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Sirturo

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Description

Side Effects Nausea, joint pain, and headache may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. 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: symptoms of liver damage (such as nausea/vomiting that doesn't stop, loss of appetite, dark urine, stomach/abdominal pain, yellowing eyes/skin). Get medical help right away if you have any very serious side effects, including: coughing up blood, chest pain, fast/irregular heartbeat, severe dizziness, fainting.

Bedaquiline can commonly cause a rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe reaction. Tell your doctor right away if you develop any rash. 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. **Uses** This medication must be used with other medications to treat active multi-drug-resistant tuberculosis (TB) of the lungs in people with limited treatment options. Bedaquiline belongs to a class of drugs known as antibiotics. It works by stopping the growth of the bacteria that causes TB. This antibiotic treats only bacterial infections. It will not work for viral infections (such as common cold, flu). Using any antibiotic when it is not needed can cause it to not work for future infections.

How to use Sirturo Read the Medication Guide provided by your pharmacist before you start taking bedaquiline and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth with food as directed by your doctor, usually once daily for the first 2 weeks, followed by 3 times a week for the next 22 weeks. The dosage is based on your medical condition, age, and response to treatment. Children's dosage is also based on weight. The manufacturer directs to swallow the 100-milligram tablets whole. However, many similar drugs (immediate-release tablets) can be split/crushed. Follow your doctor's direction on how to take this medication. If you are using the 20-milligram tablets and do not have trouble swallowing tablets, swallow the tablets (whole or split) with water. If you are using the 20-milligram tablets and have trouble swallowing tablets, you may take your dose 2 different ways: (1) Add

your dose (up to 5 tablets) to 1 teaspoonful (5 milliliters) of water in a cup and mix well. You can then either swallow the mixture right away, or you can add the mixture to at least 1 teaspoonful (5 milliliters) of beverage or soft food and take right away. Examples of beverages you can take this with include water, milk products, apple juice, orange juice, cranberry juice, or carbonated beverages. Soft foods such as yogurt, apple sauce, mashed banana, or porridge may also be used. Make sure to take all of your dose by rinsing the cup with beverage or soft food and swallowing right away. (2) Crush tablets and mix with soft food. Soft foods such as yogurt, apple sauce, mashed banana, or porridge may be used. Mix well and take all of the mixture right away. Make sure to take all of your dose by adding more soft food and swallowing right away. Do not prepare a mixed dose ahead of time. The 20-milligram tablets may also be given through a feeding tube. For specific directions, ask your health care professional. For the best effect, take this antibiotic at evenly spaced times. If you are taking this medication daily, take it at the same time each day. If you are taking this medication 3 times a week, take it at least 48 hours apart on the same days of the week (for example, Mondays, Wednesdays, and Fridays) at the same time of day. Mark the days on the calendar when you need to take the medication. Continue to take this medication (and other TB medications) until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early or skipping doses may allow bacteria to continue to grow, which may result in a return of the infection. Tell your doctor if your condition lasts or gets worse. **Warnings** This medication may increase the risk of death. It should only be used when other treatments have not worked. Bedaquiline may cause a condition that affects the heart rhythm (QT prolongation). The risk of QT prolongation may be increased if you are taking other drugs that may cause QT prolongation. **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 bedaquiline from your body, which may affect how bedaquiline works. Examples include efavirenz, rifamycins (such as rifampin, rifapentine), among others. **Precautions** Before taking bedaquiline, 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: liver disease. Bedaquiline may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using bedaquiline, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using bedaquiline safely. Alcohol may increase the risk of liver disease. Avoid alcoholic beverages while using this medication. Bedaquiline may cause live bacterial vaccines (such as typhoid vaccine) to not work well. Tell your health care professional that you are using bedaquiline before having any immunizations/vaccinations. Older adults may be more sensitive to the side effects of this drug, especially QT prolongation (see above). Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding. **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. This medication has been prescribed for your current condition only. Do not use it later for another infection unless your doctor tells you to. Lab and/or medical tests (such as liver function, EKG, potassium/calcium/magnesium levels) should be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a daily

dose during the first 2 weeks of treatment, skip the missed dose. Take your next dose at the regular time. If you miss a dose from week 3 onward, take it as soon as you remember, then go back to your usual 3-times-a-week dosing schedule. Make sure that there is at least 24 hours between your doses and that you do not take more than the weekly dose in a 7-day period. If you are unsure of what to do after a missed dose, talk to your doctor or pharmacist. Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets. Store the 20-milligram tablets in the original container. Keep the desiccant (drying agent) in the bottle and close the bottle tightly after each use to protect from moisture. Store the 100-milligram tablets in the original container. If necessary, the 100-milligram tablets may be stored in another container for up to 3 months. Close the bottle tightly after each use to protect from light. 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.

Side Effects

Uses

Interactions

Other Details
