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Tibsovo

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Description

Side Effects Diarrhea, nausea, vomiting, stomach/abdominal pain, constipation, mouth sores, decreased appetite, dizziness, lightheadedness, headache, or tiredness may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. 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: numb/tingling skin, muscle/joint pain. Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, severe dizziness, fainting, signs of kidney problems (such as painful urination, pink/bloody urine, change in the amount of urine). Ivosidenib sometimes causes side effects due to the rapid destruction of cancer cells (tumor lysis syndrome). To lower your risk, your doctor may add a medication and tell you to drink plenty of fluids. Tell your doctor right away if you have symptoms such as: low back/side pain (flank pain), muscle spasms/weakness. Ivosidenib 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. Get medical help 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 is used to treat a certain type of blood cell cancer (acute myeloid leukemia-AML). Ivosidenib works by helping your bone marrow grow normal blood cells so you will need fewer blood transfusions. Ivosidenib is also used to treat bile duct cancer. It works by slowing the growth of cancer cells. How to use Tibsovo Read the Medication Guide provided by your pharmacist before you start taking ivosidenib and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth with or without food as directed by your doctor, usually once daily. Do not take this medication with a high-fat meal. Swallow the tablets whole. Do not crush or split the tablets. 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). Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. 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 serious side effects will increase. If you vomit after taking a dose, do not take another dose. Take your next dose at the regular time the next day. Do not double the dose to catch up. Warnings Ivosidenib has rarely caused a serious (possibly fatal) condition called differentiation syndrome in patients with acute myeloid leukemia (AML). Get medical help right away if you develop any signs of differentiation syndrome, such as fever, cough, shortness of breath, chest pain, rapid weight gain, or swelling of arms/legs. 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 ivosidenib from your body, which may affect how ivosidenib works. Examples include rifamycins (such as rifabutin), St. John's wort, drugs used to treat seizures (such as carbamazepine, phenytoin), among others. This medication can speed up the removal of other medications from your body, which may affect how they work. Examples of affected drugs include artemether/lumefantrine, daclatasvir, daridorexant, fostemsavir, itraconazole, ketoconazole, lonafarnib, mavacamten, nimodipine, rilpivirine, ticagrelor, among others. This medication may decrease the effectiveness of hormonal birth control such as pills, patch, or ring. This could cause pregnancy. Discuss with your doctor or pharmacist if you should use reliable backup birth control methods while using this medication. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well. Many drugs besides ivosidenib may affect the heart rhythm (QT prolongation), including pacritinib, among others. Precautions Before taking ivosidenib, 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. Ivosidenib 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 ivosidenib, 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 ivosidenib safely. This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). 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 QT prolongation (see above). Tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while using ivosidenib. Ivosidenib may harm an unborn baby. Ask about reliable forms of birth control while using this medication. If you become pregnant, talk to your doctor right away about the risks and benefits of this medication. It is unknown if this drug passes into breast milk. Because of the possible risk to the infant, breast-feeding is not recommended while taking this drug and for 1 month after stopping treatment. 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. Lab tests (such as complete blood counts, blood mineral levels, ECG, liver/kidney function) should be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. If you miss a dose, take it as soon as you remember. If it is within 12 hours of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. 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.

Side Effects

Uses

Interactions

Other Details
