

About acute myeloid leukemia (AML)



What is t-AML?

Therapy-related acute myeloid leukemia, also known as t-AML, is a type of secondary AML (sAML) that may occur in those who have previously been treated for cancer with chemotherapy, radiation therapy, or immunotherapy.

What is AML-MRC?

Acute myeloid leukemia with myelodysplasia-related changes, also known as AML-MRC, is a type of secondary AML (sAML) that may be present in those who have previously had certain types of blood disorders, have a specific genetic mutation, or have certain abnormal blood cells.

About VYXEOS (vix-e-ose)



How does VYXEOS work?

VYXEOS is an advancement in chemotherapy that combines 2 currently used therapies, daunorubicin and cytarabine, into tiny, bubble-shaped carriers called liposomes. The liposomes are taken up by leukemia cells (blasts) to a greater extent than by normal cells. Once inside, the liposomes release the drugs to help kill the blasts.

How is VYXEOS administered?

VYXEOS is given as an intravenous (IV) infusion using a central IV line or peripherally inserted central catheter. VYXEOS is given in cycles, known as induction and consolidation, and your doctor will determine how many cycles of treatment are needed based on your response.

What makes me eligible to receive VYXEOS treatment?

There are a variety of factors your healthcare team will consider when determining if you are a candidate for VYXEOS, such as your age, your overall health, and whether or not you have a confirmed diagnosis of t-AML or AML-MRC.

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

Treatment with VYXEOS



Will I receive my treatment in the hospital or in an outpatient setting?

Your healthcare team may decide to administer VYXEOS in an outpatient setting based on the severity of the disease, your overall health, and how close you live to an infusion center. Your healthcare team will determine what is best for you.

How long will I be on treatment?

Although induction and consolidation phases only require 2 to 3 days of treatment per cycle, you will most likely be in the hospital for several weeks to monitor your response and manage any potential complications.

Can I do anything that will increase my positivity during treatment?

It is important to remain positive during treatment. Keep participating in hobbies, like puzzles or journaling, and any fitness activities you are deemed capable of by your doctor, such as walking.

What should I tell my doctor before treatment with VYXEOS?

Before treatment, you should tell your doctor of any known or suspected pregnancy, history of heart disease, history of copper-processing disorder, additional medications you may be taking, or history of treatment with an anthracycline.

What should I tell my doctor during treatment with VYXEOS?

During treatment, you should tell your doctor if you are experiencing fever; signs of infection; bruising; bleeding; signs of heart failure such as shortness of breath or trouble breathing and swelling or fluid retention; skin damage; signs of hypersensitivity reactions; or signs of anaphylaxis such as difficulty breathing, severe itching, skin rash, hives, or swelling of the face, lips, mouth, or tongue.

What are the possible side effects of VYXEOS?

The most common side effects of VYXEOS include 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.

These are not all of the possible side effects of VYXEOS. Be sure to speak to your healthcare team about any side effects you have. You will also have blood tests done to check for side effects during treatment with VYXEOS.

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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Induction & consolidation with VYXEOS



What is the difference between induction and consolidation?

Induction is the first phase of treatment, used to control the disease and reduce the number of blasts to achieve remission (a decrease in or disappearance of signs and symptoms of cancer). Consolidation is the second, maintenance, phase of treatment, used to maintain remission and decrease the number of any remaining blasts.

Why might I need a second induction or consolidation?

Your VYXEOS dosing schedule is designed specifically for you by your healthcare team based on your response at certain benchmarks (like bone marrow assessments) during treatment.

Financial assistance



Will my insurance cover VYXEOS?

Ask your healthcare team about your insurance coverage for VYXEOS. You can also contact our dedicated reimbursement specialists at JazzCares, our patient support hotline. Call 1-855-5VYXEOS (1-855-589-9367) Monday through Friday from 9 AM to 8 PM ET.

Are there any financial assistance programs available to me?

Our patient support program, JazzCares, has dedicated specialists who are available to assist you with financial coverage options for VYXEOS. Contact our team at 1-855-5VYXEOS (1-855-589-9367) Monday through Friday from 9 AM to 8 PM ET for all questions regarding financial assistance options.

Who can answer specific questions I have regarding my treatment and insurance coverage?

Your healthcare team is the best source of information about treatment and insurance coverage with VYXEOS.

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

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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.

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including BOXED Warning, and discuss with your doctor.