

## Gilteritinib (Xospata)

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### About This Medicine

GILTERITINIB (GIL te RI ti nib) treats leukemia. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Changes in your eyesight
- Nausea and vomiting (throwing up)
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Tiredness
- General discomfort, a feeling of being unwell
- Fever
- Swelling of the hands, feet, or any other part of the body
- Changes in your liver and kidney function
- Joint, muscle and bone pain
- Feeling dizzy
- Headache
- Trouble breathing
- Cough
- Rash
- Low blood pressure

**Note:** Each of the side effects above was reported in 20% or greater of people treated with gilteritinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- A serious syndrome may happen with the use of this medicine that is known as differentiation syndrome, which can be life-threatening. It can cause fever, weight gain, swelling, low blood pressure, rash, and breathing problems. This can occur as early as 1 day into therapy and up to 3 months after starting this medicine. **Immediately report any of these symptoms to your healthcare provider.**
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your care team know right away.**
- Abnormal electrocardiogram (EKG/ECG)
- Inflammation (swelling) of your pancreas

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## How to Take Your Medicine

- Swallow the medicine whole with a cup of water, with or without food. Do not break, crush, or chew tablets.
- Take this medicine at approximately the same time each day.
- **Missed dose:** If you miss a dose, and it is less than 12 hours until your next dose, skip the missed dose and go back to your normal schedule. If you miss a dose, and it is more than 12 hours until your next dose, take the missed dose. Do not take 2 doses within 12 hours. Do not take 2 doses at the same time or extra doses.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Protect from light, moisture, and humidity. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

## Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.



- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- If you are dizzy, get up slowly after sitting or lying.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.

## Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with gilteritinib. Also, check with your care team before starting any new prescription, over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Feeling dizzy or lightheaded
- Extreme tiredness and/or coma
- Extreme weakness that interferes with normal activities



- Confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells, or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Blurry vision or other changes in eyesight
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Wheezing and/or trouble breathing
- Cough that is bothersome
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Severe pain in your abdomen that may spread to your back
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Signs of differentiation syndrome such as fever, weight gain, swelling, and/or trouble breathing. **Immediately report any of these symptoms to your healthcare provider.**
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Decreased or very dark urine
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- Pain that does not go away, or is not relieved by prescribed medicines

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 6 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 2 months after the last dose.
- **Fertility warning:** The effect of this medicine on fertility is not known. If you plan to have children, talk with you care team.

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