



Provincial Health Services Authority

For the Patient: Gilteritinib
Other names: XOSPATA®

- **Gilteritinib** (gil" te ri' ti nib) is a drug that is used to treat some types of cancer. It is a tablet that you take by mouth.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to gilteritinib before taking gilteritinib.
- **Blood tests** may be taken regularly during treatment. The dose and timing of your treatment may be changed based on the test results and/or other side effects.
- It is important to **take** gilteritinib exactly as directed by your doctor. Make sure you understand the directions.
- You may **take** gilteritinib with food or on an empty stomach.
- If you **miss a dose** of gilteritinib, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- If you **vomit** the dose of gilteritinib, do not take a second dose. Skip the missed dose and go back to your usual dosing times. Let your doctor know as a medication to prevent nausea may be required for future doses.
- Other drugs such as itraconazole (SPORANOX®) and rifampin (RIFADIN®) may **interact** with gilteritinib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of gilteritinib.
- Gilteritinib may affect **fertility** in men. If you plan to have children, discuss this with your doctor before being treated with gilteritinib.
- Gilteritinib may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with gilteritinib. Ask your doctor how long you should continue using birth control after your treatment has ended. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment and for at least two months afterwards.

- **Store** gilteritinib tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- **Tell** doctors, dentists, and other health professionals that you are being treated with gilteritinib before you receive any treatment from them.

Changes in blood counts

Gilteritinib may cause temporary changes in your blood counts. Your doctor will be following these changes carefully by performing blood tests. Adjustment of your treatment may be needed in certain circumstances.

| BLOOD COUNTS | MANAGEMENT |
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| <p>Normal white blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.</p> | <p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine. |
| <p>Normal platelets help your blood to clot normally after an injury (e.g., cut). When the platelet count is low, you may be more likely to bruise or bleed.</p> | <p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. <p>Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). • For minor pain, try acetaminophen (e.g., TYLENOL®). |

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

| SIDE EFFECTS | MANAGEMENT |
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| Nausea and vomiting may occur while you are taking gilteritinib. Most people have little or no nausea. | You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred , so follow directions closely. <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.* |
| Skin rashes may sometimes occur. | If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit. |
| Fever may sometimes occur. | <ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. • If you have fever (over 100°F or 38°C by an oral thermometer) plus another sign of infection, call your doctor immediately. Other signs of infection include chills, cough, or burning when you pass urine. |
| Diarrhea may sometimes occur. | If diarrhea is a problem: <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>.* |
| Constipation may sometimes occur. | <ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Food Choices to Manage Constipation</i>.* |
| Headache may sometimes occur. | <ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. |
| Tiredness and lack of energy may sometimes occur. | <ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i>.* |

| SIDE EFFECTS | MANAGEMENT |
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| Loss of appetite may sometimes occur. | Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .* |
| Sore mouth may sometimes occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection. | <ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day. • Try the ideas in <i>Food Ideas to Try with a Sore Mouth</i>.* |
| Muscle or joint pain may sometimes occur. | You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your doctor if the pain interferes with your activity. |
| Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid. | If swelling is a problem: <ul style="list-style-type: none"> • Elevate your feet when sitting. • Avoid tight clothing. |
| You may sometimes have trouble sleeping . | <ul style="list-style-type: none"> • Talk to your doctor if you continue to have trouble sleeping. • This will return to normal when you stop taking gilteritinib. |
| Taste alteration may sometimes occur. | Try the ideas in <i>Food Ideas to Cope with Taste and Smell Changes</i> .* |
| Numbness or tingling of the fingers or toes may sometimes occur. | <ul style="list-style-type: none"> • Be careful when handling items that are sharp, hot, or cold. • Tell your doctor at your next visit, especially if you have trouble with buttons, writing, or picking up small objects. |

| SIDE EFFECTS | MANAGEMENT |
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| Abnormal heart rhythm (QT prolongation) rarely occurs. | Minimize your risk of abnormal heart rhythm by: <ul style="list-style-type: none"> • always checking with your pharmacist and doctor about drug interactions when starting a new medication, herbal product, or supplement. • Tell your doctor immediately or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded, or dizzy. |
| Hair loss does not occur with gilteritinib. | |

***Please ask your chemotherapy nurse or pharmacist for a copy.**

STOP TAKING GILTERITINIB AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **allergic reaction** including dizziness, fast heart beat, face swelling, or breathing problems.
- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, shortness of breath or difficulty in breathing, cough, chest pain, chest pressure, swelling of feet or lower legs, or fainting.
- Signs of **kidney problems** such as lower back or side pain, swelling of feet or lower legs.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- **Seizures** or **loss of consciousness**.
- Sudden **abdominal pain** or tenderness; swelling or bloating of the abdomen.
- Rapid **weight gain**.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.

