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Quviviq Tablet

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Description

Side Effects Dizziness or headache may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. This medication may make you sleepy during the day. Tell your doctor if you have daytime drowsiness. Your dose may need to be adjusted. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: mental/mood changes (such as depression, thoughts of suicide), temporary weakness in your legs. This medication may cause sleep paralysis, which is a temporary inability to move or talk (for up to several minutes) while you are going to sleep or waking up. Rarely, after taking this drug, people have gotten out of bed and driven vehicles while not fully awake ("sleep-driving"). People have also sleepwalked, prepared/eaten food, made phone calls, or had sex while not fully awake. Often, these people do not remember these events. This problem can be dangerous to you or to others. If you find out that you have done any of these activities after taking this medication, tell your doctor right away. Your risk is increased if you use alcohol or other medications that can make you drowsy while taking daridorexant. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: 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. How to use Quviviq Tablet Read the Medication Guide provided by your pharmacist before you start taking daridorexant and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth as directed by your doctor, usually 30 minutes before you get into bed. This medication can be taken with or without food, but it may take longer to work if you take it with or right after a meal. Do not take this medication with alcohol or with other drugs that help you sleep. The dosage is based on your medical condition, response to treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Do not take a dose of this drug unless you have time for a full night's sleep of at least 7 hours. If you have to wake up before that, you may have trouble safely doing any activity that requires alertness, such as driving or operating machinery. () Avoid eating grapefruit or drinking

grapefruit juice while using this medication unless your doctor or pharmacist says you may do so safely. Grapefruit can increase the chance of side effects with this medicine. Ask your doctor or pharmacist for more details. Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase. Though it helps many people, this medication may sometimes cause addiction. This risk may be higher if you have a substance use disorder (such as overuse of or addiction to drugs/alcohol). Take this medication exactly as prescribed to lower the risk of addiction. Ask your doctor or pharmacist for more details. Tell your doctor if your condition lasts longer than 7 to 10 days after starting this medication, or if it gets worse.

Precautions Before taking daridorexant, tell your doctor or pharmacist if you are allergic to it; 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. Before using this medication, tell your doctor or pharmacist your medical history, especially of: a certain sleep disorder (narcolepsy), liver disease, lung disease/breathing problems (such as sleep apnea, chronic obstructive pulmonary disease-COPD), mental/mood problems (such as depression, thoughts of suicide), personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), a certain muscle weakness disorder (cataplexy). The effects of this drug can last even after you wake up the next day. The risk of daytime drowsiness is greater if you did not get at least 7 hours of sleep or took a higher dose than recommended. If that is the case, you should not drive or do anything that needs alertness the next day. Alcohol or marijuana (cannabis) can also make you more sleepy. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Older adults may be more sensitive to the side effects of this drug, especially confusion, unsteadiness, excessive drowsiness. Unsteadiness and drowsiness may increase the risk of falls. During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is unknown if daridorexant passes into breast milk. Consult your doctor before breast-feeding. Consult your pharmacist or physician.

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. Do not share this medication with others. Sharing it is against the law. As you get older, your sleep pattern may naturally change and your sleep may be interrupted several times during the night. Consult your doctor or pharmacist for ways to improve your sleep without medication, such as avoiding caffeine and alcohol close to bedtime, avoiding daytime naps, and going to bed at the same time each night. If you miss a dose, do not take it unless you have time to sleep for at least 7 hours afterward. Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications 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.

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. Other medications can affect the removal of daridorexant from your body, which may affect how daridorexant works. Examples include certain azole antifungals (such as itraconazole, ketoconazole), clarithromycin, cobicistat, certain HIV protease inhibitors (such as indinavir), nefazodone, rifampin, ritonavir, certain drugs used to treat seizures (such as carbamazepine, phenytoin), telithromycin, tucatinib, among others. The risk of serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is taken with other products that may also cause drowsiness or breathing problems. Tell your doctor or pharmacist if you are taking other products 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.

Side Effects

Uses

Interactions

Other Details
