

What is acute myeloid leukemia (AML)?



AML is a type of leukemia in the blood and bone marrow that **affects blood cells**.

AML

AML is the **most common type of acute leukemia** found in adults.

19,520/yr

An estimated **19,520 new cases** of AML diagnosed in the United States in 2018.

Types of secondary AML (sAML)

Therapy-related AML (t-AML)

t-AML is AML that develops because of past cancer treatment, such as chemotherapy, radiation therapy, or immunotherapy.

AML with myelodysplasia-related changes (AML-MRC)

AML-MRC is AML that develops because of certain types of blood disorders, a specific genetic mutation, or the presence of certain abnormal blood cells.

WHAT IS VYXEOS?

VYXEOS is an intravenous (IV) chemotherapy used for the treatment of adults with certain types of newly-diagnosed acute myeloid leukemia (AML). These types include patients whose AML is related to previously received chemotherapy or radiation therapy (also called therapy-related AML, t-AML) and AML in patients who previously had certain types of blood disorders, have a specific genetic mutation, or have certain abnormal blood cells (also called AML with myelodysplasia-related changes, AML-MRC).

IMPORTANT SAFETY INFORMATION

WARNING: VYXEOS has different dosage recommendations from other medications that contain daunorubicin and/or cytarabine. Do not substitute VYXEOS for other daunorubicin and/or cytarabine-containing products.

VYXEOS should not be given to patients who have a history of serious allergic reaction to daunorubicin, cytarabine, or any of its ingredients.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED Warning, and discuss with your doctor.

Vyxeos[®]
(daunorubicin and cytarabine) 44 mg/100 mg
liposome for injection per vial

AML Quick Facts

Roughly one-third of all AML cases are diagnosed as t-AML or AML-MRC.

Proper diagnosis of AML is determined by your doctor after reviewing symptoms, completing a bone marrow biopsy and blood cell count, and running certain tests.

68 years old

The average age of an AML patient is 68 years old.

Risk factors and symptoms of AML

Some known risk factors for AML include:

- smoking
- certain chemical exposures
- certain chemotherapy drugs
- radiation exposure
- certain blood disorders, such as myelodysplastic syndromes (MDS)
- genetic syndromes
- family history
- older age
- male gender

Some symptoms of AML in adults include:

- fever
- shortness of breath
- easy bruising or bleeding
- petechiae (red, purple, or brown spots on the skin)
- weakness or feeling tired
- weight loss or loss of appetite
- being more vulnerable to infection

IMPORTANT SAFETY INFORMATION, continued

VYXEOS can cause a severe decrease in blood cells (red and white blood cells and cells that prevent bleeding, called platelets) which can result in serious infection or bleeding and possibly lead to death. Your doctor will monitor your blood counts during treatment with VYXEOS. Patients should tell the doctor about new onset fever or symptoms of infection or if they notice signs of bruising or bleeding.

VYXEOS can cause heart-related side effects. Tell your doctor about any history of heart disease, radiation to the chest, or previous chemotherapy. Inform your doctor if you develop symptoms of heart failure such as:

- shortness of breath or trouble breathing
- swelling or fluid retention, especially in the feet, ankles, or legs
- unusual tiredness

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IMPORTANT SAFETY INFORMATION, continued

VYXEOS may cause allergic reactions including anaphylaxis. Seek immediate medical attention if you develop signs and symptoms of anaphylaxis such as:

- trouble breathing
- severe itching
- skin rash or hives
- swelling of the face, lips, mouth, or tongue

VYXEOS contains copper and may cause copper overload in patients with Wilson's disease or other copper-processing disorders.

VYXEOS can damage the skin if it leaks out of the vein. Tell your doctor right away if you experience symptoms of burning, stinging, or blisters and skin sores at the injection site.

VYXEOS can harm your unborn baby. Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Do not breastfeed while receiving VYXEOS. Females and males of reproductive potential should use effective contraception during treatment and for 6 months following the last dose of VYXEOS.

The most common side effects were bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

Call your doctor for medical advice about side effects. 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. You may also report side effects to Jazz Pharmaceuticals at 1-800-520-5568.

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