

## NATURAL HEALTH PRODUCT

### MELATONIN Sublingual

For Melatonin products with an oral route of administration, please use the Melatonin-oral monograph.

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

#### Notes

- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

#### Rules for the application of this monograph when combined with other monographs:

- Products containing melatonin must not indicate any uses or purposes related to the maintenance/support of good/general health.
- Products providing a quantity of melatonin that meets the minimum therapeutic dose must indicate a use or purpose associated with melatonin.

#### Date

April 26, 2024

#### Proper name(s), Common name(s), Source Information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source ingredient(s)	Preparation(s)
<ul style="list-style-type: none"> <li>• N-[2-(5-Methoxy-1H-indol-3-yl)ethyl]acetamide</li> <li>• N-Acetyl-5-methoxytryptamine</li> </ul>	<ul style="list-style-type: none"> <li>• Melatonin</li> <li>• Pineal hormone</li> </ul>	Melatonin	Synthetic

References: Proper names: RSC 2023; Buscemi et al. 2004; Common names: RSC 2023, Buscemi et al. 2004; Source information: RSC 2023.

#### Route of administration

Sublingual



## Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for sublingual use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Note that this list does not include prolonged-release, extended-release or delayed-release dosage forms.

## Use(s) or Purpose(s)

- (Used as a) sleep aid (to help promote sleep) (Costello et al. 2014; Wyatt et al. 2006; Brzezinski et al. 2005).
- Helps (to) increase the total sleep time (aspect of sleep quality) in people suffering from sleep restriction or altered sleep schedule (e.g. shift-work and jet lag) (Zhdanova et al. 2001; Brusco et al. 1999; Sanders et al. 1999; Skene et al. 1999; Garfinkel et al. 1995; Sack et al. 1991).
- Helps (to) prevent and/or reduce the effects of jet lag/minimize jet lag (e.g. daytime fatigue, sleep disturbance) (for people/if travelling by plane easterly across two or more time zones/flying east over two or more time zones) (Brown et al. 2009; Herxheimer and Petrie 2002; Suhner et al. 1998a; Petrie et al. 1993; Claustrat et al. 1992; Petrie et al. 1989).
- Helps (to) speed up/reduce the time it takes to fall asleep (sleep onset latency aspect of sleep quality) in people who fall asleep slowly/with delayed sleep phase disorder (van Geijlswijk et al. 2010).
- Helps (to) re-set the body's sleep-wake cycle (aspect of the circadian rhythm) (van Geijlswijk et al. 2010; Kunz et al. 2004; Sack et al. 2000).

## Note

The above claims can be combined on the product label (e.g. Helps re-set the body's sleep-wake cycle (aspect of the circadian rhythm) and increase the total sleep time (aspect of sleep quality) in people suffering from sleep restriction or altered sleep schedule).

## Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

*All uses except jet lag*

0.1 – 10 milligrams of melatonin, per day (Brzezinski et al. 2005; IOM 2004; Kayumov et al. 2001; Koda-Kimble 2001; Zhdanova et al. 2001; Brusco et al. 1999; Jean-Louis et al. 1999; Matsumoto 1999; Jorgensen and Witting 1998; Sack et al. 1997; Attenburrow et al. 1996; Zhdanova et al. 1995; Garfinkel 1995; Tzischinsky and Lavie 1994; Dollins et al. 1994; Dahlitz et al. 1991; James et al. 1987).



### *Jet lag*

0.5 – 10 milligrams of melatonin, per day (Brown et al. 2009; Herxheimer and Petrie 2002; Suhner et al. 1998a).

### **Direction(s) for use**

#### *All uses*

Take as needed, 10 to 30 minutes before bedtime. Place under the tongue until it is dissolved (Abdellah et al. 2023; Bartoli et al. 2012; Naguib and Samarkandi 1999; Jorgensen and Witting 1998).

### **Duration(s) of use**

No statement required.

### **Risk information**

#### **Caution(s) and warning(s)**

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you are taking medications for seizure, blood pressure, to suppress the immune system, to affect mental state or increase sedation, steroids or blood thinners (Wirtz et al. 2008; IOM 2004; Herxheimer and Petrie 2002; Lusardi et al. 2000; Maestroni 1993).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you have a cardiovascular, immune, liver or kidney disease, seizure disorder, asthma or diabetes (Peschke and Mühlbauer 2010; Carrillo-Vico et al. 2005; IOM 2004; der Marderosian and Beuttlers 2003; Sutherland et al. 2003; Calvo et al. 2002; Herxheimer and Petrie 2002; Sutherland et al. 2002; Cagnacci et al. 2001a; Arangino et al. 1999; Sheldon 1998; Maestroni 1993).
- **When using this product** avoid taking with alcohol or products that cause drowsiness (Herxheimer and Petrie 2002; Holliman and Chyka 1997).
- **When using this product** avoid driving or using machinery for 5 hours (Avery et al. 1998; Suhner et al. 1998b).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician** if sleeplessness persists for more than 4 weeks (chronic insomnia) (Buscemi et al. 2004; IOM 2004; Dipiro et al. 2002).

#### **Contraindication(s)**

**Do not use** if you are pregnant or breastfeeding (IOM 2004).

#### **Known adverse reaction(s)**

**Stop use if** allergy occurs or if you experience headache, confusion, or nausea (Herxheimer and



Petrie 2002).

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### **Storage conditions**

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

### **Specifications**

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.



**EXAMPLE OF PRODUCT FACTS:**

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

<b>Product Facts</b>
<b>Medicinal ingredient</b> in each tablet Melatonin <span style="float: right;">XX mg</span>
<b>Uses</b> <ul style="list-style-type: none"> <li>• Used as a sleep aid to help promote sleep.</li> <li>• Helps to reduce the effects of jet lag (e.g. daytime fatigue, sleep disturbance) for people flying east over two or more time zones.</li> <li>• Helps to speed up/reduce the time it takes to fall asleep in people who fall asleep slowly.</li> </ul>
<b>Warnings</b>
<b>As applicable<sup>1</sup>: Allergens: food allergen, gluten (gluten source), sulphites; Contains aspartame</b>
<b>Do not use if you are pregnant or breastfeeding.</b>
<b>Ask a health care practitioner before use if</b> • you are taking medications for seizure, blood pressure, to suppress the immune system, to affect mental state or increase sedation, steroids or blood thinners • you have a cardiovascular, immune, liver or kidney disease, seizure disorder, asthma or diabetes.
<b>When using this product</b> • avoid taking with alcohol or products that cause drowsiness • avoid driving or using machinery for 5 hours.
<b>Stop use if</b> allergy occurs or if you experience headache, confusion, or nausea.
<b>Ask a health care practitioner if</b> sleeplessness persists for more than 4 weeks (chronic insomnia).
<b>Directions</b> Adults 18 years and older: Take X tablet(s), 1 times a day. Take as needed, 10 to 30 minutes before bedtime. Place under the tongue until it is dissolved.
<b>Other information</b> (Add storage information)
<b>Non-medicinal ingredients</b> List all NMIs
<b>Questions?</b> (Call) 1-XXX-XXX-XXXX

<sup>1</sup> This section can be removed from the table if the product contains no allergen or aspartame.

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