PRODUCT INFORMATION

Melachron®

A chronobiology based melatonin preparation for improving the behavior of falling asleep and sleeping through the night. The patented formulation guarantees the release of melatonin for a period of up to 8 hours. Administration once a day in the evening ensures therapeutically relevant melatonin levels during the whole night and absolute vitality the following morning.

Basic Facts

Melachron® is a specially developed tablet form of the natural hormone melatonin which occurs in nearly all life forms investigated so far. This patented formulation ensures the correct biological administration of melatonin for a minimum of 6–8 hours.

Melatonin is mainly produced in the pineal gland. It is released into the blood in a specific daily rhythm. Thus it «informs» the whole body about the circadian (daily rhythm) phase. In particular, the inner clock is synchronized anew every day by this process. Melatonin is mainly produced during the night; it is hardly formed during the day. In addition to this circadian (daily) rhythm, there is also an annual rhythm because of the different lighting conditions in the various seasons. In the winter melatonin is produced and released into the blood for a longer period of time than in the summer. In some animals this causes a change in the color of fur, hibernation, willingness to mate, etc.

Up to the age of 3 months humans hardly have a melatonin day and night rhythm. After this time the nocturnal serum levels increase and a circadian rhythm develops gradually. The highest melatonin concentrations are achieved between the age of one and three years. Thereafter the production is consistently reduced. Therefore elderly individuals do not have as high values in the night as younger people do. In the latter one finds an 8- to 10-fold increase in melatonin levels during the night. Elderly persons, on the other hand, experience only a two-fold increase of their daytime values very late at night and for too short a period. This marginal difference between day and night levels is not sufficient to inform the body correctly of the change between day and night and to regulate the inner clock. Possibly this is one reason why the elderly report sleep disorders and related illnesses more often.

Effects

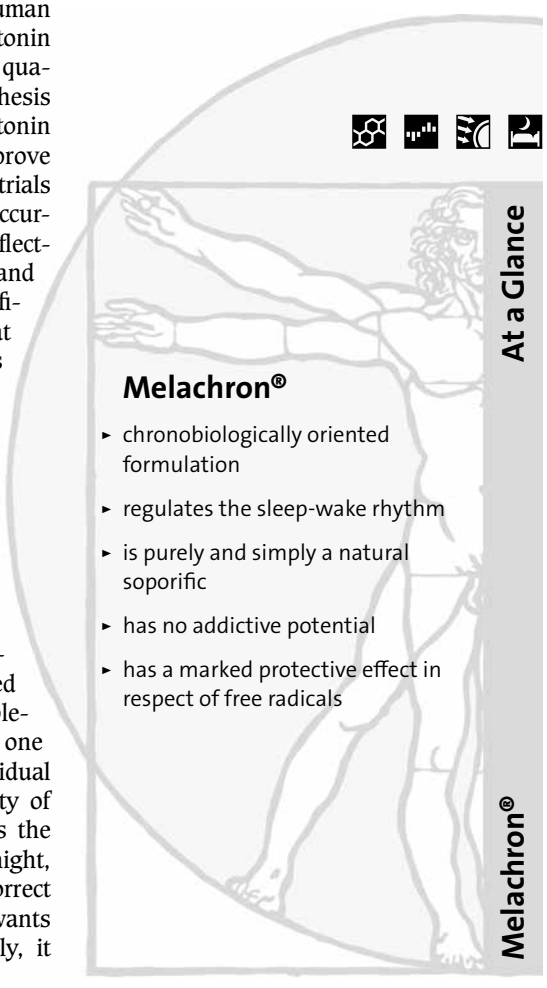
The best researched effect of melatonin is its influence on the sleep-wake rhythm. Melatonin is suited to treat difficulties in falling asleep as well as sleeping through the night. Melatonin is also able to relieve jet lag symptoms. When taken at the correct time the sleep-wake rhythm that prevailed before the flight is achieved faster. Melatonin is also suitable for shift workers who frequently suffer from disturbed sleep because they have to alter their day and night rhythm – as do those who suffer from the jet lag syndrome.

Although it has not yet been proved that melatonin prolongs survival in human beings, it was confirmed that melatonin has a very positive influence on the quality of life in aged individuals. This thesis is supported by the fact that high melatonin concentrations in the aged clearly improve general wellbeing – as shown in all trials undertaken so far – and reduce the occurrence of age-related diseases. Thus reflecting both its effect as a sleep regulator and as a highly potent antioxidant. Specifically in human beings it was proved that a restful night's sleep greatly improves general wellbeing the next day.

Indications

Sleep: melatonin was discovered by Dr. Aaron Lerner in 1958 and is being intensively researched since the beginning of the 1980's. At this time the regulatory effect of melatonin on the sleep-wake rhythm was discovered. The substance started to be used for sleep disorders and jet lag. In double-blind studies it was shown, on the one hand, that melatonin helps the individual to fall asleep and improves the quality of sleep and, on the other hand, assists the individual in sleeping through the night, provided it is administered in the correct dose and pharmaceutical form. If one wants to achieve both effects simultaneously, it must be ensured that enough melatonin is absorbed by the body at the beginning of the sleeping phase (phase of falling sleep), and that sufficient melatonin is present in the body for the next 6–8 hours or so (phase of sleeping through the night).

Clinical trials have shown that a combination of fast- and slow-release melatonin designed to fulfill these requirements (which is achieved for the first time in Melachron®) regulates sleep in a much better way than products that release melatonin only fast or only slowly.



Melachron® cannot be compared with conventional soporifics because the latter commonly have pronounced side effects and also a substantial addictive potential. In addition, some of these soporifics suppress the body's own production of melatonin. Melatonin, on the other hand, possesses no such addictive potential. Rather, it optimizes the natural sleep rhythm. Thus it does not cause morning fatigue which is commonly associated with the intake of other soporifics.

Some trials indicate that certain soporifics, even those being taken for a longer period of time can be discontinued, provided the intake of melatonin is started the very next evening. When such a change is made, the anticipated adverse effects like marked sleep disorders and/or withdrawal symptoms frequently do not occur.

Jet lag: melatonin is able to correct shifts in the sleep-wake rhythm, which are especially common during intercontinental flights or among shift workers. Several trials have shown that melatonin may accelerate the individual's re-adjustment to the altered day and night conditions and suppress jet lag symptoms.

Cell protection: in the mid-90's it was discovered that melatonin protects cells from harmful radicals. Besides, melatonin enhances the cytotoxic effect of natural killer cells (NK cells) which are important for the immune defense, and thus stimulates the endogenous immune system.

Composition

One tablet contains 3 mg (1/3 immediately releasing, 2/3 pulsatile releasing (in bursts)) pure synthetized melatonin (N-acetyl-5-methoxytryptamine) in pharmaceutical grade. Other ingredients: mannite, dicalcium phosphate, microcrystalline cellulose, magnesium stearate, SiO_2

Dosage

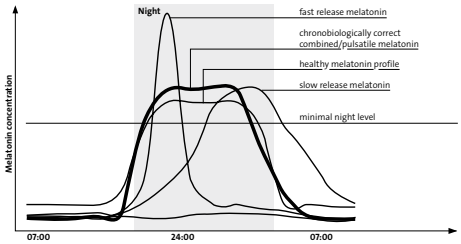
Due to its short half-life of about 30 minutes Melachron® should be taken immediately before going to bed.

Recommended dose: 1 tablet per day. In cases of highly tense and/or excessively overweight persons the dose may have to be increased to 2–3 tablets per day in order to achieve the desired effect because of the exceptional circumstances in such cases (high adrenalin levels and a large body volume).

Metabolization

Melatonin is mainly transformed into 6-hydroxymelatoninsulfate in the liver and is eliminated through the kidney. Melatonin has a very short half-life of about 30 minutes.

After taking Melachron®, approx. 1/3 of the quantity is immediately released, and the remaining 2/3 are released in several small bursts at different times (pulsatile). This helps the individual to fall asleep quickly as well as it ensures physiological serum concentrations for sleep maintenance for up to 7 hours. Thereafter physiological daytime values are achieved about 8 hours after melatonin is taken in the evening.



Side Effects, Contraindications

Melatonin is an endogenous hormone of the body. Doses of up to 800mg/day have been well tolerated in trials. However, doses in a low milligram range are sufficient to achieve the desired effect; such doses are provided by currently available melatonin preparations.

The following adverse effects have been observed; the majority of these were transient and mild: hypothermia, drowsiness/somnolence during the day (especially in persons who have been suffering from disturbed sleep for a long time and need to make up for sleep backlogs), prolonged reaction time. Reddening of the skin (erythema), abdominal cramps, impaired vision, headache (similar to migraine) and diarrhea have been reported in rare cases; however, it could not be proved whether these side effects were related to melatonin or other components (e.g. contaminants). All adverse effects were entirely reversible and of short duration. The time point of administration must be adjusted to the phase situation, the formulation, and any hepatic or renal function disorders the patient may have, in order to avoid adverse 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. The doctor should be consulted before any intake. This is especially true for persons who have to take other medications. Store in a cool, dry place and keep out of reach of children.

Melachron® Product Groups

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

Hormones & Hormone-like Substances

Chronobiology

Immune System, Cell Protection & Antioxidants

Sleep

Manufacturer:

VitaBasix®

by LHP Inc.

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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.

Subject to alterations and printing errors. Version January 2018