



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

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.

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XOSPATA Is Here for You

When you have FLT3m+ ("flit-3 mutation-positive") AML and your disease has come back or has not improved after previous treatment, it can feel like your life has been turned upside down. XOSPATA ("Zoh-spah'-tah") may be able to help.

As you begin the next step in your AML journey, this guide can help you understand your diagnosis and prepare you to take on FLT3m+ AML with XOSPATA.

Terms in **purple** are defined at the bottom of each page.

This guide should not replace the advice of your healthcare team.

Remember to talk with your doctor any time you have questions about FLT3m+ AML and your treatment with XOSPATA.

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 20-23 and click here for the [Medication Guide](#) and [Full Prescribing Information](#), including **BOXED WARNING**.

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The Facts About FLT3m+ AML

What Is Acute Myeloid Leukemia (AML)?

Acute myeloid leukemia, or AML, is a type of blood cancer that starts in the bone marrow, where blood cells are made.

AML is caused by changes to the **genes** in some developing blood cells, affecting how they develop in the bone marrow. These changes, which are called mutations, can cause the blood cells to become **leukemia** cells.

Why Do Doctors Test for Mutations?



There are many different types of mutations in AML. Doctors test for mutations with bone marrow and blood tests, which gives them more information about your type of AML. This will help them make treatment decisions that are right for you.

What Is FLT3 Mutation-Positive (FLT3m+) AML?

One of the most common types of mutations in AML occurs in the FLT3 gene. In FLT3m+ AML, mutations in the FLT3 gene cause leukemia cells to grow and multiply, leaving less room for healthy blood cells to develop.

Acute: When symptoms or signs start fast and quickly worsen.

Genes: Pieces of DNA that parents pass on to children.

Leukemia: A type of cancer that starts in blood-forming tissue, such as bone marrow.

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What Does It Mean to Relapse or Be Refractory to Treatment?

Relapse is when AML comes back after a period of improvement.

Refractory to treatment means the AML has not improved after previous treatment(s).

Why Do Doctors Test for Mutations Again at Relapse?

FLT3 mutations may be seen at diagnosis, or they may appear over time. Your doctor may have tested you again at relapse to confirm whether your AML has FLT3 mutations. Knowing your FLT3 mutation status at relapse helps doctors find a treatment that may be right for you, including a therapy that can target the FLT3 mutation.

XOSPATA is a targeted therapy for people who have relapsed or refractory FLT3m+ AML.

Select Safety Information

What are the possible side effects of XOSPATA?

XOSPATA may cause serious side effects including:

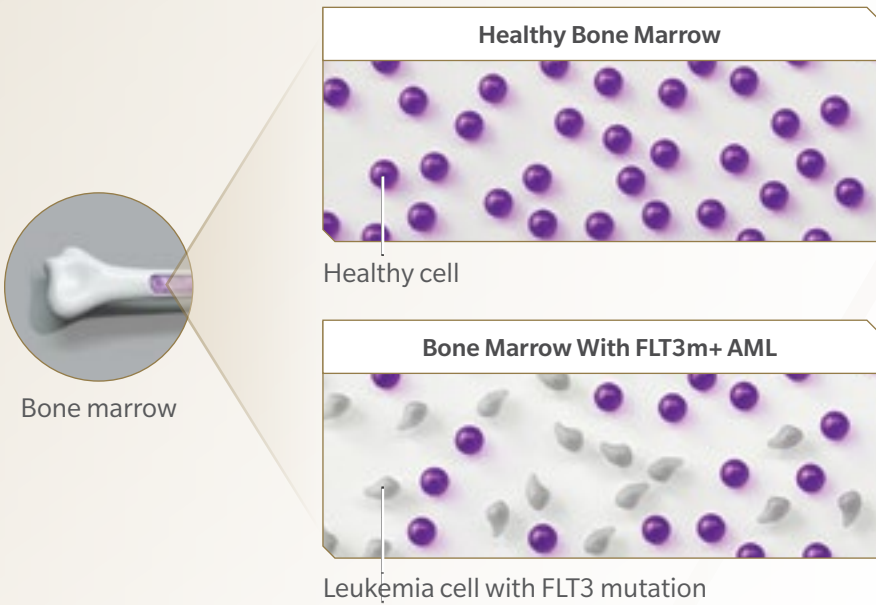
- **Posterior Reversible Encephalopathy Syndrome (PRES).** If you take XOSPATA, you may be at risk of developing a condition involving the brain called PRES. Tell your healthcare provider right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, 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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XOSPATA Targets FLT3 Mutations in AML

In FLT3m+ AML, the number of leukemia cells increases. This leaves less room in the bone marrow for healthy blood cells to develop.



The FLT3 mutation is one of the few mutations in AML that has a targeted therapy available when people relapse or become refractory—XOSPATA.

Select Safety Information

XOSPATA may cause serious side effects including:

- **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.

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XOSPATA works differently than chemotherapy by targeting FLT3m+ AML cells and may cause them to stop growing in the bone marrow.*



Bone marrow

XOSPATA Targets FLT3m+ AML Cells



This may cause the death of some leukemia cells.

Healthy Blood Cells May Develop Again



With fewer leukemia cells, the bone marrow may have more room for healthy blood cells.

*This is how XOSPATA was shown to work in laboratory studies.

Select Safety Information

XOSPATA may cause serious side effects including:

- **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.

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How XOSPATA May Help

XOSPATA was studied in comparison to chemotherapy in people who had relapsed or refractory AML and who had tested positive for a FLT3 mutation by a bone marrow or blood test.



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HOW XOSPATA MAY HELP

XOSPATA May Help People Live Longer



The final set of results in the study compared the rate of overall survival in 247 people who had taken XOSPATA with 124 people who received chemotherapy.

The term **overall survival** refers to the length of time during the study that people stayed alive beyond the start of treatment.

— In the study, **the median overall survival for people who took XOSPATA was 9 months** | **6 months** with chemotherapy | vs |

People taking **XOSPATA** had a **36%** lower risk of death during the study compared with people receiving chemotherapy.

Based on the results of the study, it was estimated that

	37% of people were alive at 1 year with XOSPATA	vs	17% with chemotherapy
	19% of people were alive at 2 years with XOSPATA	vs	14% with chemotherapy

Results may vary. Talk with your doctor about what this may mean for you.

Median: The middle value in a set of numbers, not the average.

Select Safety Information

The most common side effects of XOSPATA include: Changes in liver function tests, joint or muscle pain, tiredness, fever, pain or sores in mouth or throat, swelling of arms or legs, rash, diarrhea, shortness of breath, nausea, cough, constipation, eye problems, headache, dizziness, low blood pressure, vomiting, decreased urination. These are not all of the possible side effects of XOSPATA. Call your doctor for medical advice about side effects.

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Longer Remission Is Possible With XOSPATA

To determine how well XOSPATA works, doctors used different ways to measure how a person responded to treatment during the study. One of those methods was complete remission.

Complete remission means that no signs of leukemia cells are found in the blood or bone marrow, and blood counts have returned to normal. This does not mean that the cancer has been cured.

In the study,

<p>14% of people achieved complete remission with XOSPATA (35 out of 247 people)</p>	vs	<p>11% with chemotherapy (13 out of 124 people)</p>
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People who achieved complete remission continued to stay in remission for a median of

15 MONTHS
with XOSPATA

vs a median of **2 months**
with chemotherapy



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.

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XOSPATA Helped Reduce the Need for Transfusions in Some People

During the study, a response to XOSPATA was also measured by how many people needed blood and/or **platelet** transfusions.

For people who needed transfusions at the start of the study,



treated with XOSPATA gained independence from transfusions for up to **8 weeks** during the study (68 out of 197 people)

Platelet: A small, ring-shaped cell that helps to form clots in the blood in order to slow or stop bleeding and to help wounds heal.

Select Safety Information

Who should not take XOSPATA?

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Possible Side Effects

What Are Possible Serious Side Effects of XOSPATA?

Differentiation syndrome



What it is

- A condition that affects your blood cells
 - May be life-threatening or lead to death if not treated
 - 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 symptoms of differentiation syndrome

Symptoms

- Fever
- Cough
- Trouble breathing
- Rash
- Dizziness or lightheadedness
- Rapid weight gain
- Swelling of arms or legs
- Decreased urination

Posterior reversible encephalopathy syndrome (PRES)



What it is

- A condition that affects the brain
 - If PRES is suspected, your doctor will do a test to check for it
 - If you develop PRES, your doctor will stop treatment with XOSPATA

Symptoms

- Seizure
- Headache
- Decreased alertness
- Confusion
- Reduced eyesight, blurred vision, or other visual problems

Changes in the electrical activity of your heart (QTc prolongation)



What it is

- Can cause irregular heartbeats that can be life-threatening
 - Your doctor will do a test before you start taking XOSPATA and during your treatment with XOSPATA
 - More likely to happen in people with low blood magnesium or low blood potassium levels

Symptoms

- Feeling dizzy, lightheaded, or faint

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What Are Possible Serious Side Effects of XOSPATA? (continued)

Inflammation of the pancreas (pancreatitis)



What it is | • A condition that affects the pancreas

Symptoms | • Severe stomach (abdomen) pain that does not go away
• Pain may happen with or without nausea and vomiting

What Are the Most Common Side Effects of XOSPATA?

- Changes in liver function tests
- Joint or muscle pain
- Tiredness
- Fever
- Pain or sores in mouth or throat
- Swelling of arms or legs
- Rash
- Diarrhea
- Shortness of breath
- Nausea
- Cough
- Constipation
- Eye problems
- Headache
- Dizziness
- Low blood pressure
- Vomiting
- 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 are encouraged to report side effects to the FDA at
1-800-FDA-1088 or www.fda.gov/medwatch.**

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XOSPATA Can Be Taken in the Comfort of Your Own Home

Select Safety Information

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.

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.

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How to Take XOSPATA

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.

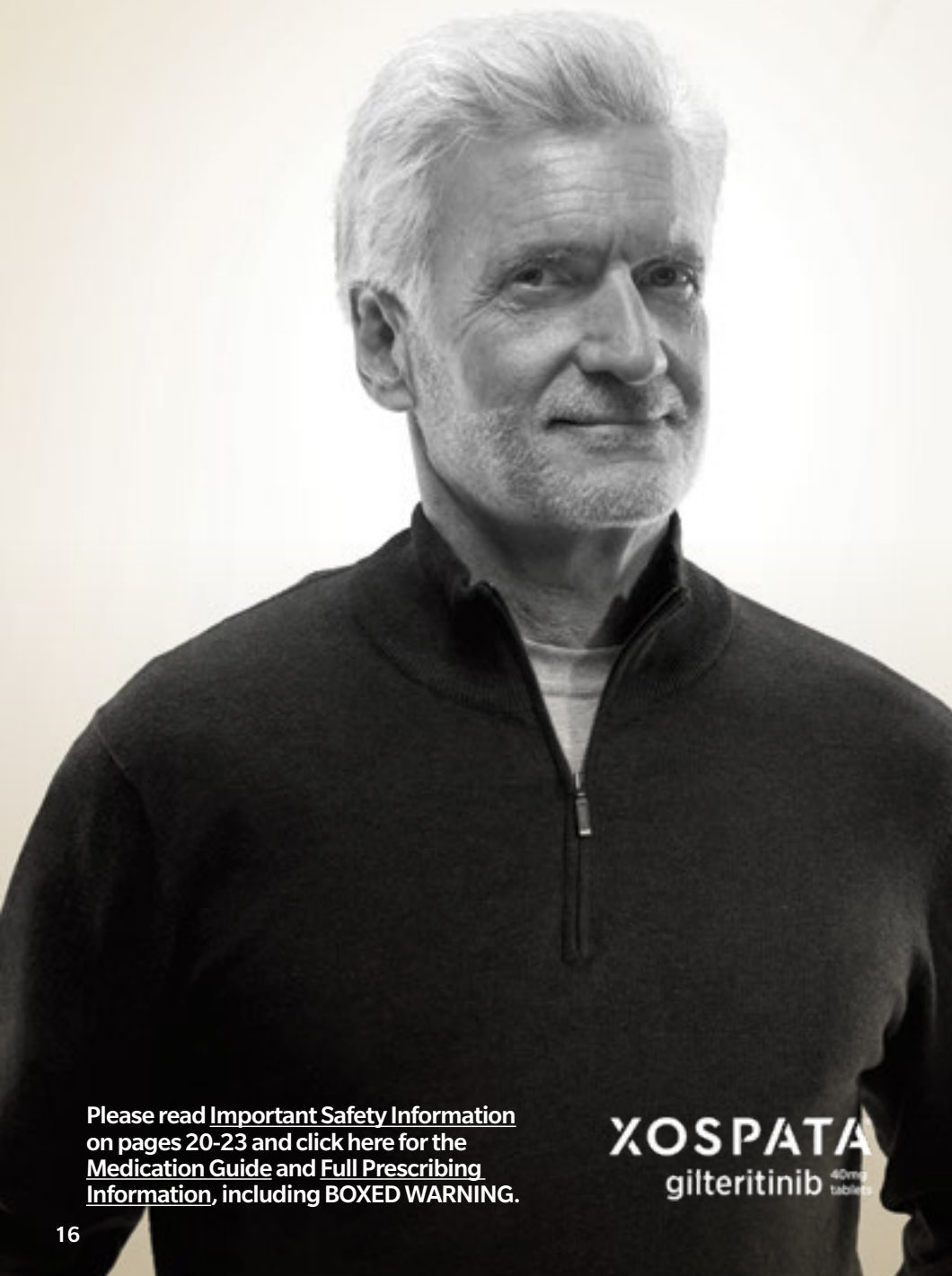
A response to XOSPATA may take time. Your doctor may treat you with XOSPATA for a minimum of 6 months, as long as your disease is not getting worse and there are no serious side effects.

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Support While on XOSPATA

XOSPATA cannot be found in your local pharmacy,
and is usually filled in a specialty pharmacy.



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SUPPORT WHILE ON XOSPATA

XOSPATA Is Filled at a Specialty Pharmacy



A **specialty pharmacy** is a pharmacy that typically fills prescriptions for specialty drugs, like XOSPATA, that are not normally available at your local drugstore.

Prescriptions from specialty pharmacies will be mailed right to your home. The specialty pharmacy will call you to confirm the address where you want your medication delivered.

Get XOSPATA Filled in 3 Steps



After your doctor writes you a prescription for XOSPATA, they can send the prescription to a specialty pharmacy or to XOSPATA Support SolutionsSM



XOSPATA Support Solutions or the XOSPATA network specialty pharmacy will confirm your insurance coverage and determine if your insurance company has any coverage restrictions



After your prescription is approved by your insurance company, it will be dispensed and shipped by a XOSPATA network specialty pharmacy and delivered right to your door

- You will get a call from your specialty pharmacy to arrange refills for your prescription

Your doctor may also be able to provide XOSPATA in their office.
Ask your doctor if this is an option for you.

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XOSPATA Support Solutions offers access and reimbursement support to help patients access XOSPATA. XOSPATA Support Solutions provides information regarding patient healthcare coverage options and financial assistance information that may be available to help patients with financial needs.

A XOSPATA Support Solutions Case Manager is just a call away:

1-844-632-9272

Monday–Friday, 8:30 AM–8:00 PM ET

Case Managers Will Work With You to:

- Look up your insurance coverage for XOSPATA
- See if your insurance has any coverage requirements or restrictions
- Identify any cost-sharing responsibilities you have through your insurance plan

The XOSPATA Patient Savings Program



Eligible* patients who have commercial insurance pay as little as \$0 per prescription and are enrolled in the program for a 12-month period. There are no income requirements.

*By enrolling in the XOSPATA Patient Savings Program ("Program"), you acknowledge that you currently meet the eligibility criteria and will comply with the following terms and conditions: The Program is for eligible patients with commercial prescription insurance for XOSPATA. The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. Patients who move from commercial insurance to federal or state health insurance will no longer be eligible, and agree to notify the Program of any such change. Patients agree not to seek reimbursement from any health insurance or third party for all or any part of the benefit received by the patient through the Program. This offer is not conditioned on any past, present, or future purchase of XOSPATA. This offer is not transferrable and cannot be combined with any other offer, free trial, prescription savings card, or discount. This offer is not health insurance and is only valid for patients in the 50 United States, Washington, DC, Puerto Rico, Guam, and Virgin Islands. This offer is not valid for cash paying patients. This Program is void where prohibited by law. No membership fees. It is illegal to sell, purchase, trade, counterfeit, duplicate, or reproduce, or offer to sell, purchase, trade, counterfeit, duplicate, or reproduce the card. This offer will be accepted only at participating pharmacies. Certain rules and restrictions apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice.

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XOSPATA Support Solutions Is Here for You

XOSPATA Support Solutions offers additional patient and caregiver support to patients like you who have been prescribed XOSPATA. This additional support helps 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. A XOSPATA Support Solutions Case Manager will assess your specific needs and customize a search of various independent organizations* that may be able to help. Examples may include:



Logistical Support

Transportation and lodging assistance for treatment



Emotional Support

Social workers, counseling services, and online communities



Informational Support

Other education and resources about acute myeloid leukemia and treatment

To learn more about how XOSPATA Support Solutions can help, 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.

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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.

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Important Safety Information (continued)

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.

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Important Safety Information (continued)

The most common side effects of XOSPATA include:

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

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.



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Important Safety Information (continued)

- 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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Questions to Ask Your Doctor

It's important to talk with your doctor and ask any questions you may have about relapsed or refractory FLT3m+ AML and your treatment with XOSPATA. Write down your questions and bring them with you to your doctor visits.

The following questions may help get you started.

How does XOSPATA fit into my overall treatment plan?

How long will I be taking XOSPATA?

How will XOSPATA affect other medicines I'm taking?
How will my other medicines affect XOSPATA?

What other tests will I need during treatment?

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Are there things I should avoid while taking XOSPATA?

How often should I schedule follow-up visits?

What is the best way to contact you if I experience any side effects, or have any additional questions?

Use this space for any other questions you have.

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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.

Please read [Important Safety Information](#) on pages 20-23 and [click here for the Medication Guide and Full Prescribing Information](#), including **BOXED WARNING**.



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