

HELPING MEN WITH EPs CHOOSE THEIR OTC TREATMENT

Learning objectives:

Understand the evidence behind VIAGRA CONNECT®



Know the difference between a medicine and medical device



Help men choose the most appropriate EP product



Historically, treatment options for erection problems (EPs) were invasive and unappealing. However, a variety of products are now available over the counter (OTC), aiming to help men aged 18 years and over to take action on EPs. However, some men are still reluctant to discuss them; over a quarter of men with EPs had not discussed their issues with anyone because they:^{1,2}

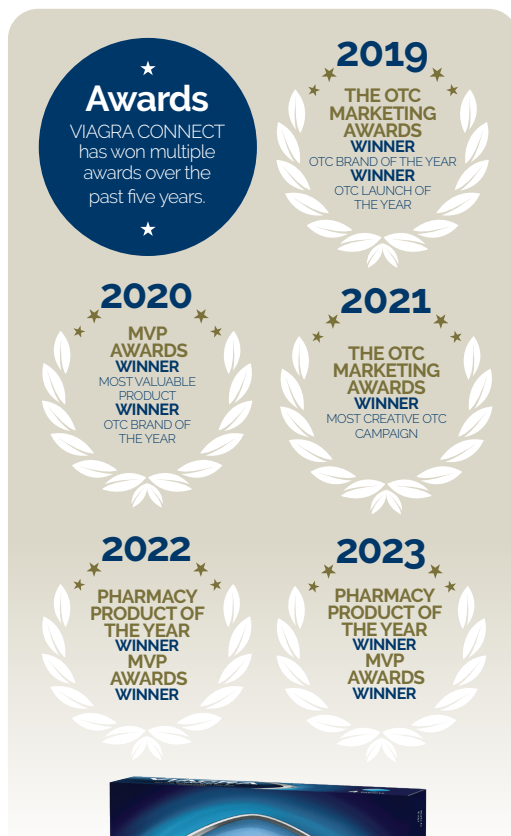
- **Feel uncomfortable**
- **Are embarrassed**
- **Feel ashamed**
- **Don't want to acknowledge the issue.**

Since its launch, VIAGRA CONNECT (sildenafil 50mg) has unlocked opportunities for pharmacists to engage with men about their health and wellbeing, providing access to a subset of the population that was previously hard to reach.

The increasing availability of different OTC products for EPs may encourage more men to break their silence and offer additional opportunities for pharmacy teams to talk about EPs and their health in general.

VIAGRA CONNECT has been available OTC for over five years and has helped over one million men with EPs.*

*Estimated from reported VIAGRA CONNECT use since launch (Kantar 2019) & UK male population 35+ years.



WHAT DOES THE EVIDENCE SAY?

This training covers the OTC products available to treat EPs. They are all indicated for men aged 18 years and over and require sexual stimulation to work.³⁻⁵

Efficacy

Sildenafil (doses 25-100mg) was assessed in clinical trials in over 8,000 patients. In fixed dose studies with the 50mg dose, 74% of men reported "improved erections".³

Tadalafil (doses 2-100mg) was evaluated in primary efficacy studies involving over 3,000 patients. 81% of men had "improved erections" (the efficacy of tadalafil 10mg was not specifically stated).⁴

The topical gel was assessed in two phase 3 trials in fewer than 300 men. It was reported to help 61-63% achieve a "meaningful response".⁵



Erection hardness

93% of men surveyed in seven countries stated that erection hardness was one of the most important attributes of EP medication for them.⁶ Sildenafil 50mg, the active ingredient in VIAGRA CONNECT, has been studied in relation to erection hardness.⁷ VIAGRA CONNECT helps men achieve a grade 4 erection hardness,⁸ which:

- **Is 24 times more likely to result in successful intercourse compared to grade 3⁹**
- **Is associated with the greatest sexual satisfaction¹⁰**
- **Has a better likelihood of treatment continuation¹¹**



Long-term evidence of safety

Sildenafil and tadalafil are oral phosphodiesterase type 5 (PDE5) inhibitors. These medicines are considered first-line drug treatments for erectile dysfunction.¹² Both of these active pharmaceutical ingredients were available on prescription for years before launching as OTC medicines. Sildenafil 50mg is backed by over 25 years of clinical experience as a licenced medication,¹³ while tadalafil 10mg is supported by 20 years of real-world clinical experience.¹⁴ There is long-term data available to support their efficacy and safety.

The topical gel formulation does not contain an active pharmaceutical ingredient. When considered separately, each ingredient in this medical device (ethanol, propylene glycol, glycerine [also known as glycerol], carbomer and potassium hydroxide)¹⁵ has a long history of pharmaceutical and cosmetic use with a strong safety profile.⁵ However, the way in which they have been combined is new and unique,⁵ therefore no long-term data is available on the safety of this formulation.

The table below gives an overview of the key features of the EP treatments available OTC.³⁻⁵

	OTC launch in the UK	Mode of action	Onset of action	Dosing instructions	Frequency of use	Side effect profile	Physical effects on sexual partner
VIAGRA CONNECT Sildenafil 50mg³ oral tablet (P)	2018	Pharmaceutical effect	25 minutes	One 50mg tablet approximately one hour before sexual activity	Maximum frequency is once per day. Can be used daily if required	Headache, flushing, dyspepsia, nausea, nasal congestion, dizziness, visual disturbance, blurred or blue-tinted vision	N/A
Tadalafil 10mg⁴ oral tablet (P)	2023	Pharmaceutical effect	30 minutes	One 10 mg tablet at least 30 minutes prior to anticipated sexual activity	Maximum frequency is once per day. Not recommended for daily use. GP consultation required if used at least twice a week	Headache, flushing, nasal congestion, dyspepsia, back pain, myalgia, pain in extremity	N/A
Topical gel⁵ (Medical device) (Class II)	2023	Physical effect	Within 10 minutes (in 60% of applications)	A pea-sized amount of gel massaged to the head of the penis for about 15 seconds just before sex	As required	Low incidence of headache Rarely causes skin irritation (burning, itching, soreness) ¹⁵	Very low incidence of vaginal irritation Contact with oral cavity was not studied, but indications are that it is safe to use in this way

Classification

Medicines (medicinal products)

Pharmacy (P) medicines such as VIAGRA CONNECT and tadalafil 10mg can only be bought from pharmacies and sold by, or under the supervision of, a pharmacist.¹⁶ As medicines actively interact with the body's systems, they are studied extensively through clinical trials that provide in-depth data on efficacy and safety. This data is reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA) to determine whether to grant the medicine a marketing authorisation (MA) indicating that the medicine is deemed effective and safe to be supplied. The MHRA continues to monitor the safety of medicines through post-market data including information on adverse events.

Medical devices

Medical devices are categorised according to their intended use and classed based on inherent risk.¹⁷ Their effectiveness relies on the skills and experience of the person using them and the fact that they can be sold without pharmacy supervision.

The MHRA regulates medical devices to ensure their quality and safety. While they do not undergo the same extensive trials as medicines, a device must meet requirements set out in the UK Conformity Assessment in order to be sold in the UK.¹⁷

Medical devices are also subject to post-market surveillance overseen by the MHRA. This process is currently being reviewed with the aim to introduce strengthened requirements in line with the Government's priority to improve patient safety. A reformed regulatory framework for medical devices in the UK will be implemented in 2025.¹⁸

Mode of action

VIAGRA CONNECT and tadalafil 10mg work systemically by increasing blood flow to the penis to augment the normal physiological response to sexual stimulation.¹²

The gel formulation works by increasing blood flow in the penis through a rapid physical cooling then gradual warming effect that stimulates penile nerve endings.⁵

Advice to all men with EPs

Regardless of which OTC product your customer chooses, or whether they choose any product at all, all men with EPs should be referred to consult with their GP within six months. EPs can be an early sign of coronary artery disease.¹⁹ If there is any buildup of plaque inside vessels that supply oxygen and blood to the heart, an early diagnosis will ensure that appropriate treatment can be started as soon as possible to reduce the risk of a future cardiovascular event.

Customer Suitability Checker

VIAGRA CONNECT recently developed a Customer Suitability Checker to provide an opportunity for customers to complete a questionnaire prior to visiting the pharmacy. This is designed to encourage empowerment and shared decision-making.

Customers may come into the pharmacy with a screenshot or downloaded copy of this checker. While it should not replace the Pharmacy Checklist, this may be a convenient way to involve customers in a conversation about their EPs.

The Customer Suitability Checker can be accessed via the VIAGRA CONNECT website by scanning this QR code:



References

1. Opinium Research June 2020. The research was conducted by Opinium among a nationally representative sample of 5,007 UK adults. The Report was commissioned/ funded by Upjohn. 2. Circle Health Group. Erectile dysfunction. 2023. [Online.] Available at: <https://www.circlehealthgroup.co.uk/treatments/erectile-dysfunction> 3. VIAGRA CONNECT 50mg film-coated tablets. SmPC. 2023. [Online.] Available at: <https://www.medicines.org.uk/emc/product/8725/smpc/print> 4. Cialis Together 10mg. SmPC. 2023. [Online.] Available at: <https://www.medicines.org.uk/emc/product/14803/smpc/print> 5. Eroxon Stimgel. About Eroxon Stimgel. 2023. [Online.] Available at: <https://hcp.eroxon.co.uk/> 6. Mulhali JP, Hassan TA, Rienow J. Understanding the sexual habits of men taking medication for erectile dysfunction (ED): survey results from 7 countries. J Urol. 2016; 195(4Suppl):e951. 7. Mulhali JP et al. Validation of the erection hardness score. J Sex Med. 2007; 4(6):1626-1634. 8. Goldstein I, et al. Oral sildenafil in the treatment of erectile dysfunction. N Engl J Med. 1998; 338(20):1397-1404. 9. Goldstein I, et al. The erection hardness score and its relationship to successful sexual intercourse. J Sex Med. 2008; 5:2374-2380. 10. Mulhali J, et al. Erectile Dysfunction: Monitoring response to treatment in clinical practice – recommendations of an International Study Panel. J Sex Med. 2007; 4(2):448-464. 11. Mazzola R, et al. Exploring the association between erectile rigidity and treatment adherence with sildenafil. J Sex Med. 2013; 10(7):1861-1866. 12. BNF. Erectile dysfunction. 2023. [Online.] Available at: <https://bnf.nice.org.uk/treatment-summaries/erectile-dysfunction/> 13. Connelly D. Three decades of Viagra. Pharm J. 2017; 298(7901): DOI:10.1211/PJ.2017.20202847 14. Cialis Together. Erectile Dysfunction Treatment | Cialis Together (tadalafil). 2023. [Online.] Available at: <https://www.cialis.together.com/en-gb/hcp> 15. Eroxon. Information leaflet. 2022. [Online.] Available at: <https://www.eroxon.co.uk/files/VE921I-EROXON-IFU-standard-300x416-26x100-vii-HR.pdf> 16. Royal Pharmaceutical Society. Medicines, Ethics and Practice. 2023. [Online.] Available at: <https://www.rpharms.com/publications/the-mep> 17. GOV.UK. Factsheet: medical devices overview. 2021. [Online.] Available at: <https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/factsheet-medical-devices-overview> 18. GOV.UK. Standard: Implementation of the Future Regulations. 2023. [Online.] Available at: <https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations> 19. Kirby M and Jackson G. Erectile dysfunction as a predictor of coronary artery disease. Trends In Urology & Men's Health. 2011; 2(4):19-23. Online references last accessed January 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, 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 (≥ 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, Haematospemia, 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