

Understanding treatment with VYXEOS, *an advancement in secondary AML therapy*



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

Explore what to expect during treatment with VYXEOS (vix-e-ose) and why this treatment has been chosen for you or your loved one with newly-diagnosed secondary acute myeloid leukemia (sAML).

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

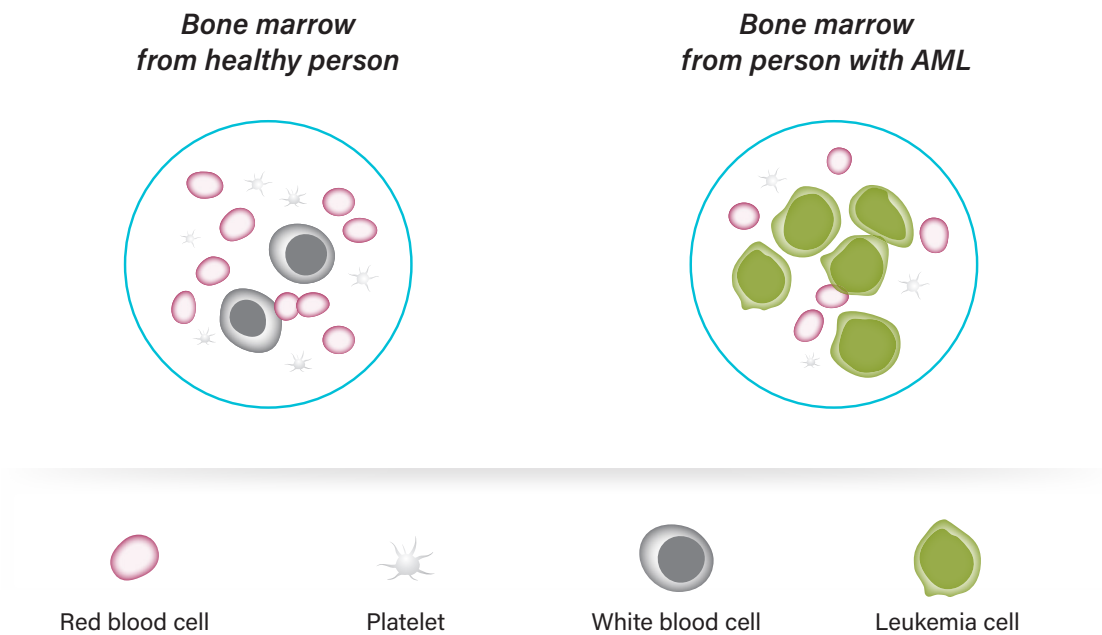
WARNING: VYXEOS has different dosage recommendations from other medications that contain daunorubicin and/or cytarabine. Do not substitute VYXEOS for other daunorubicin and/or cytarabine-containing products.

Please see additional Important Safety Information on page 17 and **full Prescribing Information**, including **BOXED Warning**.

What is acute myeloid leukemia?

Acute myeloid leukemia (AML) is the most common type of acute leukemia in adults.

In AML, the bone marrow makes abnormal red blood cells, platelets, or myeloblasts (a type of immature white blood cell). These abnormal cells are called "blasts" and are the leukemia cells. These cells divide quickly, leaving less room for healthy cells to develop, and also cause the disease to spread fast. Acute leukemia is monitored by measuring the number of blasts in the bone marrow.



IMPORTANT SAFETY INFORMATION

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

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An estimated **20,240 new cases** of AML were diagnosed in the United States in 2021



The average age of a person with AML is **68 years old**



Some known **risk factors** for AML include:

- Smoking
- Certain chemical exposures
- Certain chemotherapy drugs
- Radiation exposure
- Certain blood disorders, such as myelodysplastic syndromes (MDS)
- Certain 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
- Loss of appetite
- Recurrent infections

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What is secondary AML?



AML-MRC

May develop in those who have **previously had certain types of blood disorders (such as myelodysplastic syndromes, also called MDS), have a specific genetic mutation, or have certain abnormal blood cells.**

Your doctor may conduct further tests to confirm a diagnosis of AML-MRC before beginning treatment.

What tests can confirm an AML-MRC diagnosis?

If your doctor suspects your AML might be AML-MRC but you do not have any history of blood disorders, further testing may be conducted in order to check for certain genetic mutations or chromosomal abnormalities.



Cytogenetic tests look at chromosomes to check for certain changes that cause a genetic condition or some types of cancer.



Molecular genetic tests study individual genes to find variations or mutations that may lead to a genetic disorder.

What are chromosomes?

Chromosomes are structures in our cells that carry our DNA. In some cases, the structure of the chromosome is altered, meaning the chromosome is abnormal.

It is important your healthcare team correctly identifies AML-MRC and any genetic conditions you may have, as these can impact your treatment plan.



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

Secondary AML (sAML) is a type of AML that develops due to previous cancer treatment or certain blood cell disorders.

sAML consists of different subtypes, 2 of which are known as therapy-related AML (t-AML) and AML with myelodysplasia-related changes (AML-MRC). sAML has traditionally been treated with chemotherapy.

t-AML

May occur in those who have **previously been treated for cancer with chemotherapy, radiation therapy, or immunotherapy.**

Depending on the type of therapy previously received, t-AML can occur anytime from 2 to 10 years after treatment for cancer.

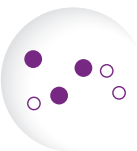
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VYXEOS is an advancement in chemotherapy used for the treatment of adults and pediatric patients 1 year and older with certain types of newly-diagnosed sAML: t-AML or AML-MRC.



For these types of AML, VYXEOS is the only chemotherapy that combines 2 currently used, effective chemotherapies into tiny, bubble-like carriers called liposomes, which carry the drugs to the bone marrow.

The liposomes are taken up by the blasts to a greater extent than by normal cells. Once inside, the liposomes release the drugs to help kill the blasts.^a This type of technology, combining 2 drugs in this way, is the first of its kind in AML treatment.



VYXEOS is given as an intravenous (IV) infusion. You will notice that the VYXEOS solution is purple.

● **Chemotherapy may help patients get to remission and the opportunity to receive a stem cell transplant, if appropriate.**

What is a stem cell transplant?

Stem cell transplant may be used to replace blood-forming cells in the bone marrow that have been destroyed by treatment with chemotherapy or radiation. With a stem cell transplant, a person receives new cells from a donor's blood or bone marrow that grow into healthy blood cells to replace the ones that were lost.

IMPORTANT SAFETY INFORMATION

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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^aResults based on early studies in animals.



If you receive a diagnosis of t-AML or AML-MRC and your healthcare team decides you will receive VYXEOS, treatment typically begins as soon as possible.

VYXEOS is given in steps known as induction and consolidation.

A full VYXEOS treatment course can consist of **up to 2 cycles of induction and up to 2 cycles of consolidation**. Your doctor will determine what is needed based on your progress.

Your healthcare team may decide to administer VYXEOS in an outpatient setting depending on your overall health before and during therapy, your ability to travel to see your providers in the outpatient setting and several other factors. Your healthcare team will discuss options with you to help determine what is best.

● **After you have finished induction and consolidation phases, treatment with VYXEOS is complete.**

Induction

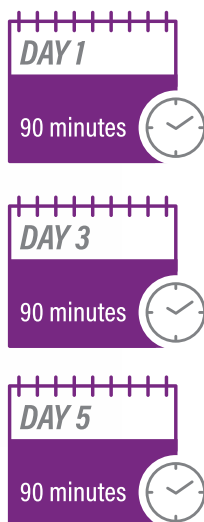
Induction is the first phase of treatment.

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)**.

Before you receive your first infusion, the doctor will perform a few tests.

Treatment schedule—first induction

- 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 second induction.

A second induction may be given if you did not reach remission after the first treatment cycle.

- Begins 2-5 weeks after first induction if there were no unacceptable side effects
- Days 1 & 3 for 90 minutes
- Days 14-21: You may have a bone marrow assessment. Depending on the results of this, you may begin first consolidation



If your results show you are in remission, you may go directly to first consolidation.

Your doctor will perform additional tests to determine if consolidation is the next step. Before consolidation can begin, cardiac function, complete blood counts, and liver and kidney function will be assessed.

Consolidation

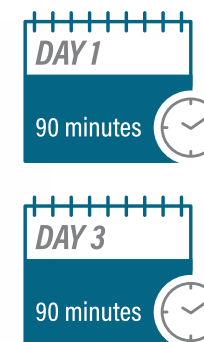
Consolidation is the next phase of treatment.

Used to maintain remission and decrease the number of remaining blasts. This phase begins after induction for patients who are in remission. Consolidation is used to kill any remaining blasts that may not be active but could regrow and cause a relapse.

A full VYXEOS treatment course can consist of up to **2 cycles of induction and up to 2 cycles of consolidation.**

Treatment schedule

- Begins 5-8 weeks after the start of last induction
- Days 1 & 3 for 90 minutes
- Days 14-21: Doctors may perform follow-up tests to determine whether you need a second consolidation



A hospital stay may be required so that blood counts can be monitored and potential complications can be managed.

The administration schedule for VYXEOS also supports the possibility of treatment in the outpatient setting. Your healthcare team will discuss options with you to help determine the best treatment approach.

- In the clinical trial, approximately half of the patients receiving VYXEOS were treated in an outpatient setting for the consolidation phase

After the consolidation phase, treatment with VYXEOS is complete. Although treatment with VYXEOS may be done, your doctor may recommend more tests, bone marrow transplant, or other treatments.

IMPORTANT SAFETY INFORMATION

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

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

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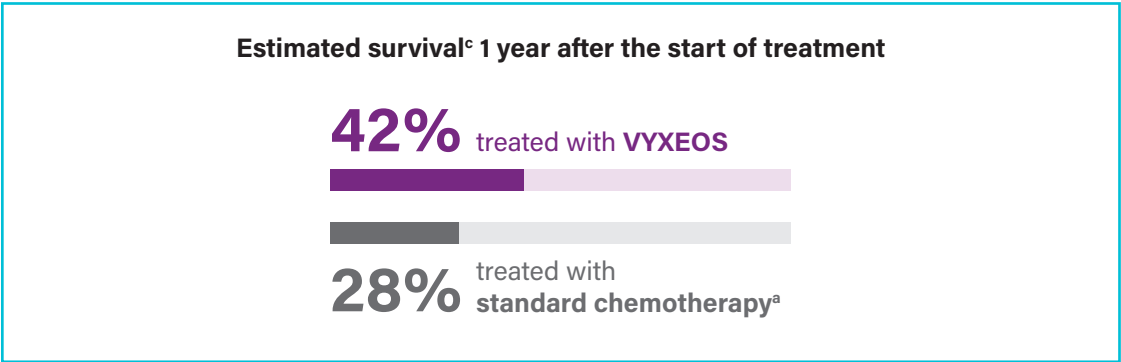
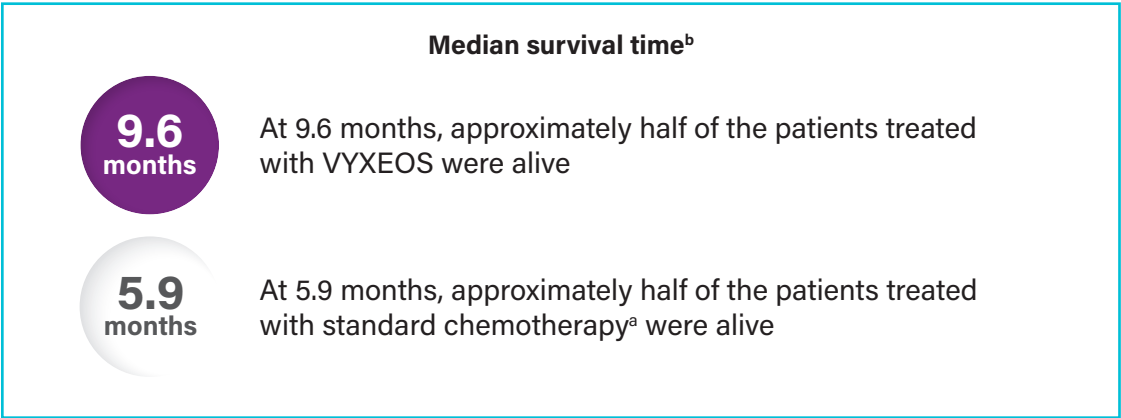
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How VYXEOS may help

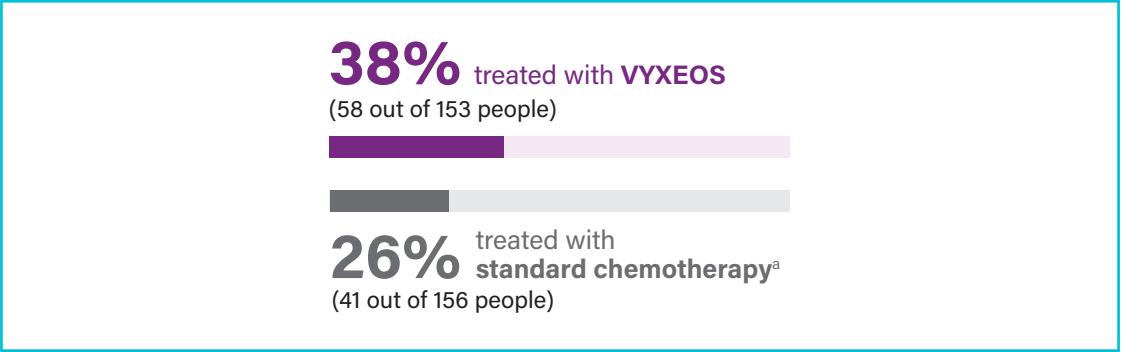
VYXEOS provides a chance to live longer and allows less time connected to an IV infusion line during treatment compared to the standard chemotherapy^a treatment.

In a clinical trial including adults with t-AML or AML-MRC in which 153 people received VYXEOS and 156 people received the standard chemotherapy^a treatment for AML:

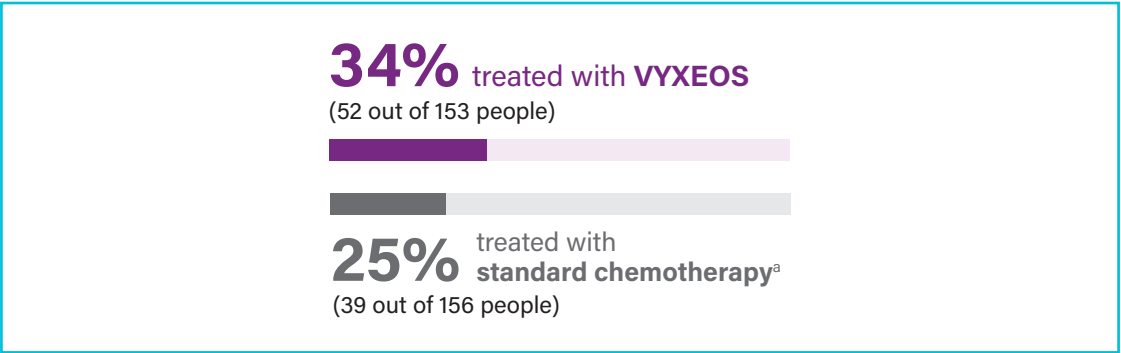
People treated with VYXEOS lived longer than those treated with standard chemotherapy^a



More people treated with VYXEOS achieved a complete response^d than those treated with standard chemotherapy^a



More people treated with VYXEOS received transplant after treatment



IMPORTANT SAFETY INFORMATION

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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^aStandard chemotherapy was cytarabine 100 mg/m² and daunorubicin 60 mg/m².

^bMedian survival time refers to the time when half of the people in the trial were alive.

^cEstimated survival was based on Kaplan-Meier-estimated percentages of the people in the trial who were still alive 1 year after the start of treatment.

^dComplete response, also known as complete remission (CR): when leukemia cells make up less than 5% of cells in your bone marrow and your blood cell counts are back to normal.

What to tell the healthcare team

BEFORE treatment begins, it is important to make your doctor aware of the following:



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 people 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 may need to be discontinued during treatment. Some medications may affect treatment with VYXEOS.



Previous chemotherapy treatment

Tell your healthcare team about any prior treatment with an anthracycline such as daunorubicin, doxorubicin, epirubicin, or idarubicin.



Known or suspected pregnancy

VYXEOS can harm an 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, do not breastfeed during treatment with VYXEOS and for at least 2 weeks after the last dose.

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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.

IMPORTANT SAFETY INFORMATION

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.

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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Helpful tips during AML treatment

Support groups



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 comfort 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 physical 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.

Please speak with your doctor before starting any new exercise or nutrition regimens.

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You are not alone in your diagnosis of AML. Below are a variety of patient and caregiver support groups and resources available for more information about AML.

American Cancer Society
cancer.org
1-800-ACS-2345 (1-800-227-2345)

Aplastic Anemia and MDS International Foundation
aamds.org
1-800-747-2820

Be The Match
bethematch.org
1-888-999-6743

BMT InfoNet
bmtinfonet.org
1-888-597-7674

CancerCare
cancercare.org
1-800-813-HOPE (1-800-813-4673)

Cancer Support Community
cancersupportcommunity.org
1-888-793-9355

Leukemia & Lymphoma Society
lls.org
1-800-955-4572

National Bone Marrow Transplant Link
nbmtlink.org
1-800-LINK-BMT (1-800-546-5268)

National Cancer Institute
cancer.gov
1-800-4-CANCER (1-800-422-6237)

National Comprehensive Cancer Network®
nccn.org/patients

Jazz Pharmaceuticals does not endorse and is not responsible for the content included in these resources.



Dedicated JazzCares specialists are available to assist you or your loved one who has started treatment, in either the inpatient or outpatient setting, with reimbursement for VYXEOS.

Ask our JazzCares specialists about...



Understanding your insurance coverage

A specialist can:

- Investigate your benefits and verify your coverage
- Help with prior authorization and appeals
- Answer reimbursement questions
- Refer you to financial assistance options



Help paying for your medication

If you have commercial insurance, you may qualify for assistance with out-of-pocket costs for VYXEOS.



Free-drug program

If you are uninsured or do not have coverage for VYXEOS, you may be able to receive VYXEOS for free, if you meet certain eligibility criteria.

- **Call the patient support hotline at 1-833-533-JAZZ (5299) Monday through Friday between 8 AM and 8 PM ET to speak with a specialist.**

Visit JazzCares.com/VYXEOS for additional information and support resources.

Insurance coverage and plans may vary. The JazzCares program sponsored by Jazz Pharmaceuticals provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional.

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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 full Prescribing Information, including BOXED Warning.



Use these pages to write down important notes and any questions you have for your healthcare team.

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Healthcare team contact information:

Name: _____

Phone: _____

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