Brightside Specialty Pharmacy

431 N. Tustin Ave., STE C, Santa Ana, CA 92705 Phone 714-707-5115

Patient Education for

MELATONIN 3 MG TABLET

Reduce or avoid alcohol consumption Read directions carefully before start of therapy Physician must know patient's complete medical history Effects in pregnancy unknown. Pt. should discuss issues with doctor Many drug-drug interactions possible with this drug May cause drowsiness or dizziness Use caution driving. Prolonged sleep problems should be evaluated (e.g. sleep apnea) This product not evaluated by the FDA for safety, purity or efficacy

Reduce or avoid drinking alcohol Read directions carefully before start of therapy Tell doctor your complete medical history Inform doctor if pregnant or planning pregnancy Review all drugs you are taking with your doctor May make you drowsy or dizzy. Drive with caution Ask MD for an evaluation of your sleep problems. Product not FDA reviewed for safety or efficacy.

Date:8/10/2022

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

MELATONIN - ORAL

USES:

Melatonin has been used for short-term treatment of

trouble sleeping (insomnia) due to sleep cycle disorders and time changes ("jet lag"). This product may help you fall asleep faster and decrease the number of times you awaken during the night. It may also help you sleep for a longer time. Melatonin is a substance that your body normally makes. It is thought to help your body's regular daily cycle, hormone production, and sleep patterns.

Some herbal/diet supplement products have been found to contain possibly harmful impurities/additives. Check with your pharmacist for more details regarding the particular brand you use.

The FDA has not reviewed this product for safety or effectiveness. Consult your doctor or pharmacist for more details.

HOW TO USE:

This product is taken by mouth with or without food,

usually before bedtime or as directed by the package label. Follow all directions on the product package. If you have any questions, ask your doctor or pharmacist.

Do not take a dose of this drug unless you have time for at least 6 to 8 hours of sleep after taking this medication.

Dosage is based on your age, medical condition, and response to treatment. If you are taking the extended-release tablets, do not crush or chew them. Doing so can release all of the drug at once, increasing the risk of side effects. Also, do not split

extended-release tablets unless they have a score line and your doctor or pharmacist tells you to do so. Swallow the whole or split tablet without crushing or chewing.

If you are using the chewable form, chew thoroughly before swallowing.

If you are using a liquid form, carefully measure your dose using a medication-measuring device or spoon. Do not use a household spoon because you may not get the correct dose. Some brands of this medication should be shaken well before each use.

If you are using the rapidly dissolving tablets, dry your hands before handling the tablet. Some brands are meant to be placed on the tongue, while others are placed under the tongue. Follow your brand's directions for placing your dose either on or under the tongue. Allow it to dissolve completely, then swallow it with saliva. You do not need to take this medication with water.

This medication may start to work within 30 minutes. If your condition lasts or gets worse, or if you think you may have a serious medical problem, get medical help right away.

SIDE EFFECTS:

Headache, dizziness, shaking, nausea, or abdominal

cramps may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. This product may also make you drowsy or less alert during the day. Consult your doctor or pharmacist if you have daytime drowsiness.

Tell your doctor right away if any of these unlikely but serious side effects occur: mental/mood changes (such as depression, confusion).

A very serious allergic reaction to this product is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at

www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking melatonin, tell your doctor or

pharmacist if you are allergic to it; or to other ingredients in this product; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

If you have any of the following health problems, consult your doctor or pharmacist before using this product: diabetes, high blood pressure, immune system disorder, liver disease, mental/mood disorder (such as depression), seizure disorder (such as epilepsy).

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Liquid and chewable forms of this product may contain sugar or aspartame. Liquid forms may also contain alcohol. Caution is advised if you have diabetes, alcohol dependence, liver disease, phenylketonuria (PKU), or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely.

Caution is advised when using this product in children due to a possible risk of changes in sexual development. Consult the doctor for details.

During pregnancy, this medication should be used only when clearly needed. It may have an effect on the release of eggs (ovulation). If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss with your doctor the benefits and risks of using this medication during pregnancy.

This medication passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug are: "blood thinners" (such as warfarin, heparin), blood pressure medications (especially nifedipine), products that contain caffeine (including coffee, tea, some sodas), drugs that may affect your immune system (such as azathioprine, cyclosporine, prednisone), fluvoxamine.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), other drugs for sleep or anxiety (such as alprazolam,

lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES:

Keep all regular medical and laboratory appointments.

MISSED DOSE:

Not applicable.

STORAGE:

Refer to storage information printed on the package. If

you have any questions about storage, ask your pharmacist. Keep all medicines and herbal products away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

Information last revised April 2022.

Copyright(c) 2022 First Databank, Inc.