



After FLT3m+ AML Has Turned
Your Life Upside Down

TURN HERE FOR HELP

XOSPATA is the only FDA-approved targeted therapy for people with FLT3m+ AML when the disease has come back or has not improved after previous treatment



Your XOSPATA Dosing Tracker

Ask your doctor about this free tool to track your daily dose of XOSPATA. Bottle and tracker shown are not actual size. See page 2 for instructions for use.

AML=acute myeloid leukemia; FDA=Food and Drug Administration; FLT3=FMS-like tyrosine kinase 3; m+=mutation-positive.

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 4-6 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including BOXED WARNING.

XOSPATA[®]
gilteritinib 40mg
tablets

Using Your XOSPATA Dosing Tracker



Bottle shown with tracker affixed.

1

Remove Dosing Tracker from the bag provided and peel off its backing to reveal the adhesive surface. If you did not receive a tracker with this brochure, you can ask your doctor to request one for you

2

Attach Dosing Tracker **to the side of your XOSPATA prescription bottle**. Avoid covering the XOSPATA name on the bottle

3

After taking your daily dose of XOSPATA, **flip the toggle to the right** on the corresponding day of the Dosing Tracker

4

At the end of each week, **flip all toggles back to the left** to reset the Dosing Tracker

5

After getting XOSPATA refilled, remember to **remove the Dosing Tracker and attach it to your new XOSPATA prescription bottle**

Keep XOSPATA in the original container to protect it from light, moisture, and humidity.

MAKING XOSPATA PART OF YOUR DAILY ROUTINE

It's important to take XOSPATA exactly as your healthcare provider tells you so you can get the most out of your treatment. That means taking your dose of XOSPATA every day at the same time each day.

Using your Dosing Tracker every day can help you stay on schedule.



Set an alarm to take XOSPATA at the same time every day



Match your dosing schedule with an activity you do at the same time every day, such as taking XOSPATA with breakfast



Ask a family member or close friend to help keep track of the medicines you take and when you need to take them

Select Safety Information

Who should not take XOSPATA?

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

Please read Important Safety Information on pages 4-6 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including BOXED WARNING.

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How to Take XOSPATA in the Comfort of Your Home

Take XOSPATA by mouth, once a day



Recommended starting dose =
Three 40 mg tablets (120 mg)



Do not break, crush, or chew.
Take tablets whole with a cup of water

Tablets shown are not actual size.

Take XOSPATA exactly as your healthcare provider tells you.

- Do not change your dose or stop taking XOSPATA without talking to your healthcare provider
- Take XOSPATA 1 time a day, at about the same time each day
- Swallow XOSPATA tablets whole. Do not break, crush, or chew tablets
- XOSPATA can be taken with or without food

If You Miss a Dose of XOSPATA or Do 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 within 12 hours.

A response to XOSPATA may take time. Your doctor may treat you with XOSPATA for a minimum of 6 months, as long as your disease is not getting worse and there are no serious side effects.

For more information about XOSPATA, visit XOSPATA.com.

Select Safety Information

XOSPATA may cause serious side effects including:

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.

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Indication and Important Safety Information

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.

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.

Please see additional Important Safety Information on pages 5-6 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including BOXED WARNING.

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Important Safety Information (continued)



• **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:

- | | | |
|------------------------------------|-----------------------|-----------------------|
| • 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 |



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.

Please see additional Important Safety Information on page 6 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including BOXED WARNING.

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Important Safety Information (continued)

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.

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XOSPATA SUPPORT SOLUTIONSSM IS HERE FOR YOU

Bottle shown with tracker affixed.
Instructions for use are on page 2.

If you do not have a Dosing Tracker, you can
ask your doctor to request one for you.

XOSPATA Support Solutions offers support to patients who have been prescribed XOSPATA. A Case Manager can connect you and your loved ones to educational resources and support* based on your particular needs to help you manage your disease and daily life while on treatment.

To speak with a XOSPATA Support Solutions Case Manager, call:

 1-844-632-9272  Monday–Friday, 8:30 am–8:00 pm ET

* Support is provided through third-party organizations that operate independently and are not controlled or endorsed by Astellas. Availability of support and eligibility requirements are determined by these organizations.

Please read Important Safety Information on pages 4-6 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including **BOXED WARNING**.



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