

# QUESTIONS TO GUIDE CONVERSATIONS ABOUT CARE

Managing someone else's care can feel overwhelming, and when talking with doctors it's often hard to know where to begin.

The following questions may be helpful at the next appointment or visit with the care team.



## About My Loved One's Care

- How will treatment be monitored if it is taken at home?

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- What tests should be scheduled before treatment?

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- Whom can I call if I have questions and the doctor is unavailable?

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- Are there any support groups you can recommend to us?

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### Select Safety Information

#### What is the most important information I should know about XOSPATA?

XOSPATA may cause serious side effects including Differentiation Syndrome. Differentiation Syndrome is a condition that affects your blood cells and may be life-threatening or lead to death if not treated. Differentiation Syndrome can happen as early as 1 day after starting XOSPATA and during the first 3 months of treatment. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome while taking XOSPATA: fever, cough, dizziness or lightheadedness, rapid weight gain, trouble breathing, swelling of your arms or legs, rash, decreased urination. If you develop any of these symptoms of differentiation syndrome, your healthcare provider may treat you with a corticosteroid medicine and may monitor you in the hospital.

#### WHAT IS XOSPATA

XOSPATA is a prescription medicine used to treat adults with acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation when the disease has come back or has not improved after previous treatment(s). Your healthcare provider will perform a test to make sure XOSPATA is right for you. It is not known if XOSPATA is safe and effective in children.

Please read Important Safety Information on pages 3-4 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including BOXED WARNING.

**XOSPATA**<sup>®</sup>  
gilteritinib 40mg tablets



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## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about XOSPATA?



XOSPATA may cause serious side effects including Differentiation Syndrome. Differentiation Syndrome is a condition that affects your blood cells and may be life-threatening or lead to death if not treated. Differentiation Syndrome can happen as early as 1 day after starting XOSPATA and during the first 3 months of treatment. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome while taking XOSPATA: fever, cough, dizziness or lightheadedness, rapid weight gain, trouble breathing, swelling of your arms or legs, rash, decreased urination. If you develop any of these symptoms of differentiation syndrome, your healthcare provider may treat you with a corticosteroid medicine and may monitor you in the hospital.

### Who should not take XOSPATA?



Do not take XOSPATA if you are allergic to gilteritinib or any of the ingredients in XOSPATA.

### What are the possible side effects of XOSPATA?

XOSPATA may cause serious side effects including:

• See “What is the most important information I should know about XOSPATA?” above.



• **Posterior Reversible Encephalopathy Syndrome (PRES).** If you take XOSPATA, you may be at risk of developing a condition involving the brain called PRES. Tell your healthcare provider right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision, or other visual problems. Your healthcare provider will do a test to check for PRES. Your healthcare provider will stop XOSPATA if you develop PRES.



• **Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats that can be life-threatening.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) before you start taking XOSPATA and during your treatment with XOSPATA. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint. The risk of QT prolongation is higher in people with low blood magnesium or low blood potassium levels. Your healthcare provider will do blood tests to check your potassium and magnesium levels before and during your treatment with XOSPATA.



• **Inflammation of the pancreas (pancreatitis).** Tell your healthcare provider right away if you have severe stomach (abdomen) pain that does not go away. This pain may happen with or without nausea and vomiting.

**The most common side effects of XOSPATA include:**

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|------------------------------------|-----------------------|-----------------------|
| • Changes in liver function tests  | • Rash                | • Eye problems        |
| • Joint or muscle pain             | • Diarrhea            | • Headache            |
| • Tiredness                        | • Shortness of breath | • Dizziness           |
| • Fever                            | • Nausea              | • Low blood pressure  |
| • Pain or sores in mouth or throat | • Cough               | • Vomiting            |
| • Swelling of arms or legs         | • Constipation        | • Decreased urination |

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Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking XOSPATA if you develop certain side effects during treatment with XOSPATA.

These are not all of the possible side effects of XOSPATA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## What should I tell my doctor before taking XOSPATA?

### Tell your doctor:

- About all of your medical conditions.
- If you have heart problems, including a condition called long QT syndrome.
- If you have problems with abnormal electrolytes such as sodium, potassium, or magnesium levels.
- If you are pregnant or plan to become pregnant. XOSPATA can cause harm to your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with XOSPATA or think you may be pregnant.
  - If you are able to become pregnant, your healthcare provider may perform a pregnancy test 7 days before you start treatment with XOSPATA.
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with XOSPATA and for 6 months after the last dose of XOSPATA.
  - Males who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with XOSPATA and for 4 months after the last dose of XOSPATA.
- If you are breastfeeding or plan to breastfeed. It is not known if XOSPATA passes into your breast milk. Do not breastfeed during treatment with XOSPATA and for 2 months after the last dose of XOSPATA.
- About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. XOSPATA may affect the way other medicines work and other medicines may affect how XOSPATA works.



## How should I take XOSPATA?

- Take XOSPATA exactly as your healthcare provider tells you.
- Do not change your dose or stop taking XOSPATA unless your healthcare provider tells you to.
- Take XOSPATA 1 time a day at about the same time each day.
- Swallow XOSPATA tablets whole.
- XOSPATA can be taken with or without food.
- Do not break, crush or chew XOSPATA tablets.
- If you miss a dose of XOSPATA, take your dose as soon as possible on the same day at least 12 hours before your next scheduled dose. Return to your normal schedule the following day. Do not take 2 doses within 12 hours.



Please click here for the [Medication Guide](#) and [Full Prescribing Information](#), including **BOXED WARNING**.



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