

Starting your treatment with VYXEOS

A Guide for Patients and Caregivers

Introduction to treatment with VYXEOS (pronounced vix-e-ose)

This guide will help you along the way during your acute myeloid leukemia (AML) treatment by providing answers to questions about treatment with VYXEOS.

Topics covered in this guide include:

- What is VYXEOS?
- What is AML?
- Who should not receive VYXEOS?
- How is VYXEOS administered?
- How do I know VYXEOS is working?
- What should I tell my doctor before and during treatment with VYXEOS?
- What are the possible side effects of VYXEOS?
- What resources are available for those affected by AML?

Working closely with your healthcare team is an important part of your treatment. It may be a good idea to make a list of questions and ask a caregiver or family member to take notes during your appointment.

Indication—what is VYXEOS and what is it used for?

VYXEOS (daunorubicin and cytarabine) liposome for injection 44 mg/100 mg is an intravenous (IV) chemotherapy used for the treatment of adults with certain types of newly-diagnosed acute myeloid leukemia. These types include patients whose AML is related to previously received chemotherapy or radiation therapy (also called therapy-related AML) and AML in patients who previously had certain types of blood disorders (also called AML with myelodysplasia-related changes). Based on your medical history, your doctor can help you decide if this medication is right for you.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about VYXEOS?

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

Please see additional safety information and *full Prescribing Information*, including BOXED Warning, and discuss with your doctor.

Healthcare team contact information

Name: _____

Phone: _____


Vyxeos™
(daunorubicin and cytarabine) 44 mg/100 mg
per vial
liposome for injection

What is AML?

Acute myeloid leukemia (AML) is the most common type of acute leukemia in adults. When someone has AML, it means the bone marrow may make abnormal white blood cells, red blood cells, or platelets. These abnormal cells are called leukemia cells or blasts. Leukemia is monitored by measuring the amount of blasts. As the percentage of leukemia cells increases, the bone marrow is less able to create normal white and red blood cells and platelets.

Who should not receive VYXEOS?

VYXEOS should not be given to patients with a history of a serious allergy to any of its ingredients or to the chemotherapies cytarabine or daunorubicin.

How is VYXEOS administered?

VYXEOS is administered as an IV infusion using a central IV line or peripherally inserted central catheter. It will be given in cycles, and your doctor will determine how many cycles of therapy you will receive.

Induction

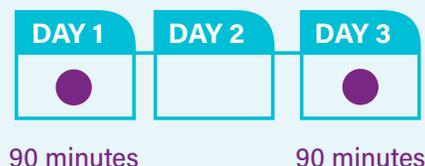
Initial cycle(s), called induction, is intended to control the disease and reduce the number of leukemia cells. Most patients will require several weeks of hospital stay to monitor blood counts and manage potential complications.



Some patients may receive a second cycle of induction treatment. Your healthcare team will help determine what is best for you.

Consolidation

Subsequent cycle(s), called consolidation, may be given to ensure the disease is being controlled and the number of leukemia cells continues to be reduced.



Not all patients receive consolidation treatment, but those who do may receive up to 2 cycles. Your healthcare team will help determine what is best for you.



When you receive your infusion, you may notice that the VYXEOS solution is purple.

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How do I know if VYXEOS is working?

A bone marrow exam can be done in 2 to 3 weeks after treatment to look for presence of leukemia cells.

IMPORTANT SAFETY INFORMATION

What should I tell my doctor before and during treatment with VYXEOS?

Before treatment

Known or suspected pregnancy. VYXEOS can harm your unborn baby and should not be received during pregnancy. Females and males of reproductive age should use effective contraception during treatment and for 6 months following the last dose of VYXEOS. Additionally, you should not breastfeed during treatment with VYXEOS, and for at least 2 weeks after the last dose.

History of heart disease. VYXEOS can cause heart-related side effects. Tell your healthcare team about any history of heart disease, radiation to the chest, or previous chemotherapy.

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

Additional medications you may be taking. It is important to tell your healthcare team about all medications you may be taking, including any vitamins or supplements, to determine what you may need to discontinue during treatment. Some medications may affect treatment with VYXEOS.

During treatment

You should immediately contact a member of your healthcare team if you experience any of the following:

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

Signs of heart failure. VYXEOS can cause heart-related side effects such as shortness of breath or trouble breathing; swelling or fluid retention, especially in the feet, ankles, or legs; or unusual tiredness.

Skin damage. 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.

Signs of hypersensitivity reactions, including anaphylaxis. VYXEOS may cause allergic reactions, including anaphylaxis. Seek immediate medical attention if you develop signs and symptoms of anaphylaxis, such as difficulty breathing, severe itching, skin rash or hives, or swelling of the face, lips, mouth, or tongue.

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.

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What are the possible side effects of VYXEOS?

The following are some of the most common side effects reported by patients receiving VYXEOS:

- 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
- vomiting

What resources are available for those affected by AML?

There are a variety of patient and caregiver support groups and resources available for information about AML:

American Cancer Society

www.cancer.org
1-800-ACS-2345 (1-800-227-2345)

Cancer Support Community

www.cancersupportcommunity.org
1-888-793-9355

Be The Match

www.bethematch.org
1-888-999-6743

The Leukemia & Lymphoma Society

www.lls.org
1-800-955-4572

BMT InfoNet

www.bmtinfonet.org
1-888-597-7674

National Cancer Institute

www.cancer.gov
1-800-4-CANCER (1-800-422-6237)

CancerCare

www.cancer.org
1-800-813-HOPE (1-800-813-4673)

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Your healthcare team should always be your first source of information and advice. Support groups can be a way for you to connect with others who may also be undergoing a similar treatment plan. Hospital-based or clinic-based support networks may also provide social work services, financial aid, nutritional advice, and other assistance.

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 safety information and *full Prescribing Information*, including BOXED Warning, and discuss with your doctor.