

MELATONIN COMPOUND

What is this medicine?

Melatonin (Mel-a-TOE-nin)

- Melatonin is a hormone and an antioxidant that is produced by the pineal gland in the brain and may be prescribed to patients who do not produce a sufficient amount on their own.
- Melatonin may regulate the sleep-wake cycle and hormone secretions in the body.
- Melatonin may also be used for other conditions as determined by your doctor.

Compounded Drug Forms: tablet, fast-burst sublingual tablet, capsule, troche, suspension, suppository, cream, gel, topical solution

What should I tell my health care provider before I take this medicine?

- Allergy to melatonin
- Pregnant or may become pregnant; are breastfeeding
- Have an autoimmune disease
- Have high blood pressure
- Have a bleeding disorder
- Have low blood sugar
- Have a seizure disorder
- Have low mood
- Have had an organ transplant
- Are taking other sedating medications
- Are taking a hormonal contraceptive
- Are at risk for falls

How should I use this medicine?

Follow the package directions provided by Belmar Pharma Solutions and by your prescriber. Your dosage is based on your medical condition and response to therapy. Follow the dosing schedule provided carefully. This medication may be taken on an 'as needed' basis as well.

Oral dosage forms may be taken with or without food. If it upsets your stomach take it with a small meal. Pick a convenient time of day to take your dose and try to take your medication as close to that time each day as possible.

Sublingual formulations should be placed under the tongue or between the cheek and gums and held in place until fully dissolved. Avoid swallowing saliva to ensure best absorption into the bloodstream. Avoid eating or drinking 15 minutes before or after taking sublingual formulations.

Topical products can be applied to the inner arm, upper thigh, back of the knee, tops of the feet and inner wrists. It is recommended to rotate sites to ensure even retention of the hormone. Cover treated skin with clothes to avoid contact with people or pets.

Vaginal preparations should be inserted using your finger or the applicator provided. Suppositories may leak and may be more convenient to use at bedtime.

What if I miss a dose?

- If you miss a dose, take it as soon as possible.
- If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule.
- Do not take double the dose at once.

What should I watch for while using this medicine?

Belmar Pharma Solutions recommends yearly checkups with your provider.

What side effects may I notice from receiving this medicine?

Possible side effects that may occur and may go away as your body gets used to the medication include:

- Daytime sleepiness
- Trouble sleeping or nightmares
- Mild nausea or upset stomach
- Transient depression or irritability
- Bed wetting
- Headache

Serious Side Effects:

Contact your doctor immediately or seek medical attention if you experience:

- Seizures
- Severe abdominal cramping or pain, extreme diarrhea, or vomiting
- Flushing, itchy skin, or itchy bumps on skin
- Extreme involuntary urination, particularly at night
- Signs of low blood sugar
- Migraine-like headache, dizziness, fatigue
- Irregular sleep-wake cycle, confusion, disorientation, nighttime awakening, mood swings, agitation, repetitive behaviors, excitement before bedtime, nightmares, vivid dreams, a 'rocking' sensation, reduced alertness
- Changes in mood, such as feelings of sadness, nervousness, delusions, hallucinations

You may experience side effects not listed. Contact your doctor with questions.

An allergic reaction to this medication is unlikely but seek medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, swelling, severe dizziness, trouble breathing.

Where should I keep my medicine?

- Follow the storage recommendations found on your prescription label.
- Store at room temperature between 59- and 86-degrees F, unless otherwise specified on the packaging.

Additional Information:

- Do not share this medication with others.
- Keep out of reach of children and pets.
- If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go to the nearest emergency room.

If you have any questions concerning this or any of your medications, a pharmacist is available during normal business hours to answer your questions. You may report side effects to the FDA at 1-800-FDA-1088.

Consumer Information Use and Disclaimer:

This information should not be used to decide whether or not to take this medication or any other medication. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does not include

all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. For questions about the source of any of the information provided herein, pharmacists at Belmar Pharma Solutions are available. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of this medicine.

Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have questions about the best way to dispose of medications. There may be a drug take-back program in your area.

References:

1. Melatonin. Natural Products Database. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed Feb 2024.