**ABBREVIATED PRESCRIBING INFORMATION**

**Viagra Connect (sildenafil) 50 mg film-coated tablets**

**Please refer to Summary of Product Characteristics (SmPC) before prescribing**

**Indications, Dosage and Administration:** Indications: For erectile dysfunction in adult men. Dosage and Method of use: Adults: one 50 mg tablet taken with water approx. one hour before sexual activity. The maximum dosing frequency is once per day. The onset of activity may be delayed if taken with food. Patients should be advised that they may need to take Viagra Connect a number of times on different occasions (max of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If patients are still not able to achieve a sufficient penile erection they should be advised to consult a doctor. Elderly: no dosage adjustments required (≥ 65 years old). Renal Impairment: No dosage adjustments for patients with mild to moderate renal impairment. Dosage adjustments required for those with severe renal impairment, see SmPC. Hepatic Impairment: Dosage adjustments required for those with mild-moderate hepatic impairment, see SmPC. Viagra Connect is contraindicated for patients with severe hepatic impairment (see contraindications).

**Presentation:** Film-coated tablets containing sildenafil citrate equivalent to 50 mg of sildenafil.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Co-administration with nitric oxide donors (such as amyl nitrite), nitrates, ritonavir, guanylate cyclase stimulators (such as riociguat) is contraindicated. 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). 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.

**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. For a list of patients who are considered at low cardiovascular risk from sexual activity see SmPC. 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. 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. Concomitant use with other treatments for erectile dysfunction is not recommended. Effects on vision: 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: patients 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. 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: 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 or renal impairment 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.

**Interactions with other medicinal products and other forms of interaction:** Individuals receiving concomitant treatment with CYP3A4 inhibitors must be advised to consult their doctor

before taking Viagra Connect, dosing adjustments may be required, see SmPC. Patients receiving alpha blocker treatment should be stabilised on therapy prior to initiating sildenafil treatment and must be advised to consult their doctor before taking Viagra Connect as dosing adjustments may be required, see SmPC. Caution when sildenafil is initiated in patients treated with sacubitril/valsartan, see SmPC.

**Fertility, pregnancy and lactation:** There was no effect on sperm motility or morphology after single 100 mg oral doses of sildenafil in healthy volunteers. Viagra Connectis not indicated for use by women.

**Undesirable effects:** Very common (≥1/10): headache. Common (>1/100, <1/10): dizziness, visual colour distortions, visual disturbance, vison blurred, flushing, hot flush, nasal congestion, nausea, dyspepsia. For details of uncommon, rare and very rarely reported adverse events and those of unknown frequency, see SmPC.

**Reporting of adverse reactions:** Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse reactions/events should also be reported to the marketing autorisation holder at the email address: pv.ireland@viatris.com or phone 0044(0)8001218267.

**Legal Category:** Not subject to medical prescription. Supply through pharmacies only.

**Marketing Authorisation Number:** PA23055/016/001

**Marketing Authorisation Holder:** Upjohn EESV, Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Netherlands.

**Full prescribing information available on request from:** Viatris, Dublin 17. Phone 01 8322250

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