

Before treatment

1

Your doctor may perform multiple tests to determine what type of acute myeloid leukemia (AML) you have. If you receive a diagnosis of therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC), different treatment options may be discussed to ensure you receive the best care for you.

2

If your healthcare team decides you are a candidate for VYXEOS (vix-e-ose), treatment typically begins immediately.

Make your doctor aware of any important information before beginning treatment.

During treatment

VYXEOS is administered in 2 treatment phases, called induction and consolidation, as an intravenous (IV) infusion using a central IV line or a peripherally inserted central catheter. You may receive up to 2 cycles of induction and up to 2 cycles of consolidation, depending on your treatment plan. Your healthcare team will determine what is needed for you.

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.

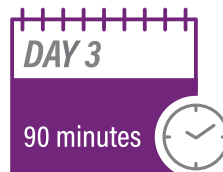
Vyxeos[®]
(daunorubicin and cytarabine) 44 mg/100 mg
liposome for injection per vial

During treatment, continued

1st induction

The first phase of treatment, known as first induction, is used to control the disease and reduce the number of leukemia cells (blasts) to achieve remission (a decrease in or disappearance of signs and symptoms of cancer). Most patients will require several weeks of hospital stay to monitor blood counts and manage potential complications.

- Given in a 1-week time period
- Days 1, 3, & 5 for 90 minutes



Days 14-21: Doctors may assess your bone marrow to see if VYXEOS is working by looking at how many blasts remain.

The next step will depend on the results of your bone marrow assessment. If there are still too many blasts left, you may begin **2nd induction**. If your results show you are in remission, you may go directly to **1st consolidation**.

2nd induction *(if needed)*

Second induction may be given if you did not reach remission after the first induction.

- Begins 2-5 weeks after 1st induction
- Days 1 & 3 for 90 minutes



Days 14-21: You will have a bone marrow assessment.

Depending on the results of your bone marrow assessment, you may begin **1st consolidation**.

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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During treatment, continued

1st consolidation

Consolidation is the next phase of treatment, used to maintain remission and decrease the number of remaining blasts. This phase will begin as soon as possible after recovery from induction.

- Begins 5-8 weeks after start of last induction
- Days 1 & 3 for 90 minutes



Days 14-21: Your doctors may perform follow-up tests to determine whether you need a 2nd consolidation.

2nd consolidation *(if needed)*

Second consolidation may be given to maintain remission.

- Begins 5-8 weeks after start of 1st consolidation
- Days 1 & 3 for 90 minutes



Your doctors may perform follow-up tests.

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:

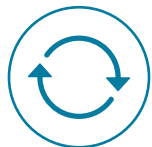
- shortness of breath or trouble breathing
- swelling or fluid retention, especially in the feet, ankles, or legs
- unusual tiredness

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More treatment details



Although infusions do not occur daily, you will most likely be in the hospital for several weeks to monitor your blood count and manage any potential complications during treatment.



Second consolidation cycles are administered to ensure the disease remains controlled.



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.



Before consolidation can begin, doctors must assess cardiac function, complete blood counts, and liver and kidney function.



Absolute neutrophil count (ANC) and platelet count, which are measured with a blood test, will be assessed before consolidation to determine if consolidation is the next appropriate step.



The most common side effects reported by patients receiving 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.

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.

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Helpful tips during AML treatment



Feelings of sadness, anxiety, and loneliness are normal during treatment.

Talk with your doctor about these concerns. Your healthcare team can provide you with sources of information and advice.



Accept support.

Reach out to family, friends, and any support groups that may be able to offer advice and solace for those going through chemotherapy.



Stay positive.

Chemotherapy can leave you feeling lonely and worried about the future. Continue your normal hobbies as much as possible. Reading, doing puzzles, journaling, and meditating may help you maintain a positive attitude.



Stay physically active.

Take walks and engage in any fitness activities that are okayed by your doctor. Keeping your body in the best possible shape may help during treatment.



Eat healthy.

During chemotherapy, it is important to fuel your body with sources of vitamins and nutrients to keep energy levels steady.

IMPORTANT SAFETY INFORMATION, continued

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.