

ORAL CHEMOTHERAPY EDUCATION



GILTERITINIB

Name of your medication

Generic name — gilteritinib (GIL-teh-RIH-tih-nib)

Brand name — Xospata® (zoh-SPAH-tuh)

Approved uses

Gilteritinib is used to treat adult patients with FMS-like tyrosine kinase 3 (FLT3) mutation-positive acute myeloid leukemia.

Dose and schedule

Taking gilteritinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of gilteritinib is 120 milligrams (120 mg) to be taken by mouth at a scheduled time once daily.
- Gilteritinib can be taken with or without food.
- Gilteritinib should be taken whole with a cup of water and not opened, crushed, cut, or dissolved. If you are unable to swallow gilteritinib, talk to your care provider or pharmacist for possible options.
- Only take the missed dose if it has been less than 12 hours since you were supposed to take it and on the same day. Then take the next dose at the regularly scheduled time.
- Do not take the missed dose if it has been more than 12 hours since you should have taken it or is not the same day you should have taken it. Simply take the next dose at the regularly scheduled time.
- Do not take two doses on the same day.
- Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Gilteritinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle gilteritinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store gilteritinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep gilteritinib out of reach of children and pets.
- Leave gilteritinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give gilteritinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the gilteritinib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)

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3. Gently transfer the gilteritinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is **not** recommended to be used with gilteritinib.
 - If you have any unused gilteritinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of gilteritinib.
 - If you are traveling, put your gilteritinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Gilteritinib

Below are common side effects that have been known to happen in about one third or more of patients taking gilteritinib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect

Management

Changes in electrolytes and other laboratory values

- Serum creatinine
- High glucose
- High triglycerides
- High liver enzyme values
- Low calcium
- Low albumin
- Increased creatine kinase
- Low phosphorus
- Low potassium
- Low sodium

Changes in some lab values may occur and will be monitored by a simple blood test.

- You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem.
- More severe changes may occur, which can be a sign of a serious problem.
- Your healthcare provider should check your potassium and magnesium levels.

Notify your care provider if you have any of the following:

- Shortness of breath
- Chest discomfort
- Weakness or fatigue
- New aches and pains
- Headaches
- Dizziness
- Swelling of your legs or feet
- Red- or brown-colored urine

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Possible Side Effect	Management
Muscle or joint pain	<ul style="list-style-type: none"> • Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. • Stay as active as possible, but know it is okay to rest as needed. • Tell your care provider if pain interferes with your activity. <p>If the pain bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
Changes in liver function	<p>Your liver function should be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
Fluid retention or swelling	<ul style="list-style-type: none"> • Do not stand for long periods of time. • Keep your legs elevated when sitting or lying down. • Try not to eat salty foods, which can increase swelling. • Avoid tight-fitting clothing and shoes. • Weigh yourself daily. <p>Contact your provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Swelling in the hands, feet, or legs • Shortness of breath • Weight gain of five pounds or more in one week

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Possible Side Effect	Management
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
<p>Cough or shortness of breath</p>	<p>A cough that does not produce any mucous or congestion relief (dry cough) may occur while taking this medication. If you experience any breathing problems or shortness of breath, notify your care provider immediately. This may be a serious side effect of the medication.</p>
<p>Respiratory tract infection</p>	<ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid people with fevers, flu, or other infections. • Maintain good personal hygiene. • Report symptoms of a respiratory infection (e.g., cough, sneezing, runny nose, fever, scratchy or sore throat) to your provider.
<p>Rash or itchy skin</p>	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing. • Avoid using perfumes and colognes as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. • Sunlight can make symptoms worse. <ul style="list-style-type: none"> – Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs from 10 am to 4 pm. – Wear long-sleeved clothing, with UV protection if possible. – Wear broad-brimmed hats. – Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. – Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>

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Serious side effects of gilteritinib

- Gilteritinib can cause a very serious side effect known as differentiation syndrome. Patients with differentiation syndrome may have a fever, shortness of breath or trouble breathing, swelling, and weight gain. Be sure to let your care team know if you experience a fever, have trouble breathing, or have sudden weight gain.
- Posterior reversible encephalopathy syndrome (PRES) may rarely occur when taking gilteritinib. Tell your healthcare provider right away if you have a seizure or a quickly worsening headache, confusion, or vision problems.
- Gilteritinib can cause changes to the electrical activity of your heart called QTc prolongation. Tell your healthcare provider right away if you feel faint, lightheaded, or dizzy.
- Gilteritinib may be harmful to your pancreas. Seek medical attention if you have severe abdominal pain or tenderness, fever, or vomiting.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since gilteritinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take gilteritinib, it is important to know the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or gilteritinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking gilteritinib. Men and women of childbearing age and potential should use effective contraception during therapy. Women should continue contraception for a minimum of six months after the last dose of gilteritinib. Men should continue contraception for a minimum of four months after the last dose of gilteritinib.

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- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking gilteritinib and for two months after the last dose of gilteritinib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on gilteritinib, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining your gilteritinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.xospata.com>

Product prescribing information: <https://astellas.us/docs/xospata.pdf>

Product resources: <https://www.xospata.com/resources-for-you/#>

Updated – February 8, 2021

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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