

ivosidenib

Pronunciation: EYE-voe-SID-e-nib

Other Name(s): Tibsovo®

Appearance: tablet

This handout gives general information about this cancer medication.

You will learn:

- who to contact for help
- what the medication is
- how it is given
- what to expect while on medication



This handout was created by Ontario Health (Cancer Care Ontario) together with patients and their caregivers who have also gone through cancer treatment. It is meant to help support you through your cancer treatment and answer some of your questions.

This information does not replace the advice of your health care team. Always talk to your health care team about your treatment.

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact: _____

Evenings, weekends and holidays: _____

What is this treatment for?

Ivosidenib is used to treat a certain type of blood cancer, called acute myeloid leukemia (AML), and bile duct cancer.

What should I do before I start this treatment?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- kidney or liver problems,
- heart problems (including irregular heartbeat),
- too much or too little salt in your body (such as sodium, potassium, calcium or magnesium), or
- any allergies.

Ivosidenib tablets contain a small amount of lactose. Tell your health care team if you cannot have lactose.



Remember To:

- ✓ Tell your health care team about all of the other medications you are taking.
- ✓ Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the [Hepatitis B and Cancer Medications](#) pamphlet for more information.

How is this treatment given?

- This medication is usually taken once a day by mouth. Talk to your health care team about how and when to take your medication.
- Take ivosidenib whole, with a full glass of water on an empty stomach, at least one hour before or two hours after eating.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. These may increase the quantity of the medication in your blood and increase the side effects.
- If you forget to take a dose of your ivosidenib:
 - If it has been less than 12 hours from the missed dose, take the dose as usual. Then take your next dose at the normal scheduled time.
 - If it has been longer than 12 hours, do not take the dose. Take your next dose at the normal scheduled time. Do not take extra (double up) to make up for the missed dose.
- If you vomit (throw up) after taking your medication, do not take an extra dose. Take your next dose at the normal scheduled time.

Warning: If you take too much of this medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

DO this while on treatment

- ✓ DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.

DO NOT do this while on treatment



- × DO NOT take any other medications, such as vitamins, over-the-counter (non-prescription) drugs, or natural health products without checking with your health care team.
- × DO NOT start any complementary or alternative therapies, such as acupuncture or homeopathic medications, without checking with your health care team.
- × DO NOT use tobacco products (such as smoking cigarettes or vaping) or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- × DO NOT drive, operate machinery or do any tasks that need you to be alert if you feel dizzy.
- × DO NOT eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. These may increase the quantity of the medication in your blood and increase the side effects.

Will this treatment interact with other medications or natural health products?

Yes, this medication can interact with other medications, vitamins, foods, traditional medicines and natural health products. Interactions can make this medication not work as well or cause severe side effects.

Tell your health care team about all of your:

- prescription and over-the-counter (non-prescription) medications
- other drugs and substances, such as cannabis/marijuana (medical or recreational)
- natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements, or traditional medicines

Check with your health care team before starting or stopping any of them.



Talk to your health care team **BEFORE** taking or using these :

- Anti-inflammatory medications such as ibuprofen (Advil[®] or Motrin[®]), naproxen (Aleve[®]) or Aspirin[®].
- Over-the-counter products such as dimenhydrinate (Gravol[®])
- Natural health products such as St. John's Wort
- Traditional medicines
- Supplements such as vitamin C
- Grapefruit juice
- Alcoholic drinks
- Tobacco
- All other drugs or substances, such as marijuana or cannabis (medical or recreational)

What to do if you feel unwell, have pain, a headache or a fever

- ✓ **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken **in your mouth (oral temperature)** is:
 - 38.3°C (100.9°F) or higher at any time
- OR
- 38.0°C (100.4°F) or higher for at least one hour.



If you do have a fever:

- ✓ **Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.**
- ✓ Ask your health care team for the [Fever](#) pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- ✓ Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.



Talk to your health care team before you start taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.



Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

How will this treatment affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this treatment may affect your sexual health
- How this treatment may affect your ability to have a baby, if this applies to you

This treatment may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until at least **1 month** after your last treatment dose. Talk to your health care team about which birth control options are best for you.
- This treatment may make hormonal birth control, such as birth control pills, less effective (not work as well). If you choose to use a hormonal birth control, make sure you also use a barrier or non-hormonal birth control method (such as condoms). Talk to your health care team about the best birth control options for you.
- Do not breastfeed while on this treatment and for at least **1 month** after your last dose.

How to safely store and handle this medication

- Keep ivosidenib tablets in the original packaging at room temperature in a dry place, away from heat and light.
- Keep out of sight and reach of children and pets.
- Do not throw out any unused ivosidenib tablets at home. Bring them to your pharmacy to be thrown away safely.

How to safely touch oral anti-cancer medication

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.

What to do if anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

- Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this treatment?

The following table lists side effects that you may have when getting ivosidenib. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on ivosidenib.

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Diarrhea</p> <p>What to look for?</p> <ul style="list-style-type: none"> Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol, until your diarrhea has stopped. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p>	<p>Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day).</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Nausea and vomiting</p> <p>(Generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Nausea is feeling like you need to throw up. You may also feel light-headed. • You may feel nausea within hours to days after your treatment. <p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than to treat it once it happens. • If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (like coffee, tea) and avoid alcohol. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea & Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◦ nausea lasts more than 48 hours ◦ vomiting lasts more than 24 hours or if it is severe 	<p>Contact your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours.</p>
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. • Check with your health care team before starting any new exercise. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Ask family or friends to help you with things like housework, shopping, and child or pet care. • Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). • Avoid driving or using machinery if you are feeling tired. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	
<p>Low neutrophils (white blood cells) in the blood (neutropenia) (Rare in patients with bile duct cancer) (May be severe)</p> <p>When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. • Do not take medications that treat a fever before you take your temperature (for example, Tylenol® (acetaminophen), or Advil® (ibuprofen)). • Do not eat or drink anything hot or cold right before taking your temperature. <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> • 38.3°C (100.9°F) or higher at any time OR • 38.0°C (100.4°F) or higher for at least one hour. <p>What to do?</p> <p>If your health care team has told you that you have low neutrophils:</p> <ul style="list-style-type: none"> • Wash your hands often to prevent infection. • Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. • Keep a digital thermometer at home so you can easily check for a fever. 	<p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you MUST get emergency medical help right away.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>If you have a fever:</p> <p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>	
<p>Low platelets in the blood (Rare in patients with bile duct cancer) (May be severe)</p> <p>When platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the Low Platelet Count pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Watch for signs of bleeding: <ul style="list-style-type: none"> ◦ bleeding from your gums ◦ unusual or heavy nosebleeds ◦ bruising easily or more than normal ◦ black coloured stools (poo) or blood in your stools (poo) ◦ coughing up red or brown coloured mucus ◦ dizziness, constant headache or changes in your vision ◦ heavy vaginal bleeding ◦ red or pink coloured urine (pee) <p>What to do?</p> <p>If your health care team has told you that you have low platelets:</p> <ul style="list-style-type: none"> • Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication. • Check with your healthcare team before you go to the dentist. • Take care of your mouth and use a soft toothbrush. • Try to prevent cuts and bruises. • Ask your health care team what activities are safe for you. • Your treatment may have to be delayed if you have low platelets. Your health care team may recommend blood transfusion. 	<p>Talk to your health care team if you have any signs of bleeding. If you have bleeding that doesn't stop or is severe, you MUST get emergency medical help right away.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>If you have signs of bleeding:</p> <ul style="list-style-type: none"> • If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes. <p>If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.</p>	
<p>Differentiation syndrome (Seen in some patients receiving treatment for AML)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Symptoms may include <ul style="list-style-type: none"> ◦ fever ◦ cough ◦ trouble breathing ◦ rash ◦ decreased urination ◦ dizziness or light-headedness ◦ rapid weight gain ◦ swelling of your arms or legs <p>What to do?</p> <ul style="list-style-type: none"> • If your health care team provides you with an alert card, carry this with you at all times. It tells you and your healthcare professionals about differentiation syndrome and its symptoms. Show this card to healthcare professionals involved in your care so that they know you are taking ivosidenib • If you have any symptoms of differentiation syndrome, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away. 	<p>If you have any symptoms of differentiation syndrome, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>
<p>Pains or cramps in the belly</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Pain or cramps in your belly. • Constipation and diarrhea can cause pain in your belly. <p>What to do?</p> <ul style="list-style-type: none"> • If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Higher than normal white blood cells in the blood (Seen in some patients receiving treatment for AML)</p> <ul style="list-style-type: none"> • You may have higher white blood cell levels in the blood. This can happen in the first few weeks of treatment and may last for a few weeks. • Your health care team will do a blood test to check your white blood cell levels before and during your treatment. <p>What to look for?</p> <ul style="list-style-type: none"> • High white blood cell levels usually do not cause any symptoms. • Rarely, in severe cases, you may have: <ul style="list-style-type: none"> ◦ fever ◦ breathing problems ◦ severe headache ◦ changes in your vision <p>What to do?</p> <ul style="list-style-type: none"> • In rare cases, you may be given a medication to treat higher white blood cells. <p>Talk to your health care team right away if you have any severe symptoms. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>	<p>Talk to your health care team right away if you have any severe symptoms. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>

Other rare, but serious side effects are possible with this treatment.

If you have **any** of the following, talk to your cancer health care team or get emergency medical help right away:

- irregular heartbeat, chest pain or fainting spells
- new pain, numbness or tingling of your hands or feet; having trouble doing tasks (like doing up buttons, writing, walking)
- bloating, feeling of fullness or swelling of the belly, unusual weight gain (seen in patients with bile duct cancer)
- yellowish skin or eyes, unusually dark pee or pain on the right side of your belly (seen in patients with bile duct cancer)

