

Gilteritinib (Xospata)

About This Medicine

Gilteritinib is used to treat cancer. It is given orally (by mouth).

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 patients 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 medical 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 doctor know right away.**
- Abnormal electrocardiogram (EKG/ECG)
- Inflammation 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 medical 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.
- **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.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic 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.
- **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 nurse or your doctor 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 nurse or doctor 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 nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your doctor or nurse 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 doctor'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 doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist 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 doctor or pharmacist 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 the Doctor

Call your doctor or nurse 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
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 6 months after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 2 months after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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