



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.

Date

July 31, 2018

Proper name(s), Common name(s), Source material(s)

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

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

References: Proper names: O' Neil et al. 2013, Martindale 2012, Buscemi et al. 2004; Common name: O' Neil et al. 2013, Buscemi et al. 2004; Source material: O' Neil et al. 2013.

Route of administration

Sublingual (Buscemi et al. 2004)

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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ Helps 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; Shamir et al. 2000; Brusco et al. 1999; Sanders et al. 1999; Skene et al. 1999; Dolberg et al. 1998; Garfinkel et al. 1995; Haimov 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 travelling by plane easterly across two or more time zones/if flying east over two or more time zones) (Brown et al. 2009; Herxheimer and Petrie 2009; 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 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).

The following combined use(s) or purpose(s) is/are also acceptable:

- ▶ 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 (e.g. shift work and jet lag) (van Geijlswijk et al. 2010; Kunz et al. 2004; Zhdanova et al. 2001; Sack et al. 2000; Shamir et al. 2000; Brusco et al. 1999; Sanders et al. 1999; Skene et al. 1999; Dolberg et al. 1998; Garfinkel et al. 1995; Haimov et al. 1995; Sack et al. 1991).
- ▶ Helps re-set the body's sleep-wake cycle (aspect of the circadian rhythm) and prevent and/or reduce the effects of jet lag/minimize jet lag (e.g. daytime fatigue, sleep disturbance) (for people travelling by plane easterly across two or more time zones/if flying east over two or more time zones) (van Geijlswijk et al. 2010; Brown et al. 2009; Herxheimer and Petrie 2009; Kunz et al. 2004; Sack et al. 2000; Suhner et al. 1998a; Petrie et al. 1993; Claustrat et al. 1992, Petrie et al. 1989).

Dose(s)

Subpopulation(s)

Adults 18 years and older (IOM 2004)



Quantity(ies)

All uses except jet lag

0.1-10 milligrams of melatonin, per day (Brzezinski et al. 2005; IOM 2004; Andrade et al. 2001; Kayumov et al. 2001; Koda-Kimble 2001; Smits et al. 2001; Zhdanova et al. 2001; Citera et al. 2000; Shamir et al. 2000; Brusco et al. 1999; Jean-Louis et al. 1999; Matsumoto 1999; Dolberg et al. 1998; Lewy et al. 1998; Attenburrow et al. 1996; Garfinkel 1995; Haimov et al. 1995; Tzischinsky and Lavie 1994; Dollins et al. 1993; 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 2009; Suhner et al. 1998a).

Direction(s) for use

All uses except jet lag

Take once a day, at or before bedtime (Murray et al. 2006; Kayumov et al. 2001; Zhdanova et al. 2001).

Jet lag

Take once a day at bedtime, while travelling, and at destination until adapted to the new time zone/daily pattern (Brown et al. 2009; Herxheimer and Petrie 2009).

Duration(s) of use

All Products

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (Buscemi et al. 2004; IOM 2004).

Risk information

Caution(s) and warning(s)

All uses except jet lag

Consult 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).



All uses

- ▶ Avoid taking with alcohol or products that cause drowsiness (Herxheimer and Petrie 2009; Holliman and Chyka 1997).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking medications for seizure, blood pressure, to suppress the immune system (immunosuppressive medications), to affect mental state or increase sedation, steroids or blood thinners (Herxheimer and Petrie 2009; Wirtz et al. 2008; IOM 2004; Scheer et al. 2004; GAO 2001; Lusardi et al. 2000; Lissoni et al. 1999; Holliman and Chyka 1997; Maestroni 1993).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have cardiovascular, immune, liver or chronic kidney disease, hormonal or seizure disorders, asthma, depression, diabetes, low blood sugar, or migraine (Peschke and Mühlbauer 2010; der Marderosian and Beuttlers 2003; Herxheimer and Petrie 2009; Carrillo-Vico et al. 2005; IOM 2004; Scheer et al. 2004; Sutherland et al. 2003; Calvo et al. 2002; Sutherland et al. 2002; Cagnacci et al. 2001a; Cagnacci et al. 2001b; GAO2001; Lusardi et al. 2000; Arangino et al. 1999; Sheldon 1998; Maestroni 1993; Carman et al. 1976).

Contraindication(s)

- ▶ Do not use this product if you are pregnant or breastfeeding (IOM 2004).
- ▶ Do not drive or use machinery for 5 hours after taking melatonin (Avery et al. 1998; Suhner et al. 1998b).

Known adverse reaction(s)

Stop use if allergy occurs or if you experience headache, confusion, or nausea (Herxheimer and Petrie 2009).

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

No statement required.

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.

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