

Prescribing information for Silandyl (Sildenafil) 25 mg (not available in the UK) 50 mg, 75 mg and 100 mg Orodispersible Film (Refer to Summary of Product Characteristics (SPC) for full information).

Presentations: Silandyl 25 mg - Each orodispersible film contains 35.1 mg sildenafil citrate, equivalent to 25 mg sildenafil (not available in the UK). Silandyl 50 mg - Each orodispersible film contains 70.2 mg sildenafil citrate, equivalent to 50 mg sildenafil. Silandyl 75 mg - Each orodispersible film contains 105.3 mg sildenafil citrate, equivalent to 75 mg sildenafil. Silandyl 100 mg - Each orodispersible film contains 140.4 mg sildenafil citrate, equivalent to 100 mg sildenafil. Film: rectangular or square, flexible, opaque light blue strip.

Indications: Treatment of erectile dysfunction (ED) in adult men, defined as the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. Sexual stimulation is required for Silandyl to be effective.

Dosage and administration: Silandyl is intended for oral use and should be taken without water; if desired, it may also be taken with water. The orodispersible film should be placed in the mouth, on the tongue, and allowed to dissolve before swallowing. The recommended dose is 50 mg taken as needed approximately one hour before sexual activity. Based on efficacy and tolerability, the dose may be increased to 100 mg or decreased to 25 mg. Maximum recommended dose: 100 mg. Maximum frequency: once per day. The onset of action may be delayed when taken with food.

Special populations:

- Elderly (≥ 65 years old): No dosage adjustment required.
- Renal impairment: Mild to moderate impairment: standard dosing. Severe 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: in patients with hepatic impairment (e.g. cirrhosis) a 25 mg dose should be considered. Based on efficacy and tolerability, the dose may be increased step-wise to 50 mg up to 75 mg and 100 mg as necessary.
- Paediatric population: Not indicated for individuals below 18 years.
- Concomitant medications: In patients taking CYP3A4 inhibitors (excluding ritonavir), consider starting with 25 mg. For patients on alpha-blockers, ensure they are stable before starting sildenafil. Consider sildenafil at 25 mg dose.
- Effect on bleeding: There is no safety information on the administration of sildenafil to patients with bleeding disorders or active peptic ulceration. Therefore, sildenafil should be administered to these patients only after careful benefit-risk assessment.

Patients should be advised that in the event of any sudden visual defect, they should stop taking Silandyl and consult a physician immediately.

Contra-indications: Hypersensitivity to sildenafil or excipients. Concomitant use with nitric oxide donors or nitrates in any form. Use with guanylate cyclase stimulators (e.g. riociguat). Patients for whom sexual activity is inadvisable due to severe cardiovascular disorders. History of vision loss due to non-arteritic anterior ischaemic optic neuropathy (NAION). Severe hepatic impairment, hypotension ($<90/50$ mmHg), recent stroke or myocardial infarction, hereditary degenerative retinal disorders (e.g. retinitis pigmentosa).

Warnings and precautions: Assess cardiovascular status before initiating therapy. Use with caution in patients with anatomical deformation of the penis or predisposition to priapism. Priapism (erections >4 hours) requires immediate medical attention. Discontinue if sudden vision loss occurs. Avoid

combination with other PDE5 inhibitors or ED treatments.

As dizziness and altered vision were reported in clinical trials with sildenafil, patients should be aware of how they react to SILANDYL, before driving or operating machinery.

Interactions:

- CYP3A4 inhibitors (e.g. ketoconazole, erythromycin) increase sildenafil levels: start with 25 mg.
- Ritonavir significantly increases sildenafil exposure: not advised; do not exceed 25 mg within 48 hours.
- Alpha-blockers: may lead to symptomatic hypotension. Stabilise therapy before sildenafil initiation.
- Alcohol: does not potentiate hypotensive effects.
- Grapefruit juice may modestly increase sildenafil levels.

Pregnancy and Lactation: Not indicated for use in women.

Undesirable Effects: Common adverse reactions include headache, flushing, dyspepsia, nasal congestion, dizziness, and visual disturbances. Rare but serious events include priapism and sudden visual loss. Cardiovascular events have been reported post-marketing in patients with risk factors.

Sudden cardiac death*, Myocardial infarction, Ventricular arrhythmia*, Atrial fibrillation, Unstable angina and Cerebrovascular accident, Transient ischaemic attack, Seizure*, Seizure recurrence*, Syncope, Stevens-Johnson Syndrome (SJS)*, Toxic Epidermal Necrolysis (TEN)*

*Reported during post-marketing surveillance only **Visual colour distortions: Chloropsia, Chromatopsia, Cyanopsia, Erythropsia and Xanthopsia ***Lacrimation disorders: Dry eye, Lacrimal disorder and Lacrimation increased

Marketing Authorisation Numbers: PL 21039/0032 *SILANDYL 25mg (not available in the UK)*, PL 21039/0033 SILANDYL 50mg, PL 21039/0034 SILANDYL 75mg, PL 21039/0035 SILANDYL 100mg

NHS List Price:

Silandyl 50 mg 2 pack – £8.51 – 4 pack – £17.02 – 8 pack - £34.05

Silandyl 75 mg 8 pack - £35.78

Silandyl 100 mg 8 pack - £37.57

Legal Classification: POM

Marketing Authorisation Holder: IBSA Farmaceutici Via Martiri di Cefalonia, 2, 26900 Lodi (LO), Italy

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