STARTING TREATMENT WITH VYXEOS®

For adults with newly diagnosed acute myeloid leukemia (AML)

Pr Vyxeos®

daunorubicin and cytarabine liposome for injection

Jazz Pharmaceuticals

GETTING STARTED

Your healthcare professional has prescribed VYXEOS for you and you may have questions about this medication.

This brochure has been designed to help you gain a better understanding of VYXEOS, including how it works, how it is taken, potential side effects, and what you can expect from treatment. It also contains tips for taking care of yourself.

You may find that the more you know, the more equipped you will be to play an active role with your healthcare team.

Keep in mind that this booklet is not meant to substitute any guidance, advice, or help provided by your healthcare team.

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Use the *Take note* section at the back of this booklet to write down any questions you may have and how you are feeling. Share this information with your healthcare professional so that you can get answers and keep track of your health together.

What is VYXEOS?

PrVYXEOS® (daunorubicin and cytarabine liposome for injection) is used to treat adults with newly diagnosed acute myeloid leukemia (AML) – a cancer of the white blood cells.

It is given when the leukemia was caused by previous treatments (known as therapy-related AML) or when there are certain changes in the bone marrow (known as AML with "myelodysplasia-related changes").

About AML

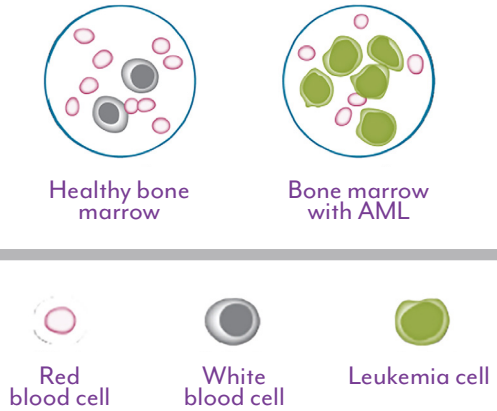
Acute myeloid leukemia is a blood cancer that starts in the bone marrow – the spongy tissue inside your bones.

The bone marrow is responsible for producing 3 types of blood cells:

- Red blood cells (RBCs) – Carry oxygen from the lungs to the rest of the body
- White blood cells (WBCs) – Help the body fight infections
- Platelets – Help the blood to clot

In AML, blood cells don't form properly in the bone marrow and young, immature cells, called "blasts," are produced instead. These young cells are unable to function the way healthy blood cells do.

As the bone marrow continues to produce more and more blasts, there is not enough room for the production of normal red blood cells, white blood cells, and platelets. When there are too many blasts and not enough healthy cells, the symptoms of AML begin to occur.



PrVyxeos®

Types of AML

Some types of AML may develop from specific causes – this is called secondary AML (sAML).

As previously mentioned, there are 2 types of sAML:

Therapy-related (t-AML)

- Occurs in people who have been previously treated for cancer with chemotherapy or radiation
- Can occur anytime from 2–10+ years after previous treatment

AML with myelodysplasia-related changes (AML-MRC)

- May develop in people who have previously had certain types of blood disorders, have a specific genetic mutation, or have certain abnormal blood cells
- Genetic tests can help your healthcare professional identify whether you have AML-MRC

How does VYXEOS work to treat AML?

VYXEOS is part of a group of medications called "antineoplastics" which are used to treat cancer.

VYXEOS contains 2 medicinal ingredients called daunorubicin [DAWN-oh-ROO-buh-sin] and cytarabine [sigh-TARE-uh-been]. These medicinal ingredients are packaged in tiny particles known as liposomes.

VYXEOS is believed to kill cancer cells by stopping them from growing and dividing. Packaging the medicinal ingredients in liposomes allows the drug to stay longer in the body. The liposomes packaging also helps the drug enter the body and kill the cancer cells.

VYXEOS should not be used if you are allergic to daunorubicin or cytarabine, or any other ingredients of this medication. If you are not sure, talk to your healthcare professional before using VYXEOS.

Tell your healthcare professional about all medications you are taking, including any drugs, vitamins, minerals, natural supplements, or alternative medications.

Some medications may interact with VYXEOS, including:

- **Cancer medications that can affect your heart (e.g., doxorubicin)**
- **Medications that can affect your liver**

Serious warnings and precautions

VYXEOS has different dosing directions than daunorubicin hydrochloride injection, cytarabine injection, daunorubicin citrate liposome injection, and cytarabine liposome injection. Your healthcare professional will make sure you are getting the right medication and dose before giving you VYXEOS. If you think you may have received a different product than usual, talk to your healthcare professional.

WHAT TO TELL YOUR HEALTHCARE PROFESSIONAL BEFORE STARTING TREATMENT

To help avoid side effects and ensure proper use, talk to your healthcare professional about any conditions you may have before taking VYXEOS, including if you:

- Have ever had a heart problem or heart attack, radiation therapy for cancers in the chest, are currently taking cancer medications that damage the heart, or you have previously taken "anthracycline" cancer medications
  - Your healthcare professional may check your heart before starting and during treatment, and may end your treatment with VYXEOS depending on the condition of your heart
- Have any allergic (hypersensitivity) reactions
  - Your healthcare professional may pause or stop treatment, or slow the rate of your infusion, if any hypersensitivity occurs
- Have had problems with your kidneys or liver
  - Your healthcare professional will monitor you during treatment
- Have ever had a condition known as Wilson's disease or other copper-related disorder, as VYXEOS contains an ingredient called "copper gluconate"
- Are pregnant, think you may be pregnant, or plan to become pregnant (plan to conceive)
  - VYXEOS may harm your unborn baby
  - If you are able to become pregnant, your healthcare professional will conduct a pregnancy test – which must show that you are not pregnant
  - You should use an effective contraception to avoid getting you or your partner pregnant during treatment, and for the next 6 months after your final dose of VYXEOS
  - If you are male, VYXEOS may affect your fertility – which means that it may be difficult for you to have a child
  - Talk to your healthcare professional if you have questions
- Are breastfeeding or planning to breastfeed
  - It is not known if VYXEOS passes into breast milk
  - Do not breastfeed during treatment with VYXEOS and talk to your healthcare professional about the best way to feed your baby during this time
- Are to be given a vaccine
  - Taking VYXEOS while getting a vaccine may result in a serious or fatal infection

Treatment with VYXEOS can increase your risk of certain side effects, including:

- Tissue death (tissue necrosis) may occur in the surrounding tissue where VYXEOS is injected
- Inflammation/swelling of the digestive tract and/or diarrhea, which may affect your ability to absorb any medications you are taking orally (through the mouth)
- A large decrease in the production of blood cells and platelets by the bone marrow
  - Low amounts of platelets may result in serious or fatal bleeding problems, and your healthcare professional:
    - Will perform blood tests before and during treatment
    - May also give you a medication to help stop you from getting an infection
    - Will check you for infections during treatment

You may feel sleepy or dizzy following treatment with VYXEOS. If this occurs, do not drive or use any tools or machinery.

VYXEOS is given as a drip (infusion) into a vein. The infusions are given by a doctor, nurse, or other healthcare professional experienced in treating AML.

Before VYXEOS is administered, you may be given other medications to treat nausea and vomiting. You may also be given a medication that will prevent an increase of uric acid levels.

Your healthcare professional will determine the appropriate dose for you, based on your height and weight.

Your treatment will be given in "courses" or "cycles" of infusions. Each course is given as a separate set of infusions and can be given weeks apart.

Induction

The first course of treatment is called "induction."

- Given in a 1-week time period on days 1, 3 and 5
- Each infusion lasts 90 minutes
- Days 14–21: Your healthcare professional may assess your bone marrow to assess your response to treatment

A hospital stay may be required so that blood counts can be monitored and potential complications can be managed. You may be required to remain in the hospital for several weeks after the induction course.

Following your first course, your healthcare professional will decide if you should receive a second induction or any subsequent courses of treatment (called consolidation) depending on how you respond and if you experience any side effects.

Second induction

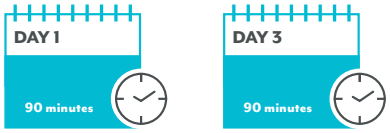
A second induction may be given if you did not reach remission after the first treatment cycle.

- Begins 2–5 weeks after first induction
- Given on days 1 and 3 for 90 minutes
- Days 14–21: You may have a bone marrow assessment and, depending on the results, you may begin consolidation

Consolidation

The next course of treatment is referred to as "consolidation." This refers to any subsequent course(s) you may receive to help maintain remission.

- Begins 5–8 weeks after the start of last induction
- Given on days 1 and 3 for 90 minutes
- Days 14–21: Your healthcare professional may perform follow-up tests to determine whether you need further treatment



Your healthcare professional will assess how you respond to treatment after each course.

Keep in mind that you may feel sleepy or dizzy after treatment with VYXEOS. If this occurs, avoid driving or using tools or machinery.

The following are side effects that have occurred in people receiving VYXEOS:

- Bruising or bleeding without injury
- Blurred or impaired vision
- Dry eye, eye swelling, eye pain, red eyes or itchy eyes
- Hearing problems
- Abdominal pain, stomach cramps, excessive gas, reflux
- Constipation
- Diarrhea
- Nausea and vomiting
- Loss of appetite
- Swelling, including of the arms and legs
- Fever
- Fatigue
- Chills
- Headache
- Dizziness
- Muscle pain, joint pain, bone pain
- Sleep problems
- Anxiety, confusion or reduced awareness
- Cough
- Itching, red skin, rash
- Hemorrhoids
- Pain around the injection site
- Pinpoint, round spots that appear on the skin

Serious side effects and what to do about them

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Very common			
Infections, including in the lungs and blood Symptoms include: Fever, chills, sore throat, cough and mouth ulcers		✓	
Febrile neutropenia (low white blood cells) Symptoms include: Fever, often with other signs of infection		✓	
Non-conduction cardiotoxicity (damage to the heart muscle) Symptoms include: chest pain		✓	

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Hemorrhage (bleeding) Symptoms include: Bruising, nosebleed and brain hemorrhage	✓		
Chest pain		✓	
Shortness of breath/ difficulty breathing		✓	
Arrhythmia (abnormal heart rhythms) Symptoms include: Irregular or rapid heartbeat, palpitations (feeling the heart pounding or racing), shortness of breath and chest pain		✓	

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Mucositis (inflammation of the mouth, stomach or intestine) Symptoms include: Mouth ulcers, altered taste, loss of appetite, difficulty eating or talking, red or swollen mouth and gums, pain in the abdomen, constipation and diarrhea	✓		
Hypersensitivity (allergic reaction) Symptoms include: Redness of skin, rash, itching, swelling and fever		✓	

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Kidney problems (often without symptoms) Symptoms include: Decreased urination, body swelling, abdominal or lower back pain, nausea, fatigue and loss of appetite		✓	
Transfusion reactions (present as adverse signs or symptoms during or within 24 hours of a blood transfusion) Symptoms include: Fever, chills, pruritus or urticaria	✓		
Pleural effusion (fluids around the lungs) Symptoms include: Shortness of breath, chest pain, fever and cough		✓	

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Hypoxia (low oxygen in tissues) Symptoms include: Shortness of breath while resting or after physical activity, waking up out of breath and wheezing	✓		
Hypotension (low blood pressure) Symptoms include: Dizziness, light-headedness, blurred vision, weakness, fatigue, nausea, palpitations, headache, feeling cold and/or pale skin	✓		

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Hypertension (high blood pressure that generally occurs without symptoms) Symptoms include: Headache, nosebleeds and shortness of breath	✓		
Common			
Thrombocytopenia (low platelets) which may lead to anemia Symptoms include: Tiredness and weakness		✓	
Rare			
Pneumonitis (inflammation of the lungs) Symptoms include: Difficulty breathing, shortness of breath, dry cough, fatigue and loss of appetite		✓	

Side effect	Talk to your healthcare professional		Stop taking the medication and get immediate medical help
	Only if severe	In all cases	
Hypothyroidism (underactive/low thyroid function) Symptoms include: Weight gain, tiredness, hair loss, muscle weakness, feeling cold, dry skin, constipation, puffy face, heavier than normal or irregular menstrual periods and enlarged thyroid gland		✓	
Hallucinations (seeing or hearing things that are not there)		✓	

Keep in mind that these are not all the possible side effects that may occur. Talk to your healthcare professional about any side effects that you may experience.

LIFESTYLE TIPS: REMEMBER TO TAKE CARE OF YOURSELF

It is important to take care of yourself – this means eating well, getting some exercise, and learning to relax to help improve your overall health and wellness.

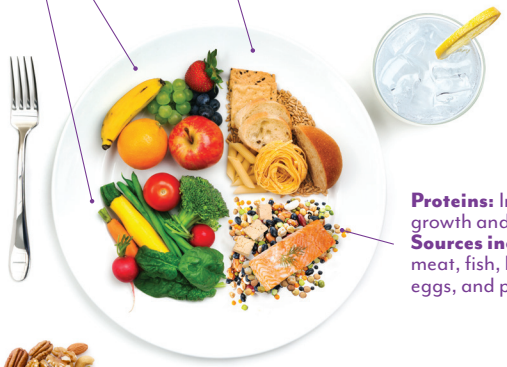
Nutrition tips

Getting a balance between different food types is important for your general health. Eating a variety of foods can help you feel better, give you energy, help you cope with side effects, and stay stronger.

A healthy diet comprises:

Fibre: Promotes healthy digestion
Sources include: Fruits, vegetables, whole-wheat bread, cereals, and brown rice

Carbohydrates: The body's main source of energy
Sources include: Breads, cereals, oatmeal, rice, and pasta



Proteins: Important for growth and tissue repair
Sources include: Lentils, meat, fish, beans, tofu, eggs, and peanut butter

Fats: Help absorb certain vitamins and essential fatty acids
Sources include: Oils (olive, coconut, avocado, etc.), butter, nuts, and seeds

Get active

Physical activity is an essential part of an overall healthy lifestyle.

Being active while getting treatment can help improve your sleep and appetite, lower blood pressure, reduce stress and anxiety, help you cope with side effects, and help improve your strength.

Try to build up to at least 30 minutes of activity each day. If you can't do that, some activity is better than none.

Almost any sport or activity can be adjusted to your fitness level, so select something that you enjoy.

Some moderate physical activities you can consider include:

Brisk walking

Tai chi

Swimming

Water aerobics

Household chores such as vacuuming, raking leaves, or doing the laundry

Talk to your healthcare professional about the diet requirements and level of exercise that is most appropriate for you.

Practise good hygiene

People with AML may be at greater risk of developing an infection since it is a cancer that affects the blood – particularly white blood cells that are an important part of the immune system.

To help prevent developing an infection, try:

- ✓ Washing your hands often
- ✓ Using moisturizing lotions to soften the skin and avoid cracks
- ✓ Wearing rubber gloves when washing dishes, cleaning, or gardening
- ✓ Using an electric shaver to avoid cutting yourself
- ✓ Cleaning any cut or scrape immediately with warm water and soap
- ✓ Avoiding crowds and people who are sick
- ✓ Avoiding eating/handling raw foods

KEEP TRACK OF YOUR APPOINTMENTS

Use this section to help keep track of any appointments with your healthcare professional, including when you are to receive treatment.

My next appointment is...

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

Date: _____

Time: _____

Location: _____

TAKE NOTE

Bring this booklet with you to your appointments so you can write any questions you may have, record any information provided to you by your healthcare team, and keep track of how you are feeling.

TAKE NOTE

Pr Vyxeos®

Should you have any questions, don't hesitate to reach out to your healthcare team.

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