

PRESCRIBING INFORMATION

MELLOZZAN® (melatonin) 2-5mg tablets.

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

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MEDICE UK on 0204 582 2845, pv-uk@medice.co.uk

Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at <https://www.medicines.org.uk/emc>

ACTIVE INGREDIENT: melatonin 2, 3 or 5mg.

INDICATION: Insomnia in children and adolescents aged 6-17 years with Attention-Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have been insufficient.

DOSAGE and ADMINISTRATION: Insomnia in children and adolescents with ADHD: Treatment should be initiated by physicians experienced in ADHD and/or paediatric sleep medicine. Recommended starting dose of Mellozzan tablets: 0.5-2mg 30 - 60 minutes before bedtime. The dose of melatonin can be increased by 1 mg every week until effect up to a maximum 5mg per day, independent of age. The lowest effective dose should be sought. Limited data are available for up to 3 years of treatment. After at least 3 months of treatment, the physician should evaluate the treatment effect and consider stopping treatment if no clinically relevant treatment effect is seen. The patient should be monitored at regular intervals (at least every 6 months) to check that Mellozzan is still the most appropriate treatment. During ongoing treatment, especially if the treatment effect is uncertain, discontinuation attempts should be done regularly, e.g. once per year. If the sleep disorder has started during treatment with medicinal products for ADHD, dose adjustment or switching to another product should be considered.

Renal impairment: Caution should be used when melatonin is administered to patients with renal impairment. Hepatic impairment: Mellozzan tablets are not recommended in patients with moderate or severe hepatic impairment. Mellozzan tablets are not recommended for children below 6 years with ADHD.

Administration: The tablets can be crushed and mixed with water directly before administration. It is recommended that food is not consumed 2 hours before and 2 hours after intake of Mellozzan tablets as intake with carbohydrate-rich meals may impair blood glucose control for several hours. Ideally, Mellozzan should be taken at least 3 hours after a meal in those with significantly impaired glucose tolerance or diabetes.

CONTRAINDICATIONS: Hypersensitivity to melatonin or excipients

SPECIAL WARNINGS AND PRECAUTIONS: Melatonin may cause drowsiness. Melatonin tablets are not recommended in patients with autoimmune diseases as case reports have described exacerbation of an autoimmune disease in patients taking melatonin. Due to the uncertainty of the effect, caution should be exercised for use in people with epilepsy.

INTERACTIONS: Melatonin is mainly metabolised via CYP1A enzymes. CYP1A2 inhibitors may increase the plasma concentrations of melatonin considerably. Concomitant treatment with the

CYP1A2 inhibitor fluvoxamine (also a CYP2C19 inhibitor) should be avoided. Caution should be exercised with concomitant CYP1A2 inhibitors (ciprofloxacin, norfloxacin and verapamil). Contraceptives containing ethinylestradiol and gestagen can inhibit CYP1A2 and lead to an increase of melatonin concentration, which may require a dose reduction. Hormonal substitution therapy has been reported to delay melatonin T_{max} . Caution is indicated in moderately pronounced inhibitors of CYP1A2, such as 5- or 8-methoxypsoralen (5 or 8-MOP), cimetidine or caffeine as an increase of the plasma concentration of melatonin is expected. CYP1A2 inducers may decrease the plasma concentrations of melatonin. Dose adjustment of melatonin may be needed if given concomitantly with the CYP1A2 inducers: carbamazepine, phenytoin, rifampicin, omeprazole and cigarette smoking (halved exposure compared to after 7 days of smoking abstinence). Adrenergic agonists/antagonists, opiate agonists/antagonists, antidepressants, prostaglandin inhibitors, tryptophan and alcohol affect the endogenous secretion of melatonin in the epiphysis. Alcohol should not be used concomitantly since it may reduce the effect of melatonin on sleep. Melatonin may reduce the hypotensive effect of nifedipine, caution must be taken during concomitant treatment and exercised with other calcium antagonists. The combination of warfarin or other vitamin K antagonists with melatonin may require dose adjustment of the anticoagulant drugs and should be avoided. Melatonin may enhance the sedative properties of benzodiazepine-related hypnotics therefore concomitant treatment should be avoided. Administration of NSAIDs should be avoided in the evening as these may suppress endogenous melatonin levels. Beta-blockers may suppress the endogenous melatonin and should therefore be administered in the morning.

PREGNANCY, LACTATION and FERTILITY: Mellozzan is not recommended during pregnancy or in women of childbearing potential not using contraceptives, or breastfeeding women. High doses of melatonin and use for longer periods than indicated may compromise fertility in humans.

DRIVING: Melatonin may cause dizziness and should therefore be used with caution if the effects of drowsiness are likely to be associated with a safety risk.

UNDESIRABLE EFFECTS: Melatonin causes few and no serious adverse reactions in the short term, up to three months. Long-term effects are poorly studied. No very common side effects have been reported. In children, the most common adverse reactions were headache, hyperactivity, dizziness and abdominal pain. **Common:** Headache, somnolence. **Other serious side effects:** Hyperbilirubinemia, proteinuria, chest pain, herpes zoster, leukopenia, thrombocytopenia, hypocalcaemia, hyponatraemia, angina pectoris, haematuria, priapism, prostatitis, hepatic enzyme increased, hyperglycaemia. **Consult SmPC for all side effects.**

PHARMACEUTICAL PRECAUTIONS: Store in the original container in order to protect from light.

LEGAL CATEGORY: POM.

Product	NHS Cost (for 30 pack)	Marketing Authorisation Number:
Mellozzan 2mg	£10.89	PL 11243/0050
Mellozzan 3mg	£10.89	PL 11243/0051
Mellozzan 5mg	£10.89	PL 11243/0053

MARKETING AUTHORISATION HOLDER: MEDICE Arzneimittel Pütter GmbH & Co. KG, Kuhloweg 37, 58638 Iserlohn, Germany.

Marketed in the UK by: MEDICE UK Ltd., Ground Floor, Unit B, The Chase, Foxholes Business Park, Hertford, Herts, SG13 7NN, Tel: 0204 582 2845, Email: medicalinformation@medice.co.uk.

Mellozzan is a registered trademark of EQL Pharma AB.

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