



Gilteritinib (Xospata®)

Pronounce: GIL te RI ti nib

Classification: Kinase inhibitor

About Gilteritinib (Xospata®)

A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells. Gilteritinib works in certain leukemias with a mutation in the FLT3 gene. Your oncology team will test you for this mutation, which must be present to receive the medication.

How to Take Gilteritinib

Gilteritinib is given in tablet form to be taken by mouth, typically once a day. You should take this medication with a full glass of water. It can be taken without food. Do not crush, break or chew the tablets. Try to take your dose at the same time each day. If you miss a dose and it has been less than 12 hours since your regular dose time, take it as soon as you remember. If it has been more than 12 hours, skip the dose. Do not take 2 doses at once to make up for a missed dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include carbamazepine, dexamethasone, phenytoin, rifampin, phenobarbital, and St. John's Wort, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw it in the trash.

Where do I get this medication?

Depending on your prescription coverage, this medication may be available at your local retail pharmacy or through a specialty pharmacy. Your oncology team will work with your prescription drug plan to identify the appropriate supplier for this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to

qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources if they are available.

Possible Side Effects of Gilteritinib

There are many things you can do to manage the side effects of gilteritinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Differentiation Syndrome

This results from the changes gilteritinib causes to blood cell production in patients with leukemia. Symptoms of differentiation syndrome include fever (temperature $>100.4^{\circ}\text{F}$ or 38°C), sudden weight gain, bone or joint pain, and fluid build-up around the heart, lungs, and/or chest, causing shortness of breath or difficulty breathing. This syndrome is treated with high doses of steroids (like dexamethasone or prednisone) and diuretics (fluid pills). Your healthcare providers will monitor for these signs or symptoms, but it is also important for you to tell your provider promptly if you experience any of these symptoms.

Muscle or Joint Pain/Aches and Headache

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Liver Toxicity

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

Fever

Fever can be a side effect of this medication. Contact your care provider for a temperature of $100.4^{\circ}\text{F}/38^{\circ}\text{C}$ or greater.

Lung Problems and Pneumonia

This medication can cause various types of pneumonia and/or interstitial lung disease. Symptoms include cough, shortness of breath, and fatigue. Report these symptoms to your oncology care team.

Peripheral Edema

Peripheral [edema](#) is swelling of the extremities caused by the retention of fluid. It can cause swelling of the hands, arms, legs, ankles, and feet. The swelling can become uncomfortable. Notify your oncology care team if you are experiencing any new or worsening swelling.

Diarrhea

Your oncology care team can recommend medications to relieve [diarrhea](#). Also, try eating [low-fiber](#), bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, noncaffeinated fluid a day to prevent dehydration.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for [suggestions to relieve the constipation](#).

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage [nausea and vomiting](#). In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy, or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Mouth Ulcers (Mucositis)

Certain cancer treatments can cause [sores or soreness in your mouth](#) and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek, or throat becomes white, ulcerated, or painful. Performing [regular mouth care](#) can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight-ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages, and citrus juices.

Low Blood Pressure

This medication can cause low blood pressure (hypotension). Patients should have their blood pressure checked regularly during therapy. Report any headaches, vision changes, or dizziness to your oncology care team.

Laboratory Changes

This medication can change many laboratory values. Your healthcare team will monitor your lab values throughout treatment and replace/treat as necessary.

Fatigue

[Fatigue](#) is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Less common, but important side effects:

- **Posterior Reversible Encephalopathy Syndrome (PRES):** In rare cases, this medication has caused a neurological disorder called posterior reversible encephalopathy syndrome (PRES), also called reversible posterior leukoencephalopathy (RPLS). Symptoms of PRES/RPLS include headache, seizure, lethargy, confusion, blindness, and other visual and neurological disturbances. Report any of these symptoms to your healthcare team immediately.
- **QT Prolongation:** This medication can cause an abnormal heart rhythm called QT prolongation. Your healthcare provider should check your heart rhythms with an electrocardiogram (ECG) before and during treatment with this medication. Let your oncology care team know right away if you feel abnormal heartbeats or if you feel dizzy or faint.

- **Pancreatitis:** This medication can cause an inflammation of the pancreas called pancreatitis. Notify your oncology team immediately if you experience severe stomach/abdominal pain with or without nausea and vomiting that does not go away.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 6 months after treatment for women and 4 months after treatment for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication and for 2 months after completion of treatment.

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