VYXEOS Quick Facts

About VYXEOS (vix-e-ose)

sAML:
t-AML or AML-MRC

VYXEOS is used to treat **2 types of secondary acute myeloid leukemia (sAML):** therapy-related AML (t-AML) and AML with myelodysplasia-related changes (AML-MRC).

VYXEOS is a combination of **2 chemotherapies, daunorubicin and cytarabine,** into tiny, bubble-like carriers called liposomes.

The VYXEOS **solution is purple.** It is given as an intravenous (IV) injection.

Induction and consolidation with VYXEOS

For first **induction therapy,** VYXEOS is given as an infusion for **90 minutes on Days 1, 3, and 5 of treatment.**

For **consolidation therapy,** VYXEOS is given as an infusion for **90 minutes on Days 1 and 3 of treatment.**

WHAT IS VYXEOS?

VYXEOS is an intravenous (IV) chemotherapy used for the treatment of certain types of newly-diagnosed acute myeloid leukemia (AML) in adults and pediatric patients 1 year and older, including 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 (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 per vial
liposome for injection

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You may receive up to **2 cycles of induction and 2 cycles of consolidation.**

In a clinical trial including older adult patients with t-AML or AML-MRC in which patients received either VYXEOS or the standard AML chemotherapy treatment

9.6 months vs 5.9 months

Approximately **half of the patients treated with VYXEOS were alive at 9.6 months** compared to 5.9 months for those treated with standard chemotherapy.[a]

42% vs 28%

VYXEOS estimated survival at 1 year for patients was 42% compared to 28% for patients with standard chemotherapy.[a]

38% vs 26%

38% of patients **achieved complete remission[b] with VYXEOS** compared to 26% of patients with standard chemotherapy,[a] meaning more patients responded to treatment with VYXEOS.

34% vs 25%

34% of patients **received a hematopoietic stem cell transplant (HSCT) with VYXEOS** compared to 25% of patients with standard chemotherapy.[a]

[a]Standard chemotherapy was cytarabine 100 mg/m^2 and daunorubicin 60 mg/m^2.
[b]Complete remission is the disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured.

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.

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IMPORTANT SAFETY INFORMATION, continued

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

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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