Basic Facts

Melatonin (N-acetyl-5-methoxytryptamine) is a natural hormone which regulates the biological clock of man. It is produced in the pineal gland and cyclically released into blood in small quantities at a certain rhythm. In this way it «informs» the entire body about the current circadian (daily rhythm) phase. Melatonin can be found in human beings, animals, plants and even monocellular and phylogenetically very old algae (3 billion years). Melatonin is mainly secreted when it is dark. During the day hardly any melatonin is produced. Due to the different conditions of light there exists, in addition to the circadian (daily) rhythm, also an annual rhythm. In winter, melatonin is produced and released into blood over a longer period of time than in summer.

Up to the third month of life hardly any melatonin is produced. Thereafter, the serum melatonin values increase and eventually the circadian cycle develops. Between the age of one and three years the highest melatonin concentrations are reached. Elderly people no longer have the high melatonin values of young people during the night. This is possibly also the reason why the elderly complain more frequently about sleep disturbances. In young people an about 12-fold increase in the melatonin values is observed during the night while the increase in the elderly is only about 3-fold.

Effects

The best researched and documented effect of melatonin is its influence on the sleep-wake rhythm. Melatonin is well suited to treat difficulties in falling asleep as well as in sleeping through. Melatonin has also proven to be effective to relieve jet-lag symptoms. When taken, the level of activity that existed before the flight is reached faster. Melatonin is also suitable for shift workers, who often suffer from sleep disturbances.

Although the life-prolonging effect for human beings has not yet been proven, it has been confirmed that melatonin has a very positive effect on the quality of life in old age. This thesis is supported by the fact that a restrictive food intake, which goes hand in hand with a clearly increased melatonin production, admittedly leads to a prolongation of life and to a reduced incidence of age-related diseases in all test animals examined up to now.

Indications

Sleep: After its discovery in 1958 by Dr. Aaron Lerner, melatonin has been the subject of intensive research since the beginning of the 1980s. At this time the effect of melatonin on the sleep-wake regulation was discovered and the substance used for sleep disorders and the jet lag. In double-blind studies it could be shown that melatonin helps the individual to fall asleep and increases the quality of sleep. Moreover, sleeping-through is supported. However, melatonin cannot be compared with conventional soporifics, which often have very pronounced side effects and also a quite considerable habit-forming potential. Some soporifics even suppress the production of melatonin.

Melatonin, however, has no addictive effect but optimizes the natural sleep rhythm. This is the reason why it does not cause tiredness in the morning, which is often felt by people taking soporifics.

Jet lag: Melatonin is capable of regulating the shifts in the sleep-wake rhythm which often occur in flights crossing several time zones. Several studies have proven that melatonin accelerates the adaptation to the other time zone and may even suppress jet-lag symptoms.

Immune system, cancer and aging: In the mid-90s it became known that melatonin protects the cells against harmful radicals. Melatonin also increases the cytotoxic effect of NK cells (natural killer cells), which are important for the immune defense, and stimulates the immune system. The immunosuppressive effects of cortisol can be cancelled by melatonin.

On account of the cell-protective, immuno-stimulating and antiproliferative effects of melatonin, studies were carried out in which the substance was used to treat cancer. Although these studies are not yet indicative of an increase in the cancer survival rate after administration of melatonin, the survival times of the patients seem to become longer.
Further effects of melatonin are a lowering of the intra-ocular pressure, which could be of importance for treating glaucoma, a disease characterized by increased intra-ocular pressures. The respective trials are already being carried out.

**Further (possible) fields of application are:**

- **Tinnitus:** After having taken melatonin the patients reported that their sleep had become better. Although the symptoms of tinnitus are not influenced, the better quality of sleep increases the quality of life.

- **Glaucoma:** By lowering the intra-ocular pressure.

- **Depression:** Patients with certain types of depression have low melatonin levels.

- **Hypertension:** Melatonin has a hypotensive effect.

- **Cardiovascular system:** Melatonin, by its antioxidative effects, protects the heart and vessels against harmful cholesterol deposits.

**Composition**

One capsule contains 1 mg, 3 mg or 5 mg pure, synthetized melatonin (N-acetyl-5-methoxytryptamine) in pharmaceutical grade. Other ingredients: rice flour, magnesium stearate

**Dosage**

Due to its short half-life of about 30 minutes, melatonin should be taken shortly before going to bed with plenty of fluid.

To stimulate the immune system and to improve well-being:

- up to 40 years: 1 mg daily
- 40–60 years: 1–3 mg daily
- over 60 years: 3–6 mg daily

Whenever required (stress, overweight, etc.) also higher doses may be taken:

As a soporific: up to 10 mg daily

**For shift workers:** up to 5 mg daily 30 minutes before the beginning of the subjective time of sleep

Against jet lag:

1st day: 1–3 mg at 11:00 p.m. (local time in the destination country)

2nd day: 1–3 mg at 10:30 p.m. (local time in the destination country)

3rd day: 1–3 mg at 10:00 p.m. (local time in the destination country)

**Side Effects, Contraindications**

Melatonin is an endogenous hormone. Dosages of up to 800 mg/day were well tolerated in self-experiments and in studies. In order to reach the desired effects, lower milligram-range doses, as they are guaranteed by the current melatonin preparations, are sufficient. The following undesirable effects, which – however – are mostly only transient and light, have been observed: hypothermia, sleepiness/drowsiness during the day (mainly in persons having suffered from disturbed sleep for a longer period of time and now having a rather high pent-up demand for sleep), prolonged reaction times.

Only in very rare cases reddening of the skin, abdominal cramps, visual disturbances, headache (similar to migraine) and diarrhea were described, however it could not be proven for sure whether these side effects were due to melatonin or other components. All undesirable effects were completely reversible and short-lived. The time point of administration of melatonin must be adjusted to the phase situation, to the formulation as well as to any hepatic or renal function disorders in order to avoid undesirable effects such as overdosage, phase shifting, etc.

In cases of persons taking steroid-containing medications, during pregnancy, lactation, the intake of SSRI’s (antidepressants), and in the presence of severe allergies, Melatonin should only be taken in exceptional cases and under the continued supervision of a doctor.

**Instructions**

Do not use before driving a car or operating machines.

Generally, self-medication should not be practiced and a doctor should be consulted before intake. This particularly applies to persons who continuously have to take other medications. Store in a cool, dry place and keep out of reach of children.

**Melatonin Product Groups**

Melatonin can be found in the following product groups (www.vitabasix.com):

- **Hormones & Hormone-like Substances**
- **Immune System, Cell Protection & Antioxidants**
- **Sleep**

**Important information:**

Our products are manufactured in accordance with the GMP (Good Manufacturing Practice) standard. Their quality, purity and concentration are regularly tested in independent test laboratories, in keeping with the FDA (Food and Drug Administration) guidelines.

Our products should be regarded as preventive measures or measures to enhance the individual’s general wellbeing. Patients must consult a doctor before using the products for the treatment of diseases.