XOSPATA®
gilteritinib 40mg tablets

About XOSPATA® (gilteritinib)

XOSPATA is the first FDA-approved FMS-like tyrosine kinase 3 (FLT3) inhibitor for adult patients with relapsed or refractory Acute Myeloid Leukemia with a FLT3 mutation.[1]

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.

Overview

XOSPATA is a targeted, oral medicine for the treatment of adult patients with relapsed or refractory Acute Myeloid Leukemia with a FLT3 mutation as detected by an FDA-approved test.[1]

Understanding FLT3 Mutation-positive Acute Myeloid Leukemia

Acute Myeloid Leukemia is a life-threatening cancer that impacts the blood and bone marrow, and its incidence increases with age.[2,3] The American Cancer Society estimates that in 2018, approximately 19,000 new patients will be diagnosed with AML in the U.S.[3]

AML has been associated with various genetic mutations, the most common of which is FLT3-ITD (internal tandem duplication).[4] Impacting approximately 30 percent of AML patients,[4] the FLT3-ITD mutation is associated with worsened disease free survival and overall survival.[5,6] FLT3 tyrosine kinase domain (TKD) mutations impact approximately seven percent of AML patients[4] and, although the impact of these mutations is less clear,[7] they have been associated with treatment resistance.[8]

Clinical Studies

For more information on gilteritinib clinical trials see clinicaltrials.gov.

Select Safety Information

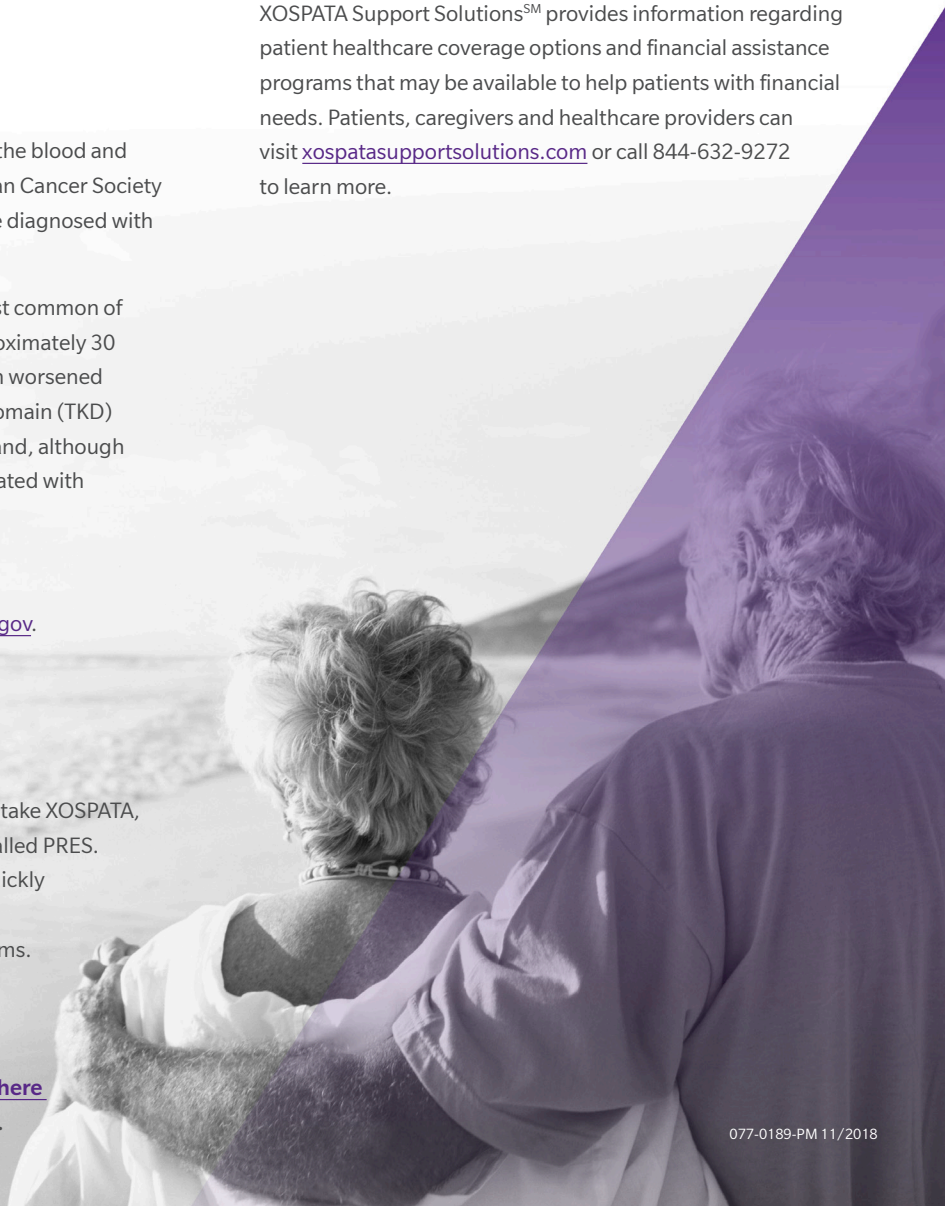
XOSPATA may cause serious side effects including:

Posterior Reversible Encephalopathy Syndrome (PRES). If you take XOSPATA, you may be at risk of developing a condition involving the brain called PRES. Tell your healthcare provider right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your healthcare provider will do a test to check for PRES. Your healthcare provider will stop XOSPATA if you develop PRES.

Please see Important Safety Information on reverse, and click here for full Prescribing Information, including Patient Information.

Patient Access and Support for XOSPATA

In the U.S. Astellas, through XOSPATA Support Solutions℠, offers access and reimbursement support to help patients access the Astellas medication prescribed by their healthcare providers. XOSPATA Support Solutions℠ provides information regarding patient healthcare coverage options and financial assistance programs that may be available to help patients with financial needs. Patients, caregivers and healthcare providers can visit xospatasupportsolutions.com or call 844-632-9272 to learn more.



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Important Safety Information

Who should not take XOSPATA?

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

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 a history of low blood potassium (hypokalemia) or low blood magnesium (hypomagnesemia).
- If you are pregnant or plan to become pregnant. XOSPATA can cause harm to your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with XOSPATA or think you may be pregnant.
  - If you are able to become pregnant, your healthcare provider may perform a pregnancy test 7 days before you start treatment with XOSPATA.
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with XOSPATA and for 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.
- 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 at least 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.

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:

- Joint or muscle pain
- Changes in liver function tests
- Fatigue
- Fever
- Diarrhea
- Shortness of breath
- Swelling due to fluid retention
- Rash
- Nausea
- Mouth sores
- Pneumonia
- Cough
- Infection that has spread through your body (sepsis)
- Headache
- Low blood pressure
- Dizziness
- Vomiting

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.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

[1] XOSPATA [package insert]. Northbrook, IL: Astellas Inc.

[2] American Cancer Society. What is acute myeloid leukemia? (02-22-2016) https://www.cancer.org/cancer/acute-myeloid-leukemia/about/what-is-aml.html. Accessed 05-10-2018.

[3] American Cancer Society. Key statistics for acute myeloid leukemia (01-04-2018). https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html. Accessed 03-12-2018.

[4] Patel JP, Gönen M, Figueroa ME, et al. Prognostic relevance of integrated genetic profiling in acute myeloid leukemia. N Engl J Med. 2012;366(12):1079-89.

[5] Whitman SP, Archer KJ, Feng L, et al. Absence of the wild-type allele predicts poor prognosis in adult de novo acute myeloid leukemia with normal cytogenetics and the internal tandem duplication of FLT3: a Cancer and Leukemia Group B study. Cancer Res. 2001;61(19):7233-9.

[6] Whitman SP, Maharry K, Radmacher MD, et al. FLT3 internal tandem duplication associates with adverse outcome and gene- and microRNA-expression signatures in patients 60 years of age or older with primary cytogenetically normal acute myeloid leukemia: a Cancer and Leukemia Group B study. Blood. 2010;116(18):3622-6.

[7] Bacher U, Haferlach C, Kern W, Haferlach T, Schnittger S. Prognostic relevance of FLT3-TKD mutations in AML: the combination matters-an analysis of 3082 patients. Blood. 2008;111(5):2527-37.

[8] Alvarado Y, Kantarjian H, Luthra R, et al. Treatment with FLT3 inhibitor in patients with FLT3-mutated acute myeloid leukemia is associated with development of secondary FLT3-tyrosine kinase domain mutations. Cancer. 2014;120(14):2142-9.

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