

MELATONIN 10 mg TIMED RELEASE DUAL ACTION

UPC CODE 0 6464206824 8 NPN # 80030987

NATURAL HEALTH PRODUCTS DIRECTORATE (NHPD) CLAIMS:

Jamieson Melatonin 10 milligram (mg) Timed Release Dual Action is approved for the following NHPD claims:

- Helps to reduce the time it takes to fall asleep (sleep onset latency aspect of sleep quality) in people with delayed sleep phase syndrome
- 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
- Helps relieve the daytime fatigue associated with jet lag
- Helps re-set the body's sleep-wake cycle (aspect of the circadian rhythm)

GENERAL INFORMATION

Melatonin is a natural substance secreted by the pineal gland in the brain. It is recognized as a key element in regulating the body's day/night metabolic rates. The secretion of melatonin is synchronized with our biological clock, which dictates the daily changes upon the body's metabolic activity. These are known as our circadian rhythms.

Melatonin is a hormone derived from serotonin and is only produced when the surrounding environment is dark.² The pineal gland receives information from the optic nerve about the ambient light levels and adjusts its melatonin output accordingly. When night falls, the pineal gland responds to the decreased light levels by greatly increasing its output of melatonin. Melatonin produces the feeling of sleepiness. After a few hours, blood melatonin levels reach a point where sleep is induced; they reach a peak a few hours after the onset of sleep and then gradually decrease throughout the sleep period. Exposure to light results in a rapid breakdown of melatonin and suppresses its production. Melatonin thus plays a critical role in our sleep/wake cycle and irregularities in melatonin production can cause sleep problems, lethargy and mood disorders.

Melatonin is also effective in people suffering from jet lag. In a Cochrane Review, melatonin was found to prevent or reduce jet lag when taken close to the target bedtime at destination. It is most recommended for people traveling across five or more time zones; however, there is still a benefit for those traveling over two to four time zones.

Melatonin is an excellent antioxidant; it is one of the most proficient free radical scavengers. While many antioxidants work in only certain areas of the body, melatonin has the ability to permeate any cell in any part of the body to remove free radicals. Free radicals are highly reactive, unstable molecules that can directly damage cells. These reactive, unstable molecules formed during oxidative metabolism have an ultimate need to steal electrons from other molecules, including cell membranes, proteins, and DNA. As an antioxidant, melatonin prevents the perpetuation of this potentially harmful chain reaction to support the health of all body cells.

Irregularities in melatonin production can cause sleep problems, lethargy and mood disorders.⁷ Melatonin production usually decreases with age.⁸ Thus, the total amount of melatonin produced is reduced substantially and the day/night cycling often becomes less pronounced.⁸ A deficiency of melatonin in the body can cause sleeplessness,⁸ and thus needs to be replenished for optimal sleep patterns to be restored.⁵

Melatonin from Jamieson Laboratories is synthesized to guarantee complete safety from Bovine spongiform encephalopathy (BSE), commonly known as mad-cow disease. Natural hormones, those which are not synthetic, are often derived from glandular extracts of cows. Thus, there can exist the danger of hormones being derived from glandular extracts of an infected animal. Synthesized Melatonin from Jamieson guarantees complete safety from BSE.

Jamieson Melatonin 10 mg provides dual action timed release support for people experiencing trouble falling and staying asleep. The first layer dissolves quickly to provide an immediate 5 mg dose of melatonin to help you fall asleep. The second layer allows a gradual release of 5 mg of melatonin over 4-6 hours to help keep you asleep for a full night's rest.

For Accidental Overdose (such as child ingesting formula) Dial 911, 0 for operator assistance or call your nearest Poison Control Centre.

For Professional Use Only

The information contained here has been accumulated from many sources. Indications are not intended as cures, they are simply a guideline to be used at your professional discretion.



Melatonin 10 mg Timed Release Dual Action is formulated from natural sources and is pharmaceutically tested to guarantee full potency and absolute clinical purity.

What makes Melatonin 10 mg Timed Release Dual Actionfrom Jamieson Laboratories different...and why does this difference mean better?

- 1) Dual action support to help restore natural sleep patterns.
- 2) Bi-layer tablet delivers immediate dose of 5 mg melatonin and then gradually releases 5 mg of melatonin over a 4 6 hour period.
- 3) Vegetarian-friendly formula.
- 4) This product contains pharmaceutical grade melatonin, which is the exact chemical duplicate of natural melatonin. It therefore provides an equally effective, yet much safer, dose of active ingredient compared to melatonin derived from animal sources. This form also assures consumers complete safety from adverse health issues such as BSE.
- 5) Free of artificial flavours, colours or preservatives.
- 6) Our premium formulations are manufactured using the 360 Pure process a minimum of 360 quality tests that guarantee traceability and reliability of raw material, product safety, full potency and absolute clinical purity.

INGREDIENT INFORMATION

EXCIPIENTS

Cellulose, Dicalcium Phosphate, Water-Soluble Cellulose, Vegetable Stearic Acid, Vegetable Magnesium Stearate, Modified Cellulose Gum, Sodium Copper Chlorophyll, Silica, Hydroxylpropylcellulose.

DIRECTIONS

Adults – Take 1 caplet daily at or before bedtime. For use beyond 4 weeks consult a health care practitioner. Store between 15°C-25°C, away from children.

INDICATED BENEFITS

- Helps to reduce the time it takes to fall asleep (sleep onset latency aspect of sleep quality) in people with delayed sleep phase syndrome
- 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
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NUTRIENT INTERACTIONS

Drug Interactions

Antidepressant medications, antipsychotic medications, blood pressure medications, blood thinning medications, anticoagulants, steroids and immunosuppressant medications. Dietary supplements such as 5-HTP, kava kava, or valerian in combination with melatonin may increase its sedative side effects.

Nutrient Depletions

Selective serotonin reuptake inhibitors (SSRIs), calcium channel blockers (nifedipine, verapamil, diltiazem, amlodipine, nimodipine, felodipine, nisoldipine, beprimil), beta-blockers may reduce melatonin production in the body, nonsteroidal anti-inflammatory drugs(NSAIDs), caffeine, tobacco, alcohol can all diminish levels of melatonin in the body.

WARNINGS AND PRECAUTIONS

Consult a health care practitioner prior to use if you have a hormonal disorder, diabetes, liver or kidney disease, cerebral palsy, seizure disorders, migraine, depression and/or hypertension or if you are taking blood pressure or sedative/hypnotic medications. If symptoms persist continuously for more than 4 weeks (chronic insomnia), consult your health care practitioner. Do not drive or use machinery for 5 hours after taking melatonin. Do not use if you are pregnant or breastfeeding. Do not use if you are taking immunosuppressive drugs.

TOXICITY, ADVERSE REACTIONS, SIDE EFFECTS

None known when taken as directed.

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REFERENCES

- Buscemi, N., Vandermeer, B., Pandya, R., Hooton, N., Tjosvold, L., Hartling, L., Baker, G., Vohra, S., Klassen, T.(2004). *Melatonin for treatment of sleep* disorders. Evidence Report/Technology Assessment No. 108. AHRQ Publication No. 05-E002-2. Rockville (MD): U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality.
- Cardinali, D.P., Pevet, P. (1998).Basic aspects of melatonin action. Sleep Medicine Reviews. 2(3):175-190.
- 3. Lewy, A.J., Wehr, T.A., Goodwin, F.K., Newsome, D.A., Markey, S.P. (1980). Light Suppresses Melatonin Secretion in Humans. *Science*. 210(4475):1267-1269.
- 4. Herxheimer A, Petrie KJ. (2002). Melatonin for the prevention and treatment of jet lag. *TheCochrane Database of Systematic Reviews*. (2):CD001520.
- Reiter, R.J., Tan, D.X., Manchester, L.C., El-Sawi, M.R. (2002). Melatonin reduces oxidant damage and promotes mitochondrial respiration: implications for aging. *Annals of the New YorkAcademy of Sciences*.959:238-250.
- Machlin, L.J., Bendich, A. (1987). Free Radical Tissue Damage: Protective Role of Antioxidant Nutrients. The Journal of the Federation of American Societies for Experimental Biology. 1:441-445.
- 7. Brusco, L.I., Fainstein, I., Marquez, M., Cardinali, D.P. (1999). Effect of melatonin in selected populations of sleep-disturbed patients. *Biological Signals and Receptors*. 8(1-2):126-31.
- 8. Karasek, M. (2004). Melatonin, Human Aging, and Age-related Diseases. *Experimental Gerontology*. 39:1723-1729.
- Stargrove, M.B., Treasure, J., McKee, D.L. (2008). Herb, Nutrient, and Drug Interactions: Clinical Applications and Therapeutic Strategies. St. Louis, MO: Mosby Elsevier.

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