SLENYTO® PROLONGED-RELEASE TABLETS 1mg and 5mg

PRESCRIBING INFORMATION: Please refer to Summary of Product Characteristics (SmPC) before prescribing.

ACTIVE INGREDIENT: Melatonin 1mg or 5mg.

INDICATIONS: Insomnia in children and adolescents aged 2-18 years with Autism Spectrum Disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.

DOSAGE AND ADMINISTRATION:
Dose titration: Recommended starting dose is 2mg once daily. If an inadequate response is observed, increase the dose to 5 mg, with a maximal dose of 10 mg. Data are available for up to two years treatment. Monitor at regular intervals (at least every 6 months) to check that Slenyto is still the most appropriate treatment. After at least 3 months, evaluate treatment effect and consider stopping if no clinically relevant treatment effect is observed. If a lower treatment effect is seen after titration to a higher dose, consider a down-titration to a lower dose before deciding on a complete discontinuation of treatment.
Administration: Once daily 0.5-1 hour before bedtime with or after food. Swallow whole, do not crush, break or chew. To facilitate swallowing, tablets may be put into food such as yoghurt, orange juice or ice-cream and then taken immediately.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS: Use caution in patients with renal insufficiency. Not recommended in patients with hepatic impairment. Children under 2 years**:** not recommended. Slenyto may cause drowsiness, therefore use with caution if the effects of drowsiness are likely to be associated with a risk to safety. Not recommended in patients with autoimmune disease. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

INTERACTIONS: Concomitant use with fluvoxamine, alcohol, thioridazine, imipramine, benzodiazepines and non-benzodiazepine hypnotics should be avoided. Use caution with 5- or 8- methoxypsoralen, cimetidine, oestrogens, CYP1A2 inhibitors, CYP1A2 inducers, NSAIDs, beta- blockers and with smoking.

FERTILITY, PREGNANCY, LACTATION: Avoid use of melatonin during pregnancy. Consider discontinuation of breastfeeding or discontinuation of melatonin therapy taking account of the benefit of breastfeeding for the child and the benefit of therapy for the woman. No known effects on fertility.

DRIVING: Melatonin has a moderate influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS: Very common: None. **Common:** Mood swings, aggression, irritability, somnolence, headache, sudden onset of sleep, sinusitis, fatigue, hangover. Consult SmPC in relation to other adverse reactions.

PHARMACEUTICAL PRECAUTIONS: Do not store above 30°C.

LEGAL CATEGORY: POM.

MARKETING AUTHORISATION HOLDER: RAD Neurim Pharmaceuticals EEC SARL, 4 rue de Marivaux, 75002 Paris, France

Marketed in the UK by Flynn Pharma Limited, Hertlands House, Primett Road, Stevenage, Herts, SG1 3EE, Tel: 01438 727822, E-mail: medinfo@flynnpharma.com.

Product	NHS List Price	Pack Size	Marketing Authorisation Number
Slenyto 1mg	£ 41.20	60 tablets	PLGB 52348/0003 EU/1/18/1318/001
Slenyto 5mg	£ 103.00	30 tablets	PLGB 52348/0004 EU/1/18/1318/003

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to RAD Neurim Pharmaceuticals EEC Limited Medical Information e-mail: regulatory@neurim.com

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