XOSPATA® gilteritinib 40mg tablets

SUPPORT SOLUTIONS℠

XOSPATA Support Solutions® Enrollment Form

WARNING: DIFFERENTIATION SYNDROME

Patients treated with XOSPATA® (gilteritinib) have experienced symptoms of differentiation syndrome, which can be fatal or life-threatening if not treated. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, or renal dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Indication

XOSPATA is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

Important Safety Information

Contraindications
XOSPATA is contraindicated in patients with hypersensitivity to gilteritinib or any of the excipients. Anaphylactic reactions have been observed in clinical trials.

PLEASE SEE IMPORTANT SAFETY INFORMATION FOR XOSPATA ON PAGES 7-8.
PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION INCLUDING BOXED WARNING FOR ADDITIONAL SAFETY INFORMATION.

XOSPATA® gilteritinib 40mg tablets SUPPORT SOLUTIONS℠

Website: XOSPATASupportSolutions.com
Phone: 1-844-632-9272
Fax: 1-844-730-8816

INSTRUCTIONS FOR HEALTHCARE PROVIDERS

- ✓ Complete this enrollment form on behalf of your patient. **Please note: All fields denoted with an asterisk (*) are required fields. Missing information will delay enrollment.**
- ✓ Have the patient read the Patient Authorization Statement on pages 2-4 and provide their signature and date to certify they have read, understand, and agree to the Statement.
- ✓ Have the healthcare provider (HCP) read the Prescriber Certification Statement on page 6 and provide their signature and date to certify that they have read, understand, and agree to the Statement.
- ✓ Complete the prescription drug information and obtain the HCP's signature and date.
- ✓ Fax the completed form to XOSPATA Support Solutions® at 1-844-730-8816 or fax it to a specialty pharmacy in the authorized XOSPATA® (gilteritinib) network.

WHAT TYPE OF PATIENT SUPPORT IS NEEDED?

☐ Benefits Investigation Support ☐ Astellas Patient Assistance Program ☐ Other Programs

STEP 1 PATIENT INFORMATION

First Name*: Last Name*: Date of Birth*: Sex: ☐ Male ☐ Female

Home Address*: City*: State*: ZIP*:

Cell Phone: Home Phone: Email:

Permission to contact patient? ☐ Yes ☐ No Best time to contact: Preferred Language: ☐ English ☐ Spanish ☐ Other *Translators for other languages may be available.*

STEP 2 PATIENT AUTHORIZATION FOR XOSPATA SUPPORT SOLUTIONS*

Patient to read the statement below and sign where indicated.

Patient Authorization Statement

My signature authorizes my doctor(s), my healthcare providers, my health plan or payer, and my pharmacy to disclose to Astellas ("Company") and its third-party suppliers, vendors, and other service providers supporting XOSPATA Support Solutions (collectively, the "Service Providers") information about me (for example, my name, Social Security number, address, insurance policy number, and income) and my medical condition (for example, my diagnosis or medications) (together, "Personally Identifiable Information"). This information can include spoken or written facts about my health and insurance benefits. It can include copies of records from my healthcare providers or health plans about my health or healthcare. I understand that my healthcare providers and my pharmacy may receive remuneration, or payment, for disclosing my information pursuant to this authorization.

I understand that XOSPATA Support Solutions is a component of Astellas Pharma Support Solutions℠ and that the Service Providers may be compensated by Astellas. The Service Providers will use and give out my information to:

(i) Assist in my enrollment in XOSPATA Support Solutions and to contact me and/or the person legally authorized to sign on my behalf;
(ii) Provide me and/or the person legally authorized to sign on my behalf with educational and other materials, information, and support related to XOSPATA Support Solutions;
(iii) Verify, investigate, assist with, and coordinate my coverage for XOSPATA with my payer;
(iv) Coordinate prescription fulfillment;

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(v) Assess my eligibility for patient assistance and/or benefits, if necessary;

(vi) Make referrals to other independent programs or alternate sources that may be available to provide assistance to me as allowed under the law, if necessary; and

(vii) Assist with analyses of the efficiencies and performance of Services provided by Service Providers.

In some instances, the Service Providers may de-identify my information and use or disclose the de-identified information (in individual or aggregated form) for any legitimate business purposes.

I understand that the Service Providers will make reasonable efforts to keep my information private; however, I understand that once my information has been disclosed to the Service Providers, how the Service Providers further disclose my information may no longer be protected under federal and state privacy laws.

This authorization will last for three (3) years from the date below or until I am no longer receiving XOSPATA® (gilteritinib) or enrolled in XOSPATA Support Solutions®, whichever is later. I do not have to provide this authorization, but if I do not, I will not be able to have my insurance coverage verified, have alternate sources of assistance researched, or access other support provided by or on behalf of XOSPATA Support Solutions. My choice as to whether to provide this authorization will not change the way my doctors, healthcare providers, or payers treat me. If I no longer wish to participate in XOSPATA Support Solutions, I shall inform my healthcare providers and/or the administrators of XOSPATA Support Solutions in writing that I do not want them to share any more information with the Service Providers, but it will not change any actions that took place before I told them. I have the right to revoke or cancel this authorization, in writing, at any time by providing written notice to my healthcare providers and/or the administrators of XOSPATA Support Solutions. Cancellation of this authorization will be valid when received by the administrators of XOSPATA Support Solutions. I understand that a cancellation is not effective to the extent that any person or entity has already acted in reliance on my authorization.

I know I have a right to see or copy the information my healthcare providers or payers have given to the Service Providers.

If an application is submitted to determine my eligibility for assistance from the Astellas Patient Assistance Program (PAP), I agree to allow Company and Service Providers to use my demographic information, including, but not limited to, Social Security number, date of birth, name, and/or address, as needed to access my credit information and information derived from public and other sources, including information from a consumer reporting agency (credit bureau), to estimate my income in conjunction with the eligibility determination process performed to determine my eligibility under the PAP. Company and Service Providers reserve the right to ask for additional documents and information at any time. I agree to notify my healthcare providers and XOSPATA Support Solutions if I become aware of changes that would affect my eligibility, including, but not limited to, changes in health insurance status or coverage, financial status, and United States residency.

If your application is approved, XOSPATA Support Solutions can send you text messages about the Program throughout your enrollment period. These text messages are optional. You can participate in the Program without signing up for text messages. When you sign up for the text messages (by providing your cell phone number), you must agree to the following conditions:

- Program will send an autodialed, pre-recorded text message (standard text message and data rates apply).
- You can opt out at any time by calling 1-844-632-9272 or replying "STOP" to the text messages.

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- Program is not responsible if a communication is not delivered due to technical difficulties like server issues, phone carrier outages, or discontinued service.
- Be aware that anyone who can open or have access to your phone might see your text messages.
- If your mobile operator is not participating in text messaging services, you will not receive text messages.
- These text messages are NOT reminders to take your medication. You are responsible to take your medication as prescribed.
- Do NOT report product complaints or adverse events (like side effects) by text message. To report these, please call XOSPATA Support Solutions® at 1-844-632-9272.
- To receive text messages, you must provide your cell phone number.

Astellas is committed to the safety and effectiveness of our products. In the event you experience an adverse drug event or side effect, Astellas requests your consent to be able to contact you, your family member, and/or your healthcare provider. This contact may be via phone, email, or any commonly used electronic form or medium. The purpose of this follow up is to help us at Astellas to better understand the event you experienced in relation to our product.

For additional information regarding how Astellas handles personal information, please visit our Privacy Policy link at: https://www.astellas.com/us/privacy-policy.

This Authorization Statement is governed by and interpreted in accordance with the laws of the state of Illinois, excluding Illinois conflict of law rules, and applicable federal law.

Patient Signature

By signing below, I provide my agreement to this written consent and authorization, which certifies that I have read and understand the above Patient Authorization Form.

Patient Name (please print): _____

Patient Signature X: _____ Date: _____

Representative Signature

If this Patient Authorization Form is being signed by a representative, please describe the representative's authority to act on behalf of the patient: _____

☐ **I am acting for another person and I hereby affirm that I have the legal right to do so, that I am the parent or legal guardian of the patient, or that I otherwise have a valid power of attorney to act on behalf of the patient.**

Representative Name (please print): _____

Representative Signature X: _____ Date: _____

STEP 3 CURRENT PHARMACY INSURANCE*

Patient Pharmacy Insurance Plan

Patient has: ☐ No insurance ☐ Medicare Part D ☐ Medicaid ☐ Private/Commercial ☐ Medicare Advantage

Pharmacy Insurer:	Patient Pharmacy Insurance Card ID:	Patient Pharmacy Insurance Card Phone:

STEP 4 ASSESSMENT FOR ASTELLAS PATIENT ASSISTANCE PROGRAM*

Has this patient been assessed for Astellas PAP?

☐ Yes ☐ No ☐ Decline Assessment

STEP 5 PATIENT RELAPSE AND FLT3 TEST DATES OR PATIENT REFRACTORY FLT3 TEST*

☐ Patient Relapse or Refractory Date: _____

☐ FLT3 Test Date: _____

STEP 6 PRESCRIBER AND PRACTICE INFORMATION

Prescriber Name* (First and Last):	Specialty:	Practice Name*:
Office Contact Name:	**Office Contact Phone*:**	**Fax*:**
Address*:		
City*:	State*:	ZIP*:
Medicaid/Medicare Provider No.*:		Tax ID No.*:
State License No.*:		UPIN/NPI*:

Preferred Specialty Pharmacy (if any): _____

☐ Self-Dispensing Practice (Please check this box if you are a self-dispensing practice)

STEP 7 PRESCRIPTION FOR XOSPATA® (gilteritinib) tablets*

In order for us to send medication to your patient, the prescription information must be complete and accurate.

Patient Name:	**Date of Birth:**
Diagnosis Code:	

Product Name: XOSPATA 40-mg tablets

Instructions: Take _____ 40-mg tablets per _____ for _____ days

Dispense: _____-day supply Refills: _____

Doctor/Prescriber Signature X: _____ Date: _____

Stamped signatures not accepted. Dispense as written.

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STEP 8 PRESCRIBER CERTIFICATION STATEMENT

By signing below, I hereby attest that I am the prescribing healthcare provider and I agree to submit requests to XOSPATA Support Solutions® because I have determined that XOSPATA® (gilteritinib) tablets is medically appropriate and I have explained such to my patient. To the best of my knowledge, the patient and physician information in this form is complete and accurate. I certify that I have received the necessary authorization to release the above-referenced information and other protected health information (as defined by the Health Insurance Portability and Accountability Act (HIPAA) of 1996) to the Service Providers for the purpose of providing access and reimbursement support, assisting in initiating or continuing therapy, and/or the evaluation of the patient's eligibility for support. I authorize Service Providers, as my designated agent and on behalf of my patients, to forward a prescription for XOSPATA by fax or other mode of delivery, to a pharmacy within the XOSPATA Support Solutions network.

I also certify that this prescription complies with all applicable state and local laws. I agree to notify the Service Providers if I become aware at any time in the future of changes in my patient's circumstances that would affect his or her eligibility, including but not limited to changes in health insurance status or coverage, financial status, United States residency status, or the indication for which XOSPATA has been prescribed for this patient. I understand that Astellas reserves the right to change or terminate the Astellas Patient Assistance Program at any time, or to refuse to provide XOSPATA under the Astellas Patient Assistance Program to any patient.

I understand that completing this enrollment form does not guarantee that assistance will be provided to my patient. If my patient obtains XOSPATA via the Astellas Patient Assistance Program, I understand that (a) any medication supplied under the Astellas Patient Assistance Program is for the use of the patient named on this form only and shall not be sold, traded, bartered, transferred, returned for credit, or submitted to any third party (including the patient or any third-party payor) for reimbursement; (b) I will receive and secure my patient's medication at my office separate from commercially purchased medication until it's dispensed to my patient, when applicable; (c) I will comply with and abide by my State Practitioner Dispensing Laws for authorized prescribers, when applicable; and (d) the provision of free drug as part of the Astellas Patient Assistance Program is not contingent on any future purchase or prescribing of XOSPATA.

I acknowledge I may be contacted by email, postal mail, or fax using the information I've provided, and I understand my personal information will be used and disclosed by Astellas in accordance with Astellas' privacy policy, available at www.astellas.com/us/privacy-policy.

I certify that a copy of the Patient Authorization Statement has been given to the patient named on page 2 and their representative and that I have provided my patient with a description of XOSPATA Support Solutions.

My signature below certifies that I have read, understand, and agree to the Prescriber Certification Statement above.

Prescriber Signature X: _____ Date: _____

Stamped signatures not accepted. This form cannot be processed without an original signature.

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Warnings and Precautions

Differentiation Syndrome (See BOXED WARNING) 3% of 319 patients treated with XOSPATA in the clinical trials experienced differentiation syndrome. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal if not treated. Symptoms and other clinical findings of differentiation syndrome in patients treated with XOSPATA included fever, dyspnea, pleural effusion, pericardial effusion, pulmonary edema, hypotension, rapid weight gain, peripheral edema, rash, and renal dysfunction. Some cases had concomitant acute febrile neutrophilic dermatosis. Differentiation syndrome occurred as early as 1 day and up to 82 days after XOSPATA initiation and has been observed with or without concomitant leukocytosis. If differentiation syndrome is suspected, initiate dexamethasone 10 mg IV every 12 hours (or an equivalent dose of an alternative oral or IV corticosteroid) and hemodynamic monitoring until improvement. Taper corticosteroids after resolution of symptoms and administer corticosteroids for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid treatment. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, interrupt XOSPATA until signs and symptoms are no longer severe.

Posterior Reversible Encephalopathy Syndrome (PRES) 1% of 319 patients treated with XOSPATA in the clinical trials experienced posterior reversible encephalopathy syndrome (PRES) with symptoms including seizure and altered mental status. Symptoms have resolved after discontinuation of XOSPATA. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XOSPATA in patients who develop PRES.

Prolonged QT Interval XOSPATA has been associated with prolonged cardiac ventricular repolarization (QT interval). 1% of the 317 patients with a post-baseline QTc measurement on treatment with XOSPATA in the clinical trial were found to have a QTc interval greater than 500 msec and 7% of patients had an increase from baseline QTc greater than 60 msec. Perform electrocardiogram (ECG) prior to initiation of treatment with XOSPATA, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. Interrupt and reduce XOSPATA dosage in patients who have a QTcF >500 msec. Hypokalemia or hypomagnesemia may increase the QT prolongation risk. Correct hypokalemia or hypomagnesemia prior to and during XOSPATA administration.

Important Safety Information (CONTINUED)

Pancreatitis 4% of 319 patients treated with XOSPATA® (gilteritinib) in the clinical trials experienced pancreatitis. Evaluate patients who develop signs and symptoms of pancreatitis. Interrupt and reduce the dose of XOSPATA in patients who develop pancreatitis.

Embryo-Fetal Toxicity XOSPATA can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with XOSPATA and for 6 months after the last dose of XOSPATA. Advise males with female partners of reproductive potential to use effective contraception during treatment with XOSPATA and for 4 months after the last dose of XOSPATA. Pregnant women, patients becoming pregnant while receiving XOSPATA or male patients with pregnant female partners should be apprised of the potential risk to the fetus.

Adverse Reactions

Fatal adverse reactions occurred in 2% of patients receiving XOSPATA. These were cardiac arrest (1%) and one case each of differentiation syndrome and pancreatitis. The most frequent (≥5%) nonhematological serious adverse reactions reported in patients were fever (13%), dyspnea (9%), renal impairment (8%), transaminase increased (6%) and noninfectious diarrhea (5%).

7% discontinued XOSPATA treatment permanently due to an adverse reaction. The most common (>1%) adverse reactions leading to discontinuation were aspartate aminotransferase increased (2%) and alanine aminotransferase increased (2%).

The most frequent (≥5%) grade ≥3 nonhematological adverse reactions reported in patients were transaminase increased (21%), dyspnea (12%), hypotension (7%), mucositis (7%), myalgia/arthralgia (7%), and fatigue/malaise (6%).

Other clinically significant adverse reactions occurring in ≤10% of patients included: electrocardiogram QT prolonged (9%), hypersensitivity (8%), pancreatitis (5%), cardiac failure (4%), pericardial effusion (4%), acute febrile neutrophilic dermatosis (3%), differentiation syndrome (3%), pericarditis/myocarditis (2%), large intestine perforation (1%), and posterior reversible encephalopathy syndrome (1%).

Lab Abnormalities Shifts to grades 3-4 nonhematologic laboratory abnormalities in XOSPATA treated patients included phosphate decreased (14%), alanine aminotransferase increased (13%), sodium decreased (12%), aspartate aminotransferase increased (10%), calcium decreased (6%), creatine kinase increased (6%), triglycerides increased (6%), creatinine increased (3%), and alkaline phosphatase increased (2%).

Drug Interactions

Combined P-gp and Strong CYP3A Inducers Concomitant use of XOSPATA with a combined P-gp and strong CYP3A inducer decreases XOSPATA exposure which may decrease XOSPATA efficacy. Avoid concomitant use of XOSPATA with combined P-gp and strong CYP3A inducers.

Strong CYP3A inhibitors Concomitant use of XOSPATA with a strong CYP3A inhibitor increases XOSPATA exposure. Consider alternative therapies that are not strong CYP3A inhibitors. If the concomitant use of these inhibitors is considered essential for the care of the patient, monitor patient more frequently for XOSPATA adverse reactions. Interrupt and reduce XOSPATA dosage in patients with serious or life-threatening toxicity.

Drugs that Target 5HT2B Receptor or Sigma Nonspecific Receptor Concomitant use of XOSPATA may reduce the effects of drugs that target the 5HT2B receptor or the sigma nonspecific receptor (e.g., escitalopram, fluoxetine, sertraline). Avoid concomitant use of these drugs with XOSPATA unless their use is considered essential for the care of the patient.

P-gp, BCRP, and OCT1 Substrates Based on *in vitro* data, gilteritinib is a P-gp, breast cancer resistant protein (BCRP), and organic cation transporter 1 (OCT1) inhibitor. Coadministration of gilteritinib may increase the exposure of P-gp, BCRP, and OCT1 substrates, which may increase the incidence and severity of adverse reactions of these substrates. For P-gp, BCRP, or OCT1 substrates where small concentration changes may lead to serious adverse reactions, decrease the dose or modify the dosing frequency of such substrate and monitor for adverse reactions as recommended in the respective prescribing information.

Specific Populations

Lactation Advise women not to breastfeed during treatment with XOSPATA and for 2 months after the last dose.