ABBREVIATED PRESCRIBING INFORMATION

Viagra Connect (sildenafil) 50 mg Film-Coated Tablet

Viagra Connect (sildenafil) 50 mg orodispersible films

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

Indications, Dosage and Administration:

Indications:

Viagra Connect is indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

In order for Viagra Connect to be effective, sexual stimulation is required.

Dosage and Method of use:

For oral use.

Film-Coated Tablets: Adults: one 50 mg tablet taken with water approx. one hour before sexual activity.

Orodispersible films: 50 mg taken on an empty stomach approx. one hour before sexual activity.

Orodispersible films can be taken with or without water.

The maximum dosing frequency is once per day. The onset of activity may be delayed if taken with food (see SmPC Section 5.2). 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/film 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: 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, individuals must be advised to consult their doctor before taking Viagra Connect, since a 25 mg tablet may be more suitable for them (see SmPC Section 4.4). Hepatic Impairment: Dosage adjustments required for those with mild-moderate hepatic impairment, individuals must be advised to consult their doctor before taking Viagra Connect, since a 25 mg tablet may be more suitable for them (see SmPC Section 4.4). Viagra Connect is contraindicated for patients with severe hepatic impairment (see contraindications).

Presentation:

Film-Coated Tablets: each tablet contains sildenafil citrate equivalent to 50 mg of sildenafil.

Orodispersible films: orodispersible film contains 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 (see SmPC Section 4.4). 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 Section 4.4). 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 SmPC section 4.3).

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 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. 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 (see SmPC Section 4.2 & 5.2). 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. Renal and Hepatic impairment: Patients with hepatic or 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 SmPC Section 4.2 & 5.2). 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.

Film-Coated Tablets: 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’.

Interaction with other medicinal products and other forms of interaction:

Effects of other medicinal products on sildenafil

In vitro studies

Sildenafil metabolism is principally mediated by the cytochrome P450 (CYP) isoforms 3A4 (major route) and 2C9 (minor route). Therefore, inhibitors of these isoenzymes may reduce sildenafil clearance and inducers of these isoenzymes may increase sildenafil clearance.

In vivo studies

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). Although no increased incidence of adverse events was observed in these patients, with the exception of individuals taking ritonavir for which co-administration with sildenafil is contraindicated, individuals must be advised to consult their doctor before taking Viagra Connect, since a 25 mg tablet may be more suitable for them.

Co-administration of the HIV protease inhibitor ritonavir, which is a highly potent P450 inhibitor, at steady state (500 mg twice daily) with sildenafil (100 mg single dose) resulted in a 300% (4-fold) increase in sildenafil C_{max} and a 1,000% (11-fold) increase in sildenafil plasma AUC. At 24 hours, the plasma levels of sildenafil were still approximately 200 ng/mL, compared to approximately 5 ng/mL when sildenafil was administered alone. This is consistent with ritonavir's marked effects on a broad range of P450 substrates. Sildenafil had no effect on ritonavir pharmacokinetics. Based on these pharmacokinetic results sildenafil should not be co-administered with ritonavir (see SmPC Section 4.3).

Co-administration of the HIV protease inhibitor saquinavir, a CYP3A4 inhibitor, at steady state (1200 mg three times a day) with sildenafil (100 mg single dose) resulted in a 140% increase in sildenafil C_{max} and a 210% increase in sildenafil AUC. Sildenafil had no effect on saquinavir pharmacokinetics (see SmPC Section 4.2). Stronger CYP3A4 inhibitors such as ketoconazole and itraconazole would be expected to have greater effects.

When a single 100 mg dose of sildenafil was administered with erythromycin, a specific CYP3A4 inhibitor, at steady state (500 mg twice daily for 5 days), there was a 182% increase in sildenafil systemic exposure (AUC). In normal healthy male volunteers, there was no evidence of an effect of azithromycin (500 mg daily for 3 days) on the AUC, C_{max}, t_{max}, elimination rate constant, or subsequent half-life of sildenafil or its principal circulating metabolite. Cimetidine (800 mg), a cytochrome P450 inhibitor and non-specific CYP3A4 inhibitor, caused a 56% increase in plasma sildenafil concentrations when co-administered with sildenafil (50 mg) to healthy volunteers.

Grapefruit juice is a weak inhibitor of CYP3A4 gut wall metabolism and may give rise to modest increases in plasma levels of sildenafil.

Single doses of antacid (magnesium hydroxide/aluminium hydroxide) did not affect the bioavailability of sildenafil.

Although specific interaction studies were not conducted for all medicinal products, pharmacokinetic analysis showed no effect of concomitant treatment on sildenafil pharmacokinetics when grouped as CYP2C9 inhibitors (such as tolbutamide, warfarin, phenytoin), CYP2D6 inhibitors (such as selective serotonin reuptake inhibitors, tricyclic antidepressants), thiazide and related diuretics, loop and potassium sparing diuretics, angiotensin converting enzyme inhibitors, calcium channel blockers, beta-adrenoreceptor antagonists or inducers of CYP450 metabolism (such as rifampicin, barbiturates). In a study of healthy male volunteers, co-administration of the endothelin antagonist, bosentan (an inducer of CYP3A4 [moderate], CYP2C9 and possibly of CYP2C19) at steady state (125 mg twice a day) with sildenafil at steady state (80 mg three times a day) resulted in 62.6% and 55.4% decrease in sildenafil AUC and C_{max}, respectively. Therefore, concomitant administration of strong CYP3A4 inducers, such as rifampin, is expected to cause greater decreases in plasma concentrations of sildenafil.

Nicorandil is a hybrid of potassium channel activator and nitrate. Due to the nitrate component it has the potential to result in a serious interaction with sildenafil.

Effects of sildenafil on other medicinal products

In vitro studies

Sildenafil is a weak inhibitor of the cytochrome P450 isoforms 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4 (IC50 > 150 μM). Given sildenafil peak plasma concentrations of approximately 1 μM after 100 mg of sildenafil, it is unlikely that Viagra Connect will alter the clearance of substrates of these isoenzymes.

There are no data on the interaction of sildenafil and non-specific phosphodiesterase inhibitors such as theophylline or dipyridamole.

In vivo studies

Consistent with its known effects on the nitric oxide/cGMP pathway (see SmPC Section 5.1), sildenafil was shown to potentiate the hypotensive effects of nitrates, and its co-administration with nitric oxide donors or nitrates in any form is therefore contraindicated (see SmPC Section 4.3).

Preclinical studies showed additive systemic blood pressure lowering effect when PDE5 inhibitors were combined with riociguat. In clinical studies, riociguat has been shown to augment the hypotensive effects of PDE5 inhibitors. There was no evidence of favourable clinical effect of the combination in the population studied. Concomitant use of riociguat with PDE5 inhibitors, including sildenafil, is contraindicated (see SmPC Section 4.3).

Concomitant administration of sildenafil to patients taking alpha-blocker therapy may lead to symptomatic hypotension in a few susceptible individuals. This is most likely to occur within 4 hours post sildenafil dosing (see SmPC Sections 4.2 and 4.4). In three specific drug-drug interaction studies, the alpha-blocker doxazosin (4 mg and 8 mg) and sildenafil (25 mg, 50 mg, or 100 mg) were administered simultaneously to patients with benign prostatic hyperplasia (BPH) stabilized on doxazosin therapy. In these study populations, mean additional reductions of supine blood pressure of 7/7 mmHg, 9/5 mmHg, and 8/4 mmHg, and mean additional reductions of standing blood pressure of 6/6 mmHg, 11/4 mmHg, and 4/5 mmHg, respectively, were observed. When sildenafil and doxazosin were administered simultaneously to patients stabilized on doxazosin therapy, there were infrequent reports of patients who experienced symptomatic postural hypotension. These reports included dizziness and light-headedness, but not syncope.

No significant interactions were shown when sildenafil (50 mg) was co-administered with tolbutamide (250 mg) or warfarin (40 mg), both of which are metabolised by CYP2C9.

Sildenafil (50 mg) did not potentiate the increase in bleeding time caused by acetyl salicylic acid (150 mg).

Sildenafil (50 mg) did not potentiate the hypotensive effects of alcohol in healthy volunteers with mean maximum blood alcohol levels of 80 mg/dl.

Pooling of the following classes of antihypertensive medication; diuretics, beta-blockers, ACE inhibitors, angiotensin II antagonists, antihypertensive medicinal products (vasodilator and centrally-acting), adrenergic neurone blockers, calcium channel blockers and alpha-adrenoceptor

blockers, showed no difference in the side effect profile in patients taking sildenafil compared to placebo treatment. In a specific interaction study, where sildenafil (100 mg) was co-administered with amlodipine in hypertensive patients, there was an additional reduction on supine systolic blood pressure of 8 mmHg. The corresponding additional reduction in supine diastolic blood pressure was 7 mmHg. These additional blood pressure reductions were of a similar magnitude to those seen when sildenafil was administered alone to healthy volunteers (see SmPC Section 5.1).

Sildenafil (100 mg) did not affect the steady state pharmacokinetics of the HIV protease inhibitors, saquinavir and ritonavir, both of which are CYP3A4 substrates.

In healthy male volunteers sildenafil at steady state (80 mg three times a day) resulted in a 49.8% increase in bosentan AUC and a 42% increase in bosentan C_{max} (125 mg two times a day).

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.

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 Connect is not indicated for use by women. There are no adequate and well-controlled studies in pregnant or breast-feeding women. No relevant adverse effects were found in reproduction studies in rats and rabbits following oral administration of sildenafil.

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 Numbers: PA23355/063/001-002

Marketing Authorisation Holder:

Viatris Healthcare Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Full prescribing information available on request from: Viatris, Dublin 17. Email : info.ie@viatris.com

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