



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

# HCP Portal User Guide

**WARNING: DIFFERENTIATION SYNDROME**

Patients treated with XOSPATA 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.

**PLEASE VISIT [XOSPATA.COM/PI](https://www.xospata.com/pi) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**



XOSPATA<sup>®</sup>, Astellas<sup>®</sup>, and the flying star logo are registered trademarks of Astellas Pharma Inc.

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077-2356-PM 09/22

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## Overview

The Xospata Support Solutions Program is an online healthcare provider tool that allows Healthcare Providers to:

- Enter new referral requests
- Obtain status updates on current referral requests
- Upload additional documentation for referral requests

## Logging On

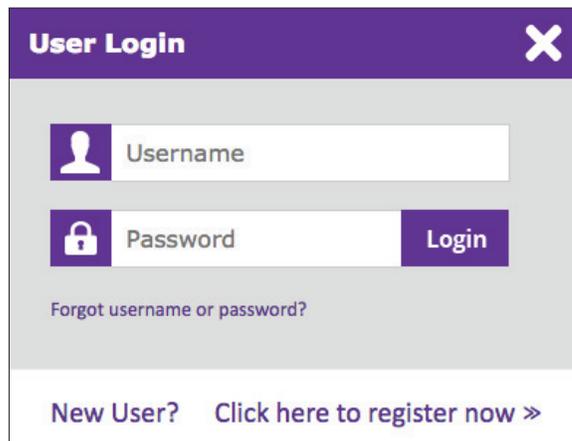
To access the Xospata® prescriber portal website, go to: <https://astellas.aspnprograms.com>



The screenshot shows the XOSPATA Support Solutions website. At the top left is the XOSPATA logo with 'gilteRitinib 40mg tablets' below it. At the top right are navigation links: Home, My Referrals, Resources, Contact, and a Login button. Below the navigation links is contact information: Phone: 866-556-2366 | Fax: 877-242-9292, and a note: 'This information is intended for US Healthcare professionals.' The main content area features a woman in a blue shirt looking thoughtful. Text on the right says: 'XOSPATA Support Solutions<sup>SM</sup> offers access and reimbursement support to help patients and their healthcare providers access XOSPATA<sup>®</sup>.' Below this is a 'Get Started' button. At the bottom of the main content area is a link: 'PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.' At the bottom of the page is the Astellas logo and copyright information: '© 2019 Astellas Pharma US, Inc. 077-0743-PM'. There is also a small icon for 'eScribe to ASPN Pharmacies, LLC Florham Park, NJ 07932'.

**First-Time Users:** Click **Get Started** to begin the registration process. Continue to page 5 of this document.

**Returning Users:** Click the **Login** button at the top right of the page. In the User Login modal that pops up, enter your User Name and Password, then click **Login**. Continue to page 6 of this document.



The User Login modal has a purple header with the text 'User Login' and a close button (X). Below the header are two input fields: 'Username' with a person icon and 'Password' with a lock icon. To the right of the Password field is a purple 'Login' button. Below the input fields is a link: 'Forgot username or password?'. At the bottom of the modal is a link: 'New User? Click here to register now >>'.

## Logging On cont.

### New User Registration

Enter the office information: Prescriber Name, Address, Phone, Fax, User Name, Email and Password.

**XOSPATA**  
gilteritinib 40mg tablets

Home My Referrals Resources Contact Login

Phone: 844-632-9272 | Fax: 844-730-8816  
This information is intended for US Healthcare professionals.

### Registration

In order to register a patient and track their status, please complete the fields to the right.

### Prescriber/Practice Registration

\*Prescriber/Practice Name  
[Text Field]

\*Address 1 [Text Field] Address 2 [Text Field]

\*Zip [Text Field] \*City [Text Field] \*State [Dropdown]

\*Phone [Text Field] Fax [Text Field]

\*User Name [Text Field] \*Email [Text Field]

\*Password [Text Field] \*Re-enter Password [Text Field]

(Passwords must be a minimum of 8 characters and include: 1 lowercase letter, 1 uppercase letter, and 1 number)  
\*Denotes this entry is mandatory.

### User Agreements

[WEBSITE ACCESS TERMS OF USE, HIPAA/BUSINESS ASSOCIATE TERMS OF USE, PRIVACY POLICY](#)

\*By clicking on this box, I verify that I have read and (i) I acknowledge my agreement, as the Covered Entity, to the terms of the HIPAA/Business Associate Agreement; and (ii) I agree to the Website Access Terms of Use and Privacy Policy.

Save

To View **WEBSITE ACCESS TERMS OF USE, HIPAA/BUSINESS ASSOCIATE TERMS OF USE, PRIVACY POLICY** click the hyperlink. When ready, click the check box to indicate agreement and then click **SAVE**.

The Registration Confirmation screen will display.

### Registration Confirmation

Thank You!

Your registration was successful.

OK

Click **OK**.

## Step 1: Creating an Enrollment Referral

Enrollment referral requests can be created in 3 steps.

**Step 1:** Enter the patient information, select or add the prescriber, and select or add an office contact.

Prescriber Information:

- If you are requesting an enrollment referral for the first time, you need to assign a prescriber to your username/password
- If you are a returning user, prescriber information will populate automatically

Identify the patient.  
Enter his or her  
information.

Click on **Add New  
Prescriber**  
(see page 7).

Click on **Add New  
Office Contact**  
(see page 8).

After entering the  
required information,  
click **Next** to confirm.

The screenshot shows the XOSPATA enrollment referral form. At the top left is the XOSPATA logo (gilteritinib 40mg tablets). At the top right are navigation links: Home, My Referrals, Resources, Contact, and a Logout button. Below the navigation is the user information: John Doe, Phone: 844-632-9272, Fax: 844-730-8816, with a note that the information is intended for US Healthcare professionals.

The form is titled "Step 1" and is divided into two main sections: "Patient Information" and "Select Product".

**Patient Information** (marked as a required field) includes the following fields:

- First Name: Lisa
- Last Name: Bell
- Address: 789 Loop Lane
- Zip: 07932, City: Florham Park, State: NJ
- Date of Birth: 08/15/1983, Gender: Male (selected), Female
- Phone: (555) 555-5555, Secondary Number: (empty)
- Email Address: lbell@email.com
- Additional Contact: (empty), Phone: (empty)
- Prescriber: (dropdown menu)
- Prescriber Contact: (dropdown menu)
- Email Address: (empty)
- Phone: (empty)

**Select Product** (XOSPATA® (gilteritinib)) includes the following fields:

- 40mg capsule (selected)
- Diagnosis Code, Refills, Quantity: (empty)
- Directions: (empty)

Callout boxes with arrows point to the following elements:

- Step 1: Enter patient-specific information and select a Product.
- Add New Prescriber button
- Add New Office Contact button
- Next button

## Step 1: Creating an Enrollment Referral cont.

On the Prescriber Information page you will add the prescriber's:

- First and Last Name
- Address, City, State and Zip
- Email Address, Phone, and Fax
- NPI and TAX ID

**Prescriber Information**

Please complete prescriber information and click Save. \*Required field

\*First Name: David      \*Last Name: Shaw

\*Address: 12 Main St      Address 2:

\*Zip: 07932      \*City: Florham Park      \*State: NJ

Email Address: dshaw@email.com      \*Phone: (555) 555-5555      \*Fax: (111) 111-1111

\*NPI #: 1111111111      \*Tax ID: 11111111111111111111111111111111      \*State License Number: 11111111

\*Medicare/Medicaid Provider #: 11111111      Self-Dispensing Pharmacy:  Yes  No

[Save](#) [Cancel](#)

Click **Save**.

You will return to the Patient Information screen. Next, identify a person who will be available to answer questions about the enrollment referral request.

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

Home My Referrals Resources Contact [Logout](#)

John Doe Phone: 844-632-9272 Fax: 844-730-8816  
This information is intended for US Healthcare professionals.

**Step 1**  
Enter patient-specific information and select a Product.

**Patient Information** \*Required field

\*First Name: Lisa      \*Last Name: Bell

\*Address: 789 Loop Lane

\*Zip: 07932      \*City: Florham Park      \*State: NJ

\*Date of Birth: 08/15/1983      \*Gender:  Male  Female

\*Phone: (555) 555-5555      Secondary Number:

Email Address: lbell@email.com

Additional Contact:      Phone:

\*Prescriber: David Shaw

Address 1: 12 Main St  
Address 2:  
Zip: 07932  
City: Florham Park  
State: NJ  
Email: dshaw@email.com  
Phone: 555-555-5555  
Fax: 111-111-1111  
NPI #: 1111111111  
Tax ID: 11111111111111111111111111111111

\*Prescriber Contact:

[Add New Prescriber](#)

**Select Product**

XOSPATA<sup>®</sup> (gilteritinib)

40mg capsule

\*Diagnosis Code      Refills      Quantity

Directions:

[Add New Office Contact](#) [Next](#)

Select your office contact, or for first time users, click, **Add New Office Contact**.



# Step 1: Creating an Enrollment Referral cont.

**Prescriber Contact Information** [X]

Please complete contact information and click Save. \*Required field

|                                   |                          |
|-----------------------------------|--------------------------|
| *First Name<br>Tiffany            | *Last Name<br>Just       |
| *Email Address<br>tjust@email.com | *Phone<br>(555) 555-5555 |

Click **Save**.

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

Home My Referrals Resources Contact

John Doe Phone: 844-632-9272 | Fax: 844-730-8816  
This information is intended for US Healthcare professionals.

**Step 1**  
Enter patient-specific information and select a Product.

**Patient Information** \*Required field

|                                  |  |
|----------------------------------|--|
| *First Name<br>Lisa              | *Last Name<br>Bell   |
| *Address<br>789 Loop Lane        |  |
| *Zip<br>07932                    | *City<br>Florham Park  |
| *State<br>NJ                     |  |
| *Date of Birth<br>08/15/1983     | *Gender<br><input type="radio"/> Male <input type="radio"/> Female |
| *Phone<br>(555) 555-5555         | Secondary Number   |
| Email Address<br>lbell@email.com |  |
| Additional Contact               | Phone  |

\*Prescriber  
David Shaw

Address 1: 12 Main St  
Address 2:  
Zip: 07932  
City: Florham Park  
State: NJ  
Email: dshaw@email.com  
Phone: 555-555-5555  
Fax: 111-111-1111  
NPI #: 1111111111  
Tax ID:  
11111111111111111111111111111111

\*Prescriber Contact  
Tiffany Just

Email Address: tjust@email.com  
Phone: 555-555-5555

**Select Product**  
XOSPATA<sup>®</sup> (gilteritinib)  
 40mg capsule

| *Diagnosis Code | Refills | Quantity |
|-----------------|---------|----------|
|                 |         |          |

Directions

Click **Next**.



## Step 2: Creating an Enrollment Referral

**Step 2:** Enter Primary Insurance and Prescription Plan information; Secondary Insurance information (if applicable); and upload insurance cards and relevant documents.

For Primary Insurance enter the Plan Name, Subscriber's Name, Member ID, and Group ID.

Secondary Medical Insurance is optional. Complete the Plan Name, Subscriber's Name, Member ID and Group ID.

Plan Type will always default to **Commercial**. This is not an editable field.

### Step 2

Enter patient insurance information and add other documentation.

#### Insurance Information

Primary Insurance (Required)

\*Plan Type  
Commercial

\*Plan Name  
Aetna

\*Subscriber's Name  
Lisa Bell

\*Policy # 1111111111      \*Group # 111111

Secondary Insurance (Optional)

Plan Type

Prescription Plan (Required)

\*Plan Type

#### Upload Scanned Insurance Card(s)

Accepted file types: PDF, JPG, PNG, GIF

Upload 0 file(s) selected

#### Upload Relevant Documents

Accepted file types: PDF, JPG, PNG, GIF

Upload 0 file(s) selected

Previous Next

## Step 2: Creating an Enrollment Referral cont.

To complete Step 2, upload the following documents: An image of the Insurance Card(s) both front and back, and other communications from the Insurance Company.

**Step 2**

Enter patient insurance information and add other documentation.

### Insurance Information

Primary Insurance (Required)

\*Plan Type  
Commercial

\*Plan Name  
Aetna

\*Subscriber's Name  
Lisa Bell

\*Policy # 1111111111      \*Group # 111111

Secondary Insurance (Optional)

Plan Type

Prescription Plan (Required)

\*Plan Type

### Upload Scanned Insurance Card(s)

Accepted file types: PDF, JPG, PNG, GIF

Upload 0 file(s) selected

### Upload Relevant Documents

Accepted file types: PDF, JPG, PNG, GIF

Upload 0 file(s) selected

Previous Next

To Attach Scanned Insurance Cards, click **Upload**.

Click **Next**.

## Step 3: Creating an Enrollment Referral

**Step 3:** Review the enrollment referral request and make any changes, if applicable.

To make any changes, click **Edit**.

Once you complete your review, click **Add Signature**.

| Insurance Information  |  |  | Edit               |
|--|--|--|--------------------|
| <b>PRIMARY INSURANCE</b><br>Aetna<br>Subscriber: Lisa Bell<br>Relation to Patient:<br>1111111111<br>GROUP#: 111111<br>PHONE:   | <b>SECONDARY INSURANCE</b><br>Subscriber:<br>Relation to Patient:<br>GROUP#:<br>PHONE: | <b>PRESCRIPTION INSURANCE</b><br>Subscriber:<br>Relation to Patient:<br>PERSON CODE:<br>ID#:<br>RXGRP#:<br>PCN:<br>RXBIN#: | ↑                  |
| Insurance Card   |  | Supporting Documentation   |                    |
| Upload   |  | Upload   |                    |
| Prescriber Information   |  | Edit   | Digital Signature  |
| David Shaw<br>NPI: 1111111111<br>TaxId: 11111111111111111111111111111111   | 12 Main St<br>Florham Park, NJ 07932<br>dshaw@email.com<br>Phone: (555) 555-5555       |  | ↑<br>Add Signature |
| Staff Contact: Tiffany Just<br>Phone: (555) 555-5555<br>Email: tjust@email.com   | Fax: (111) 111-1111  |  |                    |
| Provider Attestation   |  |  |                    |
| <p>By my signature above, I verify that I am the prescribing physician or authorized employee at the treating facility/practice and that the information being disclosed in this enrollment form is complete and accurate to the best of my knowledge. I understand that ASPN Pharmacies, LLC (ASPN) reserves the right at any time and for any reason, without my notice, to modify this enrollment form or to modify or discontinue any services or assistance provided through this Program. Finally, I authorize ASPN as my designated agent to use and disclose my patient's protected health information as may be necessary for treatment, payment, and healthcare operations, including to verify the accuracy of any information provided, to verify patient eligibility, to provide access and reimbursement support and services for my patient ("Services"), and to forward the above prescription information, by fax or other mode of delivery, to a pharmacy for fulfillment. The prescribing physician has determined that the Astellas Product for which we are requesting Services is medically appropriate for the patient and has been explained to the patient. Finally, I allow ASPN to email me regarding prescription status and insurance coverage updates.</p> |  |  |                    |
|  |  | Previous   | Create Enrollment  |

### Step 3: Creating an Enrollment Referral cont.

- 1 Sign with your mouse (optional). Enter the full name of the prescriber (required). Then, click **Apply Signature**.
- 2 Apply a signature that has been previously saved. Then, click **Apply Signature**.
- 3 Upload a written signature in PDF, JPEG, PNG or GIF format. Then, click **Upload**.

**Signature Options**

**Option 1:** You can sign the form with your mouse below.

Please continue your signature.

\*Then type in your full name.

Apply Signature Cancel Clear Signature

**Option 2:** You can select your previously saved signature from the drop down below.

Apply Signature Cancel

**Option 3:** Or upload an image of your signature.

Choose File no file selected

Full Name: Upload Cancel

**Prescriber Information** Edit Digital Signature

David Shaw 12 Main St  
NPI: 1111111111 Florham Park, NJ 07932  
TaxId: 11111111111111111111111111111111 dshaw@email.com  
Phone: (555) 555-5555  
Staff Contact: Tiffany Just Fax: (111) 111-1111  
Phone: (555) 555-5555  
Email: tjust@email.com

**Digital Signature** Add Signature

**Provider Attestation**

By my signature above, I verify that I am the prescribing physician or authorized employee at the treating facility/practice and that the information being disclosed in this enrollment form is complete and accurate to the best of my knowledge. I understand that ASPN Pharmacies, LLC (ASPN) reserves the right at any time and for any reason, without my notice, to modify this enrollment form or to modify or discontinue any services or assistance provided through this Program. Finally, I authorize ASPN as my designated agent to use and disclose my patient's protected health information as may be necessary for treatment, payment, and healthcare operations, including to verify the accuracy of any information provided, to verify patient eligibility, to provide access and reimbursement support and services for my patient ("Services"), and to forward the above prescription information, by fax or other mode of delivery, to a pharmacy for fulfillment. The prescribing physician has determined that the Astellas Product for which we are requesting Services is medically appropriate for the patient and has been explained to the patient. Finally, I allow ASPN to email me regarding prescription status and insurance coverage updates.

Previous Create Enrollment

When you are ready to submit, click **Create Enrollment**.

A message will display confirming that you created the enrollment referral request successfully.

**Enrollment Complete**

You can review the status of all your enrollment referrals by clicking here, or you can create a new enrollment referral by clicking here.



## Viewing My Request

[Home](#) [My Referrals](#) [Resources](#) [Contact](#)

To view your previous enrollment referrals, click **My Referrals**.

## Cancel

**My Enrollment Referrals Status**

Prescriber  First Name Or Last Name

| Prescriber Name | Patient Name           | Product | Referral Submitted                                | Status                                 | Info | Last Updated        | Message                           | Actions                         |
|-----------------|------------------------|---------|---|--|------|---------------------|-----------------------------------|---------------------------------|
| David Shaw      | Lisa Bell<br>8/15/1983 | XOSPATA | 8/23/2018<br><a href="#">View Enrollment Form</a> | In Process - ASPN - Pending Assignment |      | 08/23/2018 12:39 PM | <a href="#">View all messages</a> | <a href="#">Cancel Referral</a> |

To cancel a enrollment referral request, click **Cancel Referral**.

**My Enrollment Referrals Status**

Prescriber  First Name Or Last Name

| Prescriber Name | Patient Name           | Product | Referral Submitted                                | Status                                 | Info | Last Updated        | Message                           | Actions                         |
|-----------------|------------------------|---------|---|--|------|---------------------|-----------------------------------|---------------------------------|
| David Shaw      | Lisa Bell<br>8/15/1983 | XOSPATA | 8/23/2018<br><a href="#">View Enrollment Form</a> | In Process - ASPN - Pending Assignment |      | 08/23/2018 12:39 PM | <a href="#">View all messages</a> | <a href="#">Cancel Referral</a> |

To display a request's history, click the green **i** icon.

To close this display, click the **X** located on the top right corner.

**Status Info**

| Change                                | Time Stamp | Status | Changed By |
|---------------------------------------|------------|--------|------------|
| There is no history for this referral |            |        |            |

## Viewing My Request cont.

### Enrollment Referral Request History

**My Enrollment Referrals Status**

Prescriber  First Name Or Last Name

| Prescriber Name | Patient Name           | Product | Referral Submitted                                | Status                                 | Info | Last Updated        | Message                           | Actions                         |
|-----------------|------------------------|---------|---|--|------|---------------------|-----------------------------------|---------------------------------|
| David Shaw      | Lisa Bell<br>8/15/1983 | XOSPATA | 8/23/2018<br><a href="#">View Enrollment Form</a> | In Process - ASPN - Pending Assignment |      | 08/23/2018 12:39 PM | <a href="#">View all messages</a> | <a href="#">Cancel Referral</a> |

To display details of your referral, click the description under **Referral Submitted**.

**Patient Enrollment: Lisa Bell**

**Status**

Enrollment Submitted: 8/23/2018

Triage for Processing:

Product Shipped:

Cancelled:

**Attachments:**

INTAKEFORM\_15656.pdf

Insurance Card Additional Documentation

To view the uploaded attachments, click **Attachments**.

To upload additional documents, click **Upload**.

## Forgot Username or Password

In the event that a username or password is forgotten, click the **Forgot Username or Password?** link below the Login module.

**User Login**

Username

Password

[Forgot username or password?](#)

New User? [Click here to register now >>](#)

## Forgot Username or Password cont.

**Forgot Username or Password**

\*Email Address

**Submit** **Cancel**

Enter your email address and click **Submit**. A link to reset your password will be emailed to you.

**Forgot Username or Password**

**i** A link to reset your password has been emailed.

Please check your email and click the link to reset your password.

## My Profile

To change your profile, click **your name** hyperlink.

**John Doe** Phone: 844-632-9272 | Fax: 844-730-8816

This information is intended for US Healthcare professionals.

**My Profile**

You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account** \*Required field

\*Username  
John Doe **Change Password**

\*Email address  
jdoe@email.com

**My Account**

\*Prescriber/Practice Name  
John Doe

\*Phone Number Fax Number  
(555) 555-5555

**Save** **Cancel**

**Prescriber Information**

You can edit a specific prescriber's profile by clicking Edit below.

| First Name | Last Name | NPI        | Edit |
|------------|-----------|------------|------|
| David      | Shaw      | 1111111111 | edit |

**Add New Prescriber**

**Prescriber Contact Profile**

You can edit a specific contact profile by clicking Edit below.

| FirstName | LastName | Phone      | Edit |
|-----------|----------|------------|------|
| Tiffany   | Just     | 5555555555 | edit |

**Add New Prescriber Contact**

To update your password, click **Change Password**.

**My Profile**

You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account** \*Required field

\*Username  
John Doe **Change Password**

\*Email address  
jdoe@email.com

**My Account**

\*Prescriber/Practice Name  
John Doe

\*Phone Number Fax Number  
(555) 555-5555

**Save** **Cancel**

**Prescriber Information**

You can edit a specific prescriber's profile by clicking Edit below.

| First Name | Last Name | NPI        | Edit |
|------------|-----------|------------|------|
| David      | Shaw      | 1111111111 | edit |

**Add New Prescriber**

**Prescriber Contact Profile**

You can edit a specific contact profile by clicking Edit below.

| FirstName | LastName | Phone      | Edit |
|-----------|----------|------------|------|
| Tiffany   | Just     | 5555555555 | edit |

**Add New Prescriber Contact**

## Changing Prescriber Information

You can update the Prescriber Information such as First Name, Last Name, Address, Phone and Fax.

To update the Prescriber Information, click **Edit**.

**My Profile**  
You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account** \*Required field

\*Username  
John Doe Change Password

\*Email address  
jdoe@email.com

**My Account**

\*Prescriber/Practice Name  
John Doe

\*Phone Number Fax Number  
(555) 555-5555

**Prescriber Information**  
You can edit a specific prescriber's profile by clicking Edit below.

| First Name | Last Name | NPI        | Edit |
|------------|-----------|------------|------|
| David      | Shaw      | 1111111111 | edit |

[Add New Prescriber](#)

**Prescriber Contact Profile**  
You can edit a specific contact profile by clicking Edit below.

| FirstName | LastName | Phone      | Edit |
|-----------|----------|------------|------|
| Tiffany   | Just     | 5555555555 | edit |

To save your changes, click **Save**.

**Prescriber Information** ✕

Please complete prescriber information and click Save. \*Required field

\*First Name \*Last Name

\*Address Address 2

\*Zip \*City \*State

Email Address \*Phone \*Fax

\*NPI # \*Tax ID \*State License Number

\*Medicare/Medicaid Provider # Self-Dispensing Pharmacy  
 Yes  No

Save Cancel

## Changing Office Contact Information

You can update the Office Contact Information such as, First Name, Last Name, Email Address and Phone.

**My Profile**  
You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account** \*Required field

\*Username  
John Doe Change Password

\*Email address  
jdoe@email.com

**My Account**

\*Prescriber/Practice Name  
John Doe

\*Phone Number      Fax Number  
(555) 555-5555     

Save Cancel

**Prescriber Information**  
You can edit a specific prescriber's profile by clicking Edit below.

| First Name | Last Name | NPI        | Edit |
|------------|-----------|------------|------|
| David      | Shaw      | 1111111111 | edit |

Add New Prescriber

**Prescriber Contact Profile**  
You can edit a specific contact profile by clicking Edit below.

| FirstName | LastName | Phone      | Edit |
|-----------|----------|------------|------|
| Tiffany   | Just     | 5555555555 | edit |

Add New Prescriber Contact

To update the Office Contact Information, click **Edit**.

To save your changes, click **Save**.

**Prescriber Contact Information** ×

Please complete contact information and click Save. \*Required field

\*First Name  \*Last Name

\*Email Address  \*Phone

Save Cancel

### Indication

XOSPATA (gilteritinib) 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.

#### **WARNING: DIFFERENTIATION SYNDROME**

Patients treated with XOSPATA 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.

### 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.

**Pancreatitis** 4% of 319 patients treated with XOSPATA 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 ( $\geq 5\%$ ) 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 ( $\geq 5\%$ ) grade  $\geq 3$  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  $\leq 10\%$  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 5HT<sub>2B</sub> Receptor or Sigma Nonspecific Receptor** Concomitant use of XOSPATA may reduce the effects of drugs that target the 5HT<sub>2B</sub> 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.

**Please see Full Prescribing Information including BOXED WARNING for additional safety information.**