

PATIENT INFORMATION
XOSPATA® (Zoh spah' tah)
(gilteritinib)
tablets

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.

Do not take XOSPATA if you are allergic to gilteritinib or any of the ingredients in XOSPATA. See the end of this leaflet for a complete list of ingredients in XOSPATA.

Before taking XOSPATA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems, including a condition called long QT syndrome.
- have a history of low blood potassium (hypokalemia) or low blood magnesium (hypomagnesemia).
- 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 at least 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 at least 4 months after the last dose of XOSPATA.
- 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 at least 2 months after the last dose of XOSPATA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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 with a cup of water.
- 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.

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.
- **Heart rhythm problems (QT prolongation).** XOSPATA may cause a heart problem called QT prolongation. Your healthcare provider should check the electrical activity of your heart with a test called electrocardiogram (ECG) before you start taking XOSPATA and during your treatment with XOSPATA. Tell your healthcare provider right away if you have a change in your heartbeat, or if you feel dizzy, lightheaded, or faint. The risk of QT prolongation is higher in people with low blood magnesium or low blood potassium levels. Your healthcare provider will do blood tests to check your potassium and magnesium levels before and during your treatment with XOSPATA.
- **Inflammation of the pancreas (pancreatitis).** Tell your healthcare provider right away if you have severe stomach (abdomen) pain that does not go away. This pain may happen with or without nausea and vomiting.

The most common side effects of XOSPATA include:

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| • joint or muscle pain | • swelling due to fluid retention | • infection that has spread through your body (sepsis) |
| • changes in liver function tests | • rash | • headache |
| • fatigue | • nausea | • low blood pressure |
| • fever | • mouth sores | • dizziness |
| • diarrhea | • pneumonia | • vomiting |
| • shortness of breath | • cough | |

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 FDA at 1-800-FDA-1088.

How should I store XOSPATA?

- XOSPATA comes in a child-resistant package.
- Store XOSPATA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep XOSPATA in the original container.
- **Keep XOSPATA and all medicines out of the reach of children.**

General information about the safe and effective use of XOSPATA.

Medicines are sometimes prescribed for conditions not listed in the Patient Information leaflet. Do not use XOSPATA for a condition for which it was not prescribed. Do not give XOSPATA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about XOSPATA that is written for healthcare professionals.

What are the ingredients in XOSPATA?

Active ingredient: gilteritinib

Inactive ingredients: mannitol, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, magnesium stearate, hypromellose, talc, polyethylene glycol, titanium dioxide and ferric oxide.

Distributed by: Astellas Pharma US, Inc., Northbrook, Illinois 60062

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For more information about XOSPATA, call 1-800-727-7003, or visit www.XOSPATA.com.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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