

## **PRESCRIBING INFORMATION**

**Hezkue® (sildenafil) 12.5 mg/actuation, oromucosal spray, suspension.**

**Consult Summary of Product Characteristics (SmPC) before prescribing.**

**Indication:** Hezkue® 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 Hezkue® to be effective, sexual stimulation is required.

**Presentation:** Oromucosal spray suspension. Each 1 mL of suspension contains sildenafil citrate equivalent to 25 mg sildenafil. Each actuation releases 0.5 mL of suspension containing 12.5 mg of sildenafil. Each 1 mL of suspension contains 1 mg of sodium benzoate.

**Dosage and Administration:** Recommended dose in adult men is 2 mL (4 pumps) taken as needed, equivalent to 50 mg of sildenafil approximately one hour before sexual activity. Based on efficacy and tolerability, the dose may be increased to 4 mL (8 pumps), equivalent to 100 mg of sildenafil, or may be decreased to 1 mL (2 pumps), equivalent to 25 mg of sildenafil. The maximum recommended dose is 100 mg once daily. If taken with food, the onset of activity may be delayed. **Elderly:** Dosage adjustments are not required in patients ( $\geq 65$  years old). **Renal Impairment:** With mild to moderate renal impairment (creatinine clearance = 30-80 mL/min) no change in dosing is required. With severe renal impairment (creatinine clearance  $< 30$  mL/min) a 25 mg dose should be considered. Based on efficacy and tolerability, the dose may be increased step-wise to 50 mg up to 100 mg as necessary. **Hepatic Impairment:** With hepatic impairment (e.g. cirrhosis) consider a 25 mg dose. Based on efficacy and tolerability, the dose may be increased step-wise to 50 mg up to 100 mg as necessary. **Paediatric population:** Not indicated for individuals below 18 years of age. **Method of administration:** Hezkue® requires preparation before use. The bottle must be shaken, the lid replaced with the pump and nozzle and turned on. Before each use, 3 pumps are required to activate the product and this material should be discarded. After use the pump must be removed and replaced with the lid. The pump part should be washed with water and dried. The approximate volume available for patient use is 20 mL in each 30 mL bottle.

**Contraindications:** Hypersensitivity to the active substance or excipients. Co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form. Co-administration of PDE5 inhibitors, including sildenafil, with guanylate cyclase stimulators, such as riociguat. Not to be used in men for whom sexual activity is inadvisable (e.g. patients with severe cardiovascular disorders such as unstable angina or severe cardiac failure). 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 related to previous PDE5 inhibitor exposure. The safety of

sildenafil has not been studied in the following sub-groups of patients and its use is therefore contraindicated: severe hepatic impairment, hypotension (blood pressure <90/50 mmHg), recent history of stroke or myocardial infarction and known hereditary degenerative retinal disorders such as retinitis pigmentosa.

**Warnings and Precautions:** A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes before pharmacological treatment is considered. **Cardiovascular risk factors:** Consider cardiovascular status and whether any underlying conditions could be adversely affected by the vasodilatory effects of sildenafil, especially in combination with sexual activity, prior to initiating treatment. Patients with increased susceptibility to vasodilators include those with left ventricular outflow obstruction (e.g., aortic stenosis, hypertrophic obstructive cardiomyopathy), or those with multiple system atrophy manifesting as a severely impaired autonomic control of blood pressure. Sildenafil potentiates the hypotensive effect of nitrates. Serious cardiovascular events, including myocardial infarction, unstable angina, sudden cardiac death, ventricular arrhythmia, cerebrovascular haemorrhage, transient ischaemic attack, hypertension and hypotension have been reported. **Priapism:** Use with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease), and in patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia). Prolonged erections and priapism have been reported with sildenafil in post marketing experience. If an erection persists longer than 4 hours, advise to seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result. **Concomitant use with other PDE5 inhibitors or other treatments for erectile dysfunction:** The safety and efficacy of combinations of sildenafil with other PDE5 inhibitors, or other pulmonary arterial hypertension (PAH) treatments containing sildenafil, or other treatments for erectile dysfunction have not been studied. Use of such combinations is not recommended. **Effects on vision:** Visual defects have been reported spontaneously in connection with sildenafil and other PDE5 inhibitors. Non-arteritic anterior ischaemic optic neuropathy, has been reported spontaneously in connection with the intake of sildenafil and other PDE5 inhibitors. Patients should be advised that in the event of any sudden visual defect, they should stop taking Hezkue® and consult a physician immediately. **Concomitant use with ritonavir is not advised. Concomitant use with alpha-blockers:** Caution advised when administered to patients taking an alpha blocker. Co-administration may lead to symptomatic hypotension in susceptible individuals. This is most likely to occur within 4 hours post dosing. To minimise the potential for developing postural hypotension, patients should be haemodynamically stable on alpha-blocker therapy prior to initiating sildenafil treatment. Initiation of sildenafil at a dose of 25 mg should be considered. Advise patients what to do in the event of postural hypotensive symptoms. **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. Sildenafil should be administered to these patients only after careful benefit-risk assessment. **Excipients:** This medicinal product contains less than 1 mmol (23 mg) sodium per mL of suspension and is essentially 'sodium-free'. **Women:** Not indicated for use by women.

**Drug Interactions:** Consistent with its known effects on the nitric oxide/cGMP pathway sildenafil may potentiate the hypotensive effects of nitrates, and its co-administration with nitric oxide donors or nitrates in any form is contraindicated. 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. Concomitant use of riociguat with PDE5 inhibitors, including sildenafil, is contraindicated. Co-administration of sildenafil with ritonavir (HIV protease inhibitor) is not advised. A starting dose of 25 mg should be considered in patients receiving concomitant treatment with CYP3A4 inhibitors such as ketoconazole, itraconazole, erythromycin and cimetidine. Concomitant administration of sildenafil in patients taking alpha-blocker therapy may lead to symptomatic hypotension. Please see above under "Warnings & Precautions" section. Caution should be exercised when sildenafil is initiated in patients treated with sacubitril/valsartan.

**Pregnancy and Lactation:** Not indicated for use by women. There are no adequate and well-controlled studies of sildenafil in pregnant or breastfeeding women.

**Ability to Drive and Use Machines:** May have a minor influence on the ability to drive and use machines. Dizziness and altered vision are common side effects and patients should be aware of how they react to Hezkue®, before driving or operating machinery.

**Undesirable Events:** Consult SmPC for full list of side effects. **Very Common:** headache, **Common:** dizziness, visual colour distortions (chloropsia, chromatopsia, cyanopsia, erythroopsia and xanthopsia), visual disturbance, vision blurred, flushing, nasal congestion, nausea, dyspepsia, **Uncommon:** 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, gastroesophageal reflux disease, vomiting, pain in the upper abdomen, dry mouth, rash, myalgia, pain in extremity, haematuria, chest pain, fatigue, feeling hot, heart rate increased. **Rare:** 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, haemospermia, erection increased, irritability.

**Legal Category:** POM.

**Marketing Authorisation Number:** PL 59654/0001

**Presentation & Indicative Cost:** Hezkue® 12.5 mg/actuation, oromucosal spray, suspension; 30 mL bottle: £75

**Business Responsible for Sale and Supply / Further Information:** Aspargo Labs Italia S.r.l Via PO 102 00198 Roma (RM) Italy

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