Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

Ivosidenib

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Tibsovo

Brand Names: Canada

Tibsovo

Warning

- A health problem called differentiation syndrome has happened. This may cause organ problems and can be deadly. Call your doctor right away if you have bone pain, cough, fever, shortness of breath or other breathing problems, sudden weight gain, swelling in the arms or legs, or swollen gland. Call your doctor right away if you have signs of liver problems like dark urine or yellow skin or eyes; signs of kidney problems like unable to pass urine, change in amount of urine passed, or blood in the urine; or signs of low blood pressure like dizziness or passing out.

What is this drug used for?

- It is used to treat a type of leukemia.
- It is used to treat bile duct cancer.
- It is used to treat a health problem called myelodysplastic syndrome (MDS).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you take any other drugs (prescription or OTC, natural products, vitamins). There are many drugs that interact with this drug, like certain drugs that are used for HIV, infections, or seizures.
- If you are breast-feeding. Do not breast-feed while you take this drug or for 1 month after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work checked and an ECG (to see how your heart beats) as you have been told by your doctor.
- If you have high blood sugar (diabetes), talk with your doctor. This drug may raise blood sugar.
- Tell your doctor if you have signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- This drug may lower the ability of the bone marrow to make blood cells that the body needs. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. If you have questions, talk with the doctor.

- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use some other kind of birth control also like a condom when taking this drug.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you plan to get pregnant or father a child, talk with your doctor before taking this drug.
- This drug may cause harm to an unborn baby. If you may become pregnant, you must use birth control while taking this drug. If you get pregnant, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of electrolyte problems like mood changes; confusion; muscle pain, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Change in balance.
- Swelling.
- Chest pain.
- Shortness of breath.
- Any unexplained bruising or bleeding.

- Fever, chills, or sore throat.
- Patients with cancer who take this drug may be at a greater risk of getting a severe health problem called tumor lysis syndrome (TLS). This may lead to death. Call your doctor right away if you have a fast or abnormal heartbeat; any passing out; trouble passing urine; muscle weakness or cramps; upset stomach, throwing up, diarrhea, or not able to eat; or feel sluggish.
- A type of abnormal heartbeat (prolonged QT interval) can happen with this drug. Call your doctor right away if you have a fast heartbeat, a heartbeat that does not feel normal, or if you pass out.
- A nervous system problem called Guillain-Barre syndrome has rarely happened with this drug. Call your doctor right away if you have weakness; change in senses like being able to see, touch, hear, or taste; trouble breathing; or abnormal burning, numbness, pain, or tingling feeling.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Feeling tired.
- Muscle or joint pain.
- Mouth irritation or mouth sores.
- Stomach pain.
- Decreased appetite.
- Weight loss.
- Headache.
- Trouble sleeping.
- Pimples (acne).
- Constipation, diarrhea, throwing up, and upset stomach are common with this drug. If these happen, talk with your doctor about ways to lower these side effects. Call your doctor right away if any of these effects bother you,

do not go away, or are severe.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food unless you have been given specific instructions about taking this drug with regard to food.
- Avoid taking this drug with high-fat meals (about 1,000 calories and 58 g fat). Talk with your doctor about types of foods to avoid.
- Swallow whole. Do not chew, break, or crush.
- Take this drug at the same time of day.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- If you throw up after taking a dose, do not repeat the dose. Take your next dose at your normal time.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is less than 12 hours until the next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses within 12 hours of each other.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- The bottle has a desiccant in it to keep the drug dry. Keep the desiccant in the bottle. Do not eat or swallow the desiccant.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic

and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

Last Reviewed Date

2023-11-28

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

Ivosidenib - Last updated on December 12, 2022
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