



EUROHEALTH®
Guiding You to Good Health



Melatonin - BioTonin®

Regulates the Anti-Aging Process and Sleep/Wake Cycles
Régulation du Processus Anti-Âge et des cycles Sommeil/Eveil
Reguliert den Alterungsprozess und die Schlaf-Wach-Rhythmen
Regula el proceso de anti-envejecimiento y los ciclos de sueño y vigilia



CLINICALLY TESTED

120 TABLETS

Melatonin-BioTonin® - *Sleep well and wake up refreshed*

Fact Sheet for Health Professionals (rev. 2019-10)

COMPOSITION AND DOSAGE FORM

Regular Melatonin (BioTonin®) tablets:

Melatonin 1 mg and 3 mg in tamper proof blisters of 30 tablets, packed 120 tablets in a box.

Sublingual Melatonin (BioTonin®) tablets:

Melatonin 0.2 mg, 0.5 mg and 2.5 mg in tamper proof blister packs of 30 tablets packed 120 tablets in a box.

INDICATIONS

Temporary sleep disorders including those from jetlag and shift work. Melatonin functions as the biological timekeeper of the production and the secretion of most human hormones that in turn regulates all vital body-functions. As a conductor of a philharmonic orchestra, it balances the body's symphony of hormone secretion. Having this function, Melatonin, plays a key role in, controlling the aging-process, acting as a promoter of life extension and longevity; in relieving menopause discomfort, depression, arthritis, multiple sclerosis, epilepsy, coronary artery disease, high cholesterol levels, hypertension, autism, migraine, fetal alcohol syndrome, stress, Alzheimer's, Parkinson's, cancer, weak immune system, poor libido/sex drive, eye diseases. Melatonin is a strong antioxidant. There are numerous studies indicating that Melatonin increases libido/the sex drive in men and women, and that it positively affects the reproductive systems.

TOXICITY/SIDE EFFECTS

Melatonin is one of the least toxic substances known. In carefully monitored studies people have been taking as much as 6000 mg daily - for over nine months - with no sign of toxicity. In the most extensive clinical trial to date, a very high dose of Melatonin, 75 mg, has been given to 1400 women for up to four years with no significant ill effect. No alarming side effect has been reported to FDA in the years that Melatonin has been available over the counter. However, Melatonin has not been tested in long term, large-scale studies to determine its ultimate safety.

RECOMMENDED DOSAGE/DIRECTIONS FOR USE

Regular tablets: One tablet 1-2 hours before bedtime.

Sublingual tablets: One tablet 10 -20 minutes before bedtime. Put under tongue and let it "melt".

The bioavailability of Melatonin varies greatly between individuals; doses between 0.2 mg and three 3 mg tablets are all within the recommended range (0.5-9 mg).

A physician should be consulted before continual long-term use.

Melatonin should be taken only at bedtime. After administration of Melatonin, one should not operate machinery or a vehicle or perform any activity that could be affected by being tired. Pregnant or lactating women should consult a physician prior to administration of Melatonin formulations. Should not be used by children, teenagers or young adults, without a physician's advice.



MODE OF ACTION Melatonin, a hormone-like substance, is mainly secreted during nocturnal hours by the pineal gland, located “under” the brain, as a response to darkness, regulating the body’s sleep/wake patterns. Therefore, it is often referred to as “The Dark Hormone”. The ancient Greeks believed, that the pineal gland was the “seat of the soul”, a theory reaffirmed by the French physiologist and mathematician Descartes, in the early 1600’s. However, the biological role of the pineal gland and Melatonin, was not established until 1958. Melatonin secretion peaks at puberty and declines sharply with age. Stress and environmental changes can negatively affect the production of Melatonin. Intake of certain common prescription drugs, such as beta-blockers, NSAIDS and sleeping pills, as well as aspirin, caffeine, tobacco and alcohol have been shown to deplete the body’s supply of Melatonin.

Altered work-schedules and time zone changes confuse the body’s bio-rhythm, and decrease the production of Melatonin, and it typically takes several days for the body to adjust and settle into new sleep/wake patterns.

RESEARCH REPORTS SLEEP/INSOMNIA/JET LAG/SHIFT WORK
Dietary supplementation has shown Melatonin to be a natural sleep inducer and a means to reset the internal body clock as needed for the relief of temporary sleep disturbances and jetlag. Clinical studies have shown Melatonin to have an excellent effect on insomnia, jetlag and shift work maladaptation, without the side effects of conventional sleeping pills such as “hang-over” and habit-forming use-dependence.

IMMUNE DEFENSE SYSTEM
Melatonin buffers the effects of stress and reduces the gradual decline of immunity that accompanies stress. Researchers have demonstrated Melatonin’s ability to treat Cancer, slow progression of AIDS, make the body more resistant to colds, and protect the immune system from the toxic effects of chemotherapy. Numerous studies reveal that supplemental Melatonin can restore thymus gland function, boost immune function by increasing the production of T-cells, important to our natural defenses, and increase the body’s anti-tumor activity, particularly in advanced Cancer patients.

Melatonin also shows promise as a treatment for a number of other diseases and conditions, including Hypertension, high Cholesterol, various kinds of Cancer, Autism, Epilepsy, Migraine, Fetal Alcohol Syndrome, and Alzheimer’s disease.

LONGEVITY/AGING/QUALITY OF LIFE
Melatonin has strong anti-aging properties. According to the experts, Melatonin has many vital functions in our body, therefore prolonging our life span. It is considered to be “The Policeman of all Policemen”, regulating the secretion of other important bodily hormones, governing the body at large and of course also the important aging process. Many people take supplemental Melatonin every day for this purpose rather than for insomnia/sleep deprivation conditions. In such cases a dosage of 0.2 - 1 mg is normally enough.

ANTIOXIDANT/FREE RADICAL SCAVANGER
Melatonin has been shown to be an extremely potent and wide-ranging antioxidant, protecting every part of the cell in the body, including vital brain cells. Antioxidants are vital to our health because they rid the body of dangerously reactive molecules called free radicals. Over 100 diseases have now been linked with free radical damage, including Cataracts, Macular Degeneration, Alzheimer’s disease, Parkinson’s, Arthritis, Cancer and the Aging Process itself.

SEASONAL AFFECTIVE DISORDER (“SAD”)
Melatonin has been shown to be effective in persons with SAD, Seasonal Affective Disorder, which is caused by the breakdown of the circadian/body-clock rhythm.

PRODUCTION/“GMP” Supplemental Melatonin, although synthetically produced, is identical to the naturally occurring hormone in the body. However, there are significant differences in the purity of Melatonin-preparations on the market. It is very important that the active ingredients and other raw material/components used are of the highest pharmaceutical grade/quality available. Also, the production of the finished dosage form should be performed according to approved standards, which adhere to **Good Manufacturing Practices (“GMP”)**. This is applicable for all pharmaceutical products, including prescription drugs, as well as Over-the-Counter drugs (“OTC”).



Preferably, there should be a **Drug Master File ("DMF")** number for all active ingredients as issued by the **Food & Drug Administration ("FDA")**. **The highest quality pharmaceutical grade Melatonin is being offered in sublingual tablets of 0,2 mg, 0,5 mg and 2,5 mg and swallow tablets of 1,0mg and 3,0 mg.**

All products are packed in tamper proof blister packs, 30 to each blister in 120 capsules boxes. Production adheres fully to the principles of **Good Manufacturing Practices (GMP)**.

Although this product is not a drug (no medical claims are being made), it is considered to be a Dietary Supplement; no compromises are made on the quality of the ingredients, or on the production of the final dosage form. While the US market does not demand adherence to these strict rules, other markets (e.g. Europe and Asia), only accept production according to these standards, rules and regulations. As a result many products manufactured in the US, or abroad for the US market, do not meet these criteria and standards and must therefore be considered as inferior, even fraudulent.

For your safety and for efficacy reasons, make sure you only buy and use products produced in compliance with "GMP", containing pharmaceutical grade ingredients. Not all products are alike! "More" or "cheap" is not always better!

Some countries (with a strong domestic pharmaceutical industry and a strongly regulated system) have elected to restrict the availability of Melatonin-based preparations, while the authorities in the United States actually support this nonaddictive, natural alternative to traditional habit-forming sleeping pills.

CAUTION For adult use only.

Melatonin should not be taken, without the advice and close supervision of a physician, by:

- children of all ages.
- persons taking prescription steroid drugs.
- women attempting to conceive.
- pregnant women and nursing mothers.
- persons with autoimmune diseases, severe allergies and immune system cancers such as leukemia and lymphoma.
- persons with severe mental illness.

STORAGE Store at or below 20° C in sealed containers in a dry place.

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