UK ABBREVIATED PRESCRIBING INFORMATION

Please refer to Summary of Product Characteristics (SmPC) for specific information before prescribing.

ADAFLEX 1MG, 2MG, 3MG, 4MG AND 5MG TABLETS

ACTIVE INGREDIENT: Each tablet contains melatonin 1mg, 2mg, 3mg, 4mg or 5mg.

INDICATIONS: Insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.

DOSAGE AND ADMINISTRATION:

Dose: The recommended starting dose is 1-2 mg; the dose can be increased by 1 mg every week until effect up to a maximum 5 mg per day, independent of age; the lowest effective dose should be sought. After at least 3 months of treatment, the treatment effect should be evaluated and stopping treatment considered if no clinically relevant effect seen. The patient should be monitored at regular intervals to check that Adaflex is still the most appropriate treatment. During ongoing treatment, especially if the treatment effect is uncertain, discontinuation attempts should be made regularly e.g. once a year. If the sleep disorder has started during treatment with medicinal products for ADHD, dose adjustment or switching to another product should be considered.

Administration: Oral; 30-60 minutes before bedtime. The tablet can be crushed and mixed with water directly before administration; it is recommended that food is not consumed 2 h before and 2 h after intake.

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

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Use caution in patients with renal impairment or epilepsy. Not recommended in patients with moderate or severe hepatic impairment or patients with autoimmune diseases. Not recommended for children below 6 years with ADHD. Melatonin may cause drowsiness, use with caution if this effect is likely to be associated with a risk to patient safety. Melatonin tablets should be taken ideally at least 3 hours after a meal by patients with significantly impaired glucose tolerance or diabetes.

INTERACTIONS: Concomitant use with the CYP1A2 inhibitor fluvoxamine, alcohol, warfarin and other vitamin K antagonists and benzodiazepine-related hypnotics, should be avoided. Use with caution with the CYP1A2 inhibitors ciprofloxacin, norfloxacin and verapamil (which may increase plasma melatonin concentration), combined hormonal contraceptives containing ethinylestradiol and gestagen (melatonin dose may need to be reduced), 5- or 8-methoxypsoralen, cimetidine, caffeine. tCYP1A2 inducers may decrease melatonin plasma concentration – melatonin dose may need adjusting if given with carbamazepine, phenytoin, rifampicin, omeprazole and smoking. Melatonin may reduce hypotensive effect of nifedipine – use with caution – nifedipine dose may need adjustment. Caution with other calcium antagonists. Due to effect on endogenous melatonin levels, administer beta-blockers in the morning and avoid administration of NSAIDs in the evening.

PREGNANCY, LACTATION: Not recommended during pregnancy or in women of child-bearing potential not using contraceptives, or breastfeeding.

DRIVING AND USE OF MACHINES: Moderate influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS: Common: Headache, somnolence. Consult SmPC for full adverse event profile. Serious uncommon: hypertension, hyperbilirubinaemia, liver function test abnormal; Serious rare: herpes zoster, leucopenia, thrombocytopenia, hypertriglyceridaemia, hypocalcaemia, hyponatraemia, depression, angina pectoris, priapism, hepatic enzyme increased, blood electrolytes abnormal; Serious frequency unknown: hypersensitivity reaction, hyperglycaemia, angioedema, oedema of mouth, tongue oedema. LEGAL CATEGORY: POM.

MARKETING AUTHORISATION HOLDER: AGB-Pharma AB, Medicon Village, 223 81 Lund, Sweden. Marketed in the UK by AGB-Pharma AB; Tel: +44 808 189 2048; Email: uk.med.info@agb-pharma.com.

MARKETING AUTHORISATION NUMBERS: PL 52497/0001-0005.

PRICE: Adaflex 1mg, 2mg, 3mg, 4mg, 5mg tablets (30): £10.89

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AGB-Pharma AB at uk.med.info@agb-pharma.com.

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