

Medication Information Sheet

gilteritinib (GIL te RI ti nib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Xospata®

Appearance: coloured tablet

What is this medication for?

- For treating a type of blood cancer called acute myeloid leukemia (AML).

What should I do before I have this medication?

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

- heart problems (including irregular heartbeat),
- liver problems,
- kidney problems,
- a history of low levels of potassium or magnesium in your blood, or
- any allergies

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.

How will this medication affect sex, pregnancy and breastfeeding?**Talk to your health care team about:**

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

This medication may harm an unborn baby. Tell your health care team if you or your partner are

The most updated information sheet version can be found on <https://www.cancercareontario.ca/drugs>

Additional symptom management information is available from <https://www.cancercareontario.ca/symptoms>

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.

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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 **6 months** after your last dose if you are female, or until at least **4 months** after your last dose if you are male. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication and for at least **2 months** after the last dose.

How is this medication 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.
- Swallow whole with a glass of water, with or without food.
- Do not crush or chew the tablets.
- If you forget to take a dose of your gilteritinib:
 - 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 the medication, do not take another dose on the same day; take your next dose at the usual time on the next day.
- If you take too much of your 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.

What else do I need to know while on this medication?

- **Will this medication interact with other medications or natural health products?**
 - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment 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 and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements

- Check with your health care team before starting or stopping any of them.
- **What should I do if I 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.

What to DO while on this medication:

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

What NOT to DO while on this medication:

- DO NOT smoke 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 eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of drug in your blood and increase side effects.
- DO NOT drive, operate machinery or do any tasks that need you to be alert if you feel drowsy or dizzy.

How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication 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.
- **How to safely touch oral anti-cancer medications**

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 oral 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 medication?

The following table lists side effects that you may have when getting gilteritinib. 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 gilteritinib.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Liver problems</p> <p>Your health care team may check your liver function with a blood test. Liver changes do not usually cause any symptoms.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. <p>What to do?</p> <p>If you have any symptoms of liver problems, get emergency medical help right away.</p>	<p>Get emergency medical help right away</p>

Common Side Effects (25 to 49 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. 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>
<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>Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<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>Constipation</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Having bowel movements (going poo) less often than normal. • Small hard stools (poo) that look like pellets. • The need to push hard and strain to have any stool (poo) come out. • Stomach ache or cramps. • A bloated belly, feeling of fullness, or discomfort. • Leaking of watery stools (poo). • Lots of gas or burping. • Nausea or vomiting. <p>What to do?</p> <p>To help prevent constipation:</p> <ul style="list-style-type: none"> • Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. • Drink at least 6 to 8 cups of liquids each day unless your health care team 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>has told you to drink more or less.</p> <ul style="list-style-type: none"> • Be Active. Exercise can help to keep you regular. • If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation:</p> <ul style="list-style-type: none"> • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. <p>Ask your health care team for the Constipation Pamphlet for more information.</p>	
<p>Cough and feeling short of breath</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have a cough and feel short of breath. • Symptoms that commonly occur with a cough are: <ul style="list-style-type: none"> ◦ wheezing or a whistling breathing ◦ runny nose ◦ sore throat ◦ heartburn ◦ weight loss ◦ fever and chills • Rarely this may be severe with chest pain, trouble breathing or coughing up blood. <p>What to do?</p> <ul style="list-style-type: none"> • Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?". • If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. • If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	<p>Talk to your health care team. If you are not able to talk to your health care team for advice, and you have a fever or severe symptoms, you MUST get emergency medical help right away</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<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. 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>Talk to your health care team if it does not improve or if it is severe</p>
<p>Low neutrophils (white blood cells) in the blood (neutropenia)</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, Advil® or 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>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>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<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 doctor 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:</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>Headache; mild joint, muscle pain or cramps</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Mild headache • New pain in your muscles or joints, muscle cramps, or feeling achy. <p>What to do?</p> <ul style="list-style-type: none"> • Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. • Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. • Rest often and try light exercise (such as walking) as it may help. <p>Ask your health care team for the Pain pamphlet for more information.</p>	Talk to your health care team if it does not improve or if it is severe
<p>Eye problems</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Your eyes may feel dry, irritated, or painful. • They may look red and have a lot of tears. 	Talk to your health care team as soon as possible

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> They may feel sensitive to light and your vision may be blurry. <p>What to do?</p> <ul style="list-style-type: none"> Avoid wearing contact lenses. Wear sunglasses with UV protection. Use protective eyewear (goggles or helmet with face mask) when playing sports, mowing the lawn or doing anything that may get particles or fumes in your eyes. You may try artificial tears (eye drops) or ointment. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Mild swelling</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. <p>What to do?</p> <p>To help prevent swelling:</p> <ul style="list-style-type: none"> Eat a low-salt diet. <p>If you have swelling:</p> <ul style="list-style-type: none"> Wear loose-fitting clothing. For swollen legs or feet, keep your feet up when sitting. 	Talk to your health care team if it does not improve or if it is severe
<p>Dizziness</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may feel light-headed and like you might faint (pass out). 	Talk to your health care team if it does not improve or if it is severe

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to do?</p> <ul style="list-style-type: none"> • Lay down right away so you do not fall. • Slowly get up and start moving once you feel better. • Do not drive a motor vehicle or use machinery if you feel dizzy. 	
<p>Low appetite</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loss of interest in food or not feeling hungry. • Weight loss. <p>What to do?</p> <ul style="list-style-type: none"> • Try to eat your favourite foods. • Eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have no appetite. <p>Ask your health care team for the Loss of Appetite pamphlet for more information.</p>	Talk to your health care team if it does not improve or if it is severe
<p>Low blood pressure</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may feel tired, dizzy or light-headed. • You may have nausea (feeling like you need to throw up), vomiting or blurred vision. • You may faint (pass out). <p>What to do?</p> <ul style="list-style-type: none"> • Check your blood pressure often. Talk to your health care team to find out what a safe blood pressure is for you. • If you feel dizzy or unwell lay down right away so that you do not fall. Try to get up and move slowly only once you feel better. • Do not drive a motor vehicle or operate machinery if you feel dizzy. • Your blood pressure may drop when the medication is being given to you. Let your health care team know right away if you start to feel dizzy or lightheaded. 	Talk to your health care team if it does not improve or if it is severe

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<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>
<p>Rash; dry, itchy skin</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have cracked, rough, flaking or peeling areas of the skin. • Your skin may look red and feel warm, like a sunburn. • Your skin may itch, burn, sting or feel very tender when touched. <p>What to do?</p> <p>To prevent and treat dry skin:</p> <ul style="list-style-type: none"> • Use fragrance-free skin moisturizer. • Protect your skin from the sun and the cold. • Use sunscreen with UVA and UVB protection and a SPF of at least 30. • Avoid perfumed products and lotions that contain alcohol. • Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Mouth sores</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks. • In more severe cases they may make it hard to swallow, eat or brush your teeth. • They may last for 3 days or longer. 	<p>Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow</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>What to do?</p> <p>To help prevent mouth sores:</p> <ul style="list-style-type: none"> • Take care of your mouth by gently brushing and flossing regularly. • Rinse your mouth often with a homemade mouthwash. • To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. • Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. <p>If you have mouth sores:</p> <ul style="list-style-type: none"> • Avoid hot, spicy, acidic, hard or crunchy foods. • Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. • Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. <p>Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.</p>	
<p>Taste changes</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Food and drinks may taste different than usual. <p>What to do?</p> <ul style="list-style-type: none"> • Eat foods that are easy to chew, such as scrambled eggs, pasta, soups, cooked vegetables. • Taste foods at different temperatures, since the flavour may change. • Try different forms of foods, like fresh, frozen or canned. • Experiment with non-spicy foods, spices and seasonings. 	Talk to your health care team if it does not improve or if it is severe

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- irregular heartbeat, shortness of breath, chest pain or fainting spells
- symptoms of an allergic reaction such as fever, itchiness, rash, swollen lips, face or tongue, chest and throat tightness
- lower back pain, swelling and peeing less than usual
- numbness or tingling of your fingers and toes may happen after starting your treatment
- severe headache, fainting, seizures, confusion and vision loss
- pain in the centre of your belly that may extend to your back
- new swelling neck, groin, or underarm area unusually fast weight gain, bone pain

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: _____

Other Notes:

March 2022 New medication information sheet

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.