (e.g. penile/prostate cancer)

● Psychogenic causes

- General (e.g. lack of arousability)
- Situational (e.g. relationship issues, stress)

● Drugs

- Medication (e.g. antidepressants)
- Recreational drugs (e.g. alcohol, cannabis)

● Smoking

Sexual partners have an important role to play in managing EPs.¹ Understanding the potential causes of their partner's EPs may not only help them open up a conversation, but may also help them to recognise how they could offer support.

*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.

SUPPORTING HEALTHY CHOICES

Partners can help men with EPs by encouraging healthy lifestyle choices. They may find introducing these changes easier than trying to start a conversation about treatment options.

Tips to promote a healthy lifestyle that may help men with EPs:^{1,7,8}

- Encourage a **balanced, healthy diet** to help reduce the risk of vascular diseases. For example, increase the intake of wholegrains, fruits and vegetables, while avoiding processed foods and too much red meat



- Suggest **doing an activity together**, e.g. going on a daily walk to help combat obesity (cycling for more than 3 hours a week is not recommended)



- Support a **reduction in alcohol intake**, e.g. suggest alcohol-free days or 0% alcohol alternatives when out socialising



- Encourage and support **quit-smoking** attempts



- Help to implement **good sleep hygiene** to help encourage better sleep



- **Practice meditation and mindfulness together** to help improve mood and reduce stress and anxiety.



Implementing these changes may help to address some of the most common causes of EPs, i.e. those that affect blood supply to the penis (vascular causes).^{3,7}

THE IMPACT OF A SUPPORTIVE PARTNER

It can also help if partners can think of ways to spend more time together. A busy lifestyle is blamed as one the top barriers to physical intimacy.⁵

Have in mind when talking to partners that their attitude and understanding may affect the sufferer's decision-making process, including whether they are ready to seek medical advice or treatment for their EPs.¹

You can help their understanding by providing some context around the potential impact of EPs on men:

- Men who experience EPs enter a sexual situation with **negative expectations** about their sexual performance⁶
- Men with EPs have an increased risk of **depression**⁹
- EPs may be caused by an **underlying health issue**. Partners can remind men to make an appointment with their doctor for an assessment within 6 months of starting treatment.¹⁰

“ Good communication is the bedrock of any relationship, and it's particularly important for couples dealing with ED [erectile dysfunction] because it immediately dispels any doubts about infidelity and minimises any feelings of insecurity. This fosters better understanding of each other's concerns and needs.”¹¹

Dr Jeff Foster,
GP and men's health specialist

Understanding treatment

If a sexual partner is seeking information about treatment for EPs, you can advise them that medication like VIAGRA CONNECT (sildenafil 50mg tablets) is considered a first-line drug treatment, regardless of the cause.¹²

You can tell them about VIAGRA CONNECT's **online Suitability Checker**, which can be completed in confidence to assess whether it may be a suitable treatment

option. This may offer the chance to initiate a conversation with their partner.

You can also help partners understand what to expect from VIAGRA CONNECT treatment, enabling them to provide additional support.^{10,12}

- VIAGRA CONNECT increases blood flow to the penis, but it does not initiate an erection. Partners should be aware that sexual stimulation is required for these drugs to work
- VIAGRA CONNECT can start to work in 25 minutes, but it is advised to take it approximately one hour before sexual activity
- VIAGRA CONNECT might have to be taken on a few different occasions before improvement is noticed.

Bear in mind that a sexual partner-engaged approach to treatment might also:¹

- Improve treatment outcomes for EPs
- Reduce treatment withdrawal rates.

VIAGRA CONNECT is effective in improving erections in 74% of men, but it has beneficial outcomes on relationships too.¹⁰



Sildenafil 50mg, P



REBUILDING CONNECTIONS

Taking VIAGRA CONNECT can have a wider benefit than the treatment of EPs alone. It has been found to help couples enjoy a more fulfilling sexual relationship and rebuild connections, with men reporting improved relationships with their partners.¹⁰

Women have also experienced benefits from their partner taking VIAGRA CONNECT, reporting improved sexual satisfaction compared to partners of men treated with placebo.¹⁰

Dealing with partner product requests

A pharmacy survey by VIAGRA CONNECT showed that in a typical month, up to 9 women seek advice or treatment for their partners suffering with EPs.¹³ Women may specifically ask to buy VIAGRA CONNECT for their partners and may even show you a copy of a completed Suitability Checker.

When someone requests VIAGRA CONNECT for their partner, your pharmacist will need to use their clinical judgement to decide whether or not to supply the product.

Guidance suggests that it may be supplied to a person's representative provided that:¹⁴

- The supply is within the product's marketing authorisation (its licenced indications)
- The pharmacist is satisfied that it is a genuine request
- The treatment is deemed clinically appropriate.

Supply considerations¹⁴

- Who is requesting the treatment on the person's behalf and why?
- How will you ensure that the treatment is clinically appropriate? (e.g. check contraindications, referrals, previous medical history and existing medication)
- How can you get in touch with the person to assess suitability and determine whether the request is appropriate and genuine?
- Be careful not to disclose confidential information without the person's consent.

During your conversation, be empathetic to the person requesting treatment. Bear in mind that EPs can also have an emotional impact on the female partner:⁵

- **20%** feel unattractive
- **14%** feel inadequate
- **13%** blame themselves for the issue.

Consider how you can support these women, and their mental health, when discussing EPs with them.

Next steps:

Now you have completed this learning, speak to your pharmacist about the protocol you should follow in your pharmacy when somebody requests to buy VIAGRA CONNECT for their partner. Consider role-play activities to help you practise your conversations.



References

1. Li H, et al. The role of the sexual partner in managing erectile dysfunction. *Nat Rev Urol.* 2016; 13(3):168-177. 2. BAUS. Erectile dysfunction (impotence). 2024. Available at: <https://www.baus.org.uk/patients/conditions/3/erectile-dysfunction-impotence#What-treatments-are-available-for-this-problem> 3. Yafi FA, et al. Erectile dysfunction. *Nat Rev Dis Primers.* 2016; 2:16003. doi:10.1038/nrdp.2016.3 4. Rowello L. How to respond when your partner experiences erectile dysfunction (ED). 2023. Available at: <https://www.verywellmind.com/how-to-respond-to-your-partner-s-erectile-dysfunction-5197022> 5. Opinium. BCW/Viagra Connect. Let's get intimate. 2020. 6. Dewitte M, et al. A psychosocial approach to erectile dysfunction: position statements from the European Society of Sexual Medicine (ESSM). *Sex Med.* 2021; 9:100434. 7. NICE. CKS. Erectile dysfunction. 2024. Available at: <https://cks.nice.org.uk/topics/erectile-dysfunction/> 8. Ehedem I. 10 tips to prevent male impotence. Circle Health Group. 2024. Available at: <https://www.circlehealthgroup.co.uk/health-matters/mens-health/10-tips-to-prevent-male-impotence> 9. Liu Q, et al. Erectile dysfunction and depression: a systematic review and meta-analysis. *J Sex Med.* 2018; 15:1073-1082. 10. Viagra Connect 50mg film-coated tablets. SmPC. 2023. Available at: <https://www.medicines.org.uk/emc/product/8725/smpc/print> 11. Watt. P. Understanding the emotional impact of erectile dysfunction. Women talking. 2023. Available at: <https://www.womentalking.co.uk/understanding-the-emotional-impact-of-erectile-dysfunction/> 12. BNF. Erectile dysfunction. 2024. Available at: <https://bnf.nice.org.uk/treatment-summaries/erectile-dysfunction/> 13. Viagra Connect Pharmacy Survey, Wave 7. 2023. (Data on File). 14. Royal Pharmaceutical Society. Sildenafil and tadalafil (P medicines). 2023. Available at: <https://www.rpharms.com/resources/pharmacy-guides/sildenafil-tadalafil-p-medicine#28268>

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 ($\geq 1/10$): 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 Oesophagael 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 <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/ SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM), free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: pvuk@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