

Gilteritinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for acute myeloid leukemia (AML).
- It may also be used for other reasons.
- Your care team may perform a test for a specific type of abnormal gene (FMS-like tyrosine kinase 3 (FLT3)) to make sure enasidenib is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Gilteritinib (GIL-teh-RIH-tih-nib): Xospata (zoh-SPAH-tuh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Tablets taken by mouth.

Treatment Administration and Schedule

Your gilteritinib dosing instructions:

- Gilteritinib comes in 1 tablet strength: 40 mg.
- Your dose might differ, but gilteritinib is typically taken as three 30 mg tablets (120 mg total dose) by mouth 1 time a day.
- Take gilteritinib 1 time a day, at about the same time each day.
- Swallow gilteritinib tablets whole. Do not break, crush, or chew the tablet.
- Gilteritinib can be taken with or without food.
- Do not change your dose or stop taking gilteritinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking gilteritinib if you develop certain side effects.
- If you vomit or miss a dose of gilteritinib, or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next dose. Return to your normal schedule the following day. Do not take 2 doses of gilteritinib within 12 hours.
- If you take too much gilteritinib, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Gilteritinib

- Store gilteritinib at room temperature between 68°F and 77°F (20°C and 25°C).
- Keep gilteritinib in the original container to protect it from light, moisture, and humidity.
- Gilteritinib comes in a child resistant package.
- People who are or may be pregnant should wear gloves when handling the medicine.
- Keep gilteritinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused gilteritinib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)

<p>Fatigue</p>	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness
<p>Your Body May Hold Too Much Fluid (Fluid Retention) Leading to Swelling (Edema)</p>	<p>Description: Fluid retention (edema) is swelling caused by excess fluid in body tissues, often seen in the legs, ankles, feet, hands, or abdomen. It can cause tightness, weight gain, and discomfort.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Weigh yourself daily and keep a record to notice sudden weight gain. • Elevate swollen legs when sitting and avoid standing for long periods. • Wear compression stockings if your care team recommends them. • Limit salt (sodium) intake and follow any fluid restrictions your care team gives. • Stay active and do gentle movement to improve circulation. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Swelling that suddenly worsens or spreads to other areas • Pain, redness, or warmth in the affected area • Signs of shortness of breath or difficulty breathing • Swelling is persistent and does not improve with home management • Unexpected weight gain <p>Note: Your care team may ask you to contact them if your weight increases by a certain amount over a certain time period.</p>

<p>Mouth Sores or Irritation (Mucositis or Stomatitis)</p>	<p>Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Rinse your mouth after meals and at bedtime; rinse more often if sores develop. • Brush your teeth gently with a soft toothbrush or use a cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water. • Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwash. • Your care team may prescribe medicines or mouth treatments to help with pain and healing. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful mouth sores or throat pain • Trouble eating or significant weight loss
<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting
<p>Liver Problems</p>	<p>Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal

<p>Diarrhea</p>	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea
<p>Trouble Breathing and Cough</p>	<p>Description: Treatment may make you feel like it's a struggle to get enough air into your lungs. A cough is a reflex action that forcefully expels air from the lungs to clear the airways of irritants or mucus.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Stay hydrated by drinking plenty of fluids to help thin mucus. • Avoid irritants such as smoke, strong odors and chemicals, and allergens. • Use humidifiers to add moisture to the air and soothe airways. • Practice controlled breathing techniques, like pursed-lip breathing. • Elevate your head with extra pillows when resting or sleeping, if needed. • Limit physical exertion and take breaks during activities. • Tell your care team what your cough feels like and when it happens. • Keep your house clean by dusting and vacuuming regularly • Your care team may recommend medicine for cough. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Trouble breathing • Chest pain or tightness • Cough or coughing up blood

<p>Muscle or Joint Pain or Weakness</p>	<p>Description: Muscle pain is soreness, aching, cramps, stiffness, tenderness, or weakness in one or more muscles. Joint pain is pain, stiffness, swelling, or reduced movement where two bones meet.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a pain diary: note pain levels, locations, and activities that make it better or worse. • Do gentle exercise (walking, stretching, yoga) to maintain mobility and strength. Check with your care team before starting a new activity. • Use a warm compress for stiff muscles or a cold pack to reduce swelling and numb pain—use what helps the area. • Your care team may recommend or prescribe medicines, including over-the-counter pain relievers. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Pain you cannot control with usual measures • Swelling, redness, or warmth in a joint • New weakness • Trouble walking or moving
<p>Rash or Itchy Skin</p>	<p>Description: Rash or itchy skin can cause redness, swelling, and a variety of bumps or patches (small red spots, welts, blisters, or scaly dry areas).</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep your skin moisturized with creams or lotions to reduce rash and itchiness. • Wear loose-fitting clothing. • Avoid perfumes and colognes, as they may worsen rash symptoms. • Limit time spent in the heat to prevent worsening symptoms. • Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn. • Wear long-sleeved clothing with ultraviolet (UV) protection and broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with sun protective factor (SPF) 30 or higher as directed. • Use lip balm with SPF 30 or higher. • Avoid tanning beds. • Your care team may recommend medicines for symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Rash or itching that continues to worsen

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<p>Differentiation Syndrome (Boxed Warning)</p>	<p>Differentiation syndrome is a condition that affects your blood cells and may be life- threatening or lead to death. Differentiation syndrome in adults with AML has occurred as early as 1 day and up to 82 days after starting gilteritinib.</p> <p>If you develop signs and symptoms of differentiation syndrome, your care team may treat you with a corticosteroid medicine or a medicine called hydroxyurea and may monitor you in the hospital.</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Weight gain • Trouble breathing • Cough • Decreased urination • Swelling (especially in the hands, feet, or face) • Dizziness or lightheadedness
<p>Changes in the Electrical Activity of Your Heart called QT prolongation</p>	<ul style="list-style-type: none"> • Feel faint, lightheaded, or dizzy • Fast or irregular heartbeat
<p>Pancreas Problems</p>	<ul style="list-style-type: none"> • Upper stomach pain that may spread to your back and get worse with eating • Weight loss • Nausea or vomiting
<p>Posterior Reversible Encephalopathy Syndrome (PRES)</p>	<p>A neurologic condition called PRES can happen during treatment with gilteritinib.</p> <ul style="list-style-type: none"> • Severe headache • Confusion • Weakness • Seizures • Blindness or change in vision

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant:
 - If you are able to become pregnant, your care team may do a pregnancy test 7 days before you start taking gilteritinib.
 - Use an effective method of birth control during treatment and for 6 months after your last dose of gilteritinib.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 4 months after your last dose of gilteritinib.
- **Do NOT breastfeed** during treatment and for 2 months after your last dose of gilteritinib.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

Updated Date: June 18, 2026

Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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