

Filfresh[®]

Melatonin

COMPOSITION

Filfresh[®] Tablet : Each tablet contains Melatonin INN 3 mg.

PHARMACOLOGY

Melatonin is a hormone secreted by the pineal gland in the brain that helps regulate other hormones and maintains the body's circadian rhythm. It is involved in photic regulations of various kinds, including adaptation to light intensity, daily changes of light and darkness, and seasonal changes of photoperiod lengths. Darkness stimulates the production of melatonin while light suppresses its activity. Jet lag, shift work, and poor vision can disrupt melatonin cycles. Melatonin helps control the timing and release of female reproductive hormones. Many researchers also believe that melatonin levels are related to the aging process. In addition to its hormonal actions, melatonin has strong antioxidant effects. It also helps strengthen the immune system.

MECAHNISM OF ACTION

After administration, melatonin binds with its receptors. Two types of melatonin receptor subtypes – MT1 & MT2 have been identified in human. Melatonin receptors are found in the brain and some peripheral organs. The MT1 subtype is present in the pars tuberalis of the pituitary gland and the suprachiasmatic nuclei of the hypothalamus. The MT2 subtype is mainly present in the retina. Increased level of Melatonin initiates neural & endocrine signals to optimize the levels of neurotransmitters e.g. increased serotonin, increased GABA & decreased dopamine, which induces & sustains sleep, as well as, maintains body's circadian rhythm.

INDICATION AND USAGE

Filfresh[®] is used for numerous conditions but is showing the most promise in short-term regulation of sleep patterns, including jet lag.

● Insomnia

Filfresh[®] helps to induce sleep in people with

- disrupted circadian rhythms (such as those suffering from jet lag or poor vision or those who work the night shift)
- low melatonin levels (such as some elderly and individuals with schizophrenia)
- children with learning disabilities who suffer from insomnia.

● Osteoporosis

Filfresh[®] stimulates cells called osteoblasts that promote bone growth.

● In Menopause

Filfresh[®] helps peri- or postmenopausal women to regulate sleep patterns.

● Eating disorders

Filfresh[®] levels may play a role in the symptoms of anorexia.

● Sarcoidosis

● Attention Deficit Hyperactivity Disorder (ADHD)

It may be effective in managing sleep disturbances in children with this condition.

DOSAGE AND ADMINISTRATION

Adult :

Insomnia : 3-6 mg one hour before bedtime

Jet lag : 0.50 to 5 mg one hour prior to bedtime at final destination or, 1 to 5 mg 1 hour before bedtime for 2 days prior to departure and for 2 to 3 days upon arrival at final destination.

Eastbound travel - Take a preflight early evening treatment followed by treatment at bedtime for 4 days after arrival.

Westbound travel - Take for 4 days at bedtime when in the new time zone.

Sarcoidosis : 20 mg per day for 4 to 12 months.

Depression : 0.125 mg twice in the late afternoon, each dose 4 hours apart.

Difficulty falling asleep : 5 mg 3 to 4 hours before an imposed sleep period over a 4-weeks period.

Children (6 months to 14 years of age with sleep disorders) :

0.30 mg/day

CONTRAINDICATION

Melatonin should not be used by patients who have autoimmune diseases.

PREGNANCY & LACTATION

Information regarding safety and efficacy in pregnancy and lactation is not available.

PRECAUTIONS

Caffeine and fluvoxamine may increase the effects of melatonin, while melatonin may decrease the antihypertensive effect of nifedipine.

ADVERSE REACTIONS

Possible adverse effects include headache and depression. Drowsiness may be experienced within 30 minutes after taking melatonin and may persist for 1 hour and thus may affect driving skills.

DRUG INTERACTIONS

Antidepressant Medications

Melatonin reduces the antidepressant effects of desipramine and fluoxetine. In addition, fluoxetine leads to measurable depletion of melatonin in people.

Antipsychotic Medications

People with schizophrenia and tardive dyskinesia taking antipsychotic medications with melatonin has significantly reduced mouth movements compared to those who did not take the supplements.

Benzodiazepines

The combination of melatonin and triazolam improves sleep quality. In addition, there have been a few reports suggesting that melatonin supplements may help individuals stop using long-term benzodiazepine therapy.

Blood Pressure Medications

Melatonin may reduce the effectiveness of blood pressure medications like methoxamine and clonidine. In addition, calcium channel blockers (such as nifedipine, verapamil, diltiazem, amlodipine, nimodipine, felodipine, nisoldipine, and bepridil) may decrease melatonin levels. Use of beta-blockers (propranolol, acebutolol, atenolol, labetalol, metoprolol, pindolol, nadolol, sotalol, and timolol) may reduce melatonin production in the body.

Blood-Thinning Medications, Anticoagulants

Melatonin may increase the risk of bleeding from anticoagulant medications such as warfarin.

Interleukin-2

In one study of 80 cancer patients, use of melatonin in conjunction with interleukin-2 led to more tumor regression and better survival rates than treatment with interleukin-2 alone.

Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

NSAIDs such as ibuprofen may reduce the levels of melatonin in the blood.

Steroids and Immunosuppressant Medications

People should not take melatonin with corticosteroids or other medications used to suppress the immune system because the supplement may cause them to be ineffective.

Tamoxifen

Preliminary research suggests that the combination of tamoxifen (a chemotherapy drug) and melatonin may benefit certain patients with breast and other cancers.

Other Substances

Caffeine, tobacco, and alcohol can all diminish levels of melatonin in the body while cocaine and amphetamines may increase melatonin production.

OVERDOSE

There is little or no evidence of any major toxicities with melatonin, even at high doses.

STORAGE

Store in a cool & dry place, protected from light & moisture.

HOW SUPPLIED

Filfresh[®] Tablet : Each box contains 30 tablets.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH