MELATOL- melatonin liquid
PureTek Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Melatol Pediatric

DESCRIPTION

Melatonin is a naturally occurring hormone produced by the pineal gland in the brain that helps regulate the sleep-wake cycle. In children, melatonin is commonly used as a supplement to support healthy sleep patterns, particularly in those with conditions like Autism Spectrum Disorder (ASD) and Attention-Deficit/Hyperactivity Disorder (ADHD).

CLINICAL PHARMACOLOGY

Melatonin plays a crucial role in regulating circadian rhythms, including the sleep-wake cycle. Its secretion is stimulated by darkness and inhibited by light, helping to establish and maintain the body's internal clock. In children, melatonin supplementation can be beneficial for those with disrupted sleep patterns due to conditions like ASD and ADHD, promoting sleep onset and improving sleep quality.

Pharmacodynamics:

Melatonin works by binding to melatonin receptors (MT1 and MT2) in the brain, which are involved in regulating sleep and circadian rhythms. MT1 receptor activation primarily influences sleep onset, while MT2 receptor activation helps shift circadian rhythms.

Pharmacokinetics:

After oral administration, melatonin is rapidly absorbed, with peak plasma concentrations reached within 20 to 60 minutes. The bioavailability of melatonin is generally around 15%. It is metabolized primarily in the liver by the cytochrome P450 enzyme system, particularly CYP1A2, and the major metabolite, 6-sulfatoxymelatonin, is excreted in the urine. The half-life of melatonin in plasma ranges from 30 to 60 minutes. Pharmacokinetics in children may vary based on age, weight, and metabolic rate, with melatonin best administered shortly before bedtime to maximize its sleep-promoting effects.

INDICATIONS AND USAGE

Melatol™ Pediatric Sleep and Calm Liquid is intended for occasional or intermittent use to manage sleep-related issues in pediatric patients. It may be recommended for children with sleep disorders such as insomnia, ASD, or ADHD to help regulate sleep-wake cycles, improve sleep onset, and enhance overall sleep quality. This product is

intended for children aged 3 years and older and should be used under the guidance of a licensed healthcare practitioner.

CONTRAINDICATIONS

Melatol™ Pediatric Sleep and Calm Liquid is contraindicated in children with hypersensitivity or allergic reactions to melatonin or any of the ingredients in the formulation. It should not be used in children with known autoimmune disorders, as melatonin may stimulate the immune system and exacerbate these conditions. Additionally, it is contraindicated in children with severe hepatic impairment due to altered melatonin metabolism and in those receiving immunosuppressive therapy, as melatonin may reduce the effectiveness of these treatments. Melatonin use is also contraindicated during pregnancy and lactation due to insufficient safety data.

WARNINGS AND PRECAUTIONS

Consult a licensed healthcare practitioner before starting melatonin, especially if the child has a medical condition or is taking other medications. Melatonin may cause daytime drowsiness, so ensure that the child avoids activities requiring alertness, such as riding a bike or climbing, after taking melatonin. Discontinue use and seek medical advice if any adverse reactions occur.

ADVERSE REACTIONS

Possible adverse reactions include daytime drowsiness, headaches, dizziness, gastrointestinal issues such as nausea or stomach cramps, and mood changes like irritability or agitation. Allergic reactions, although rare, may include rash, itching, swelling, or difficulty breathing. The potential impact on hormonal development, particularly puberty, is not well understood, so long-term use should be monitored.

DRUG INTERACTIONS

Melatol™ Pediatric Sleep and Calm Liquid may enhance the effects of sedatives, hypnotics, and antidepressants, leading to increased drowsiness. It may also interact with medications metabolized by the liver, potentially altering their efficacy. Use with immunosuppressive drugs may reduce their effectiveness, and there is a potential increased risk of bleeding when taken with anticoagulants. Consult a licensed healthcare practitioner before administering melatonin if the child is taking other medications or supplements.

USE IN SPECIFIC POPULATIONS

Pediatric Use: Melatol™ Pediatric Sleep and Calm Liquid is specifically formulated for pediatric patients and should be used under the guidance of a licensed healthcare practitioner. The safety and efficacy of melatonin for long-term use or in high doses for children have not been fully established.

Geriatric Use: This formulation is intended for pediatric use, and data on its use in

elderly patients are not applicable.

Hepatic Impairment: Use in children with severe hepatic impairment is not recommended due to altered melatonin metabolism and increased risk of adverse effects.

Renal Impairment: There is limited data on melatonin use in children with renal impairment. Caution is advised, and a licensed healthcare practitioner should assess the risk-benefit ratio before use.

OVERDOSAGE

In case of overdose, symptoms may include excessive drowsiness, headache, dizziness, nausea, and irritability. In rare cases, more severe symptoms such as confusion, disorientation, or low blood pressure may occur. Treatment should be symptomatic and supportive. If overdose is suspected, contact a poison control center or seek immediate medical attention from a licensed healthcare provider.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Nonclinical studies have shown no evidence of carcinogenicity, mutagenicity, or impairment of fertility at doses significantly higher than those used in humans. However, the long-term effects of melatonin on growth, development, and reproductive health in pediatric populations have not been fully established.

Reproductive and Developmental Toxicology: Animal studies have not shown adverse effects on reproductive or developmental outcomes at doses comparable to those used in pediatric patients. However, since these studies may not predict human response, melatonin should only be used in children when clearly needed and under supervision.

DOSAGE AND ADMINISTRATION

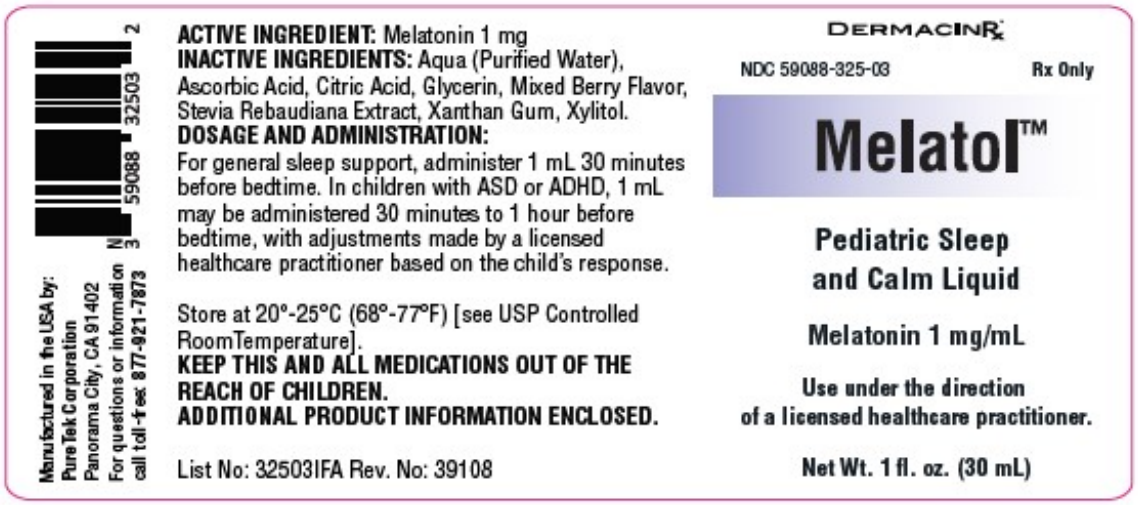
For general sleep support, administer 1 mL 30 minutes before bedtime. In children with ASD or ADHD, 1 mL may be administered 30 minutes to 1 hour before bedtime, with adjustments made by a licensed healthcare practitioner based on the child’s response.

HOW SUPPLIED

Melatol™ Pediatric Sleep and Calm Liquid is supplied in a 1 fl. oz. (30 mL) bottle (NDC 59088-325-03).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**



MELATOL

melatonin liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-325
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MELATONIN (UNII: JL5DK93RCL) (MELATONIN - UNII:JL5DK93RCL)	MELATONIN	1 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-325-03	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/17/2024	

Labeler - PureTek Corporation (785961046)

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