

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

A patient's guide to treatment with

DAURISMO[®] ▼

Glasdegib tablets for oral use

DAURISMO is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukemia (AML) in adult patients who are not candidates for standard induction chemotherapy.¹

This means DAURISMO is a prescription medicine used to treat adults who have been newly diagnosed with a blood cancer called AML, and who are not able to receive standard induction chemotherapy. DAURISMO is used with another cancer medicine: a chemotherapy called cytarabine, which is given at a low dose.¹

[Note to countries: Requires local review and approval prior to implementation]

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ABOUT THIS GUIDE

This guide will:

- Explain what acute myeloid leukemia (AML) is and introduce the approaches to treating AML
- Give you information about your treatment with DAURISMO:
 - How DAURISMO works to treat your AML
 - What you need to know before you take DAURISMO
 - How to take DAURISMO
 - Possible side effects you may experience with DAURISMO treatment
- Help you keep track of when to take your medication
- Suggest places to go for more information and answer common questions about DAURISMO
- Help explain any terms that are unfamiliar to you
 - Please see the glossary at the end of this booklet if there are any terms used that you don't understand

Acknowledgments

This guide has been prepared in conjunction with:

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www.acuteleuk.org



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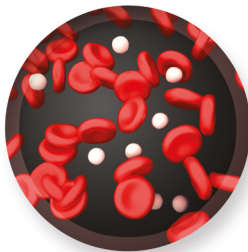
LHRM.de:
<http://www.leukaemiehilfe-rhein-main.de/>
[German language site]



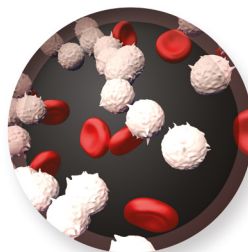
INTRODUCTION

What is AML?

- AML is a rare and fast-growing type of blood cancer²⁻⁴
- Your blood contains 3 types of blood cells, each with a different function³:
 - Red blood cells - carry oxygen and other substances around the body
 - White blood cells - fight infection and disease
 - Platelets - stop bleeding by forming blood clots
- In a healthy person, the bone marrow (the spongy tissue in the center of most bones) makes blood stem cells, which are immature cells that become mature blood cells over time³
- A blood stem cell may become a lymphoid stem cell or a myeloid stem cell³
 - A lymphoid stem cell becomes a white blood cell
 - A myeloid stem cell can become a red blood cell, a white blood cell, or a platelet
- In AML, the myeloid stem cells usually become a type of immature white blood cell called a myeloblast (or myeloid blast). The myeloblasts in AML are not normal and do not develop into healthy white blood cells³
- It is also possible for too many stem cells to become abnormal red blood cells, or platelets. These abnormal white blood cells, red blood cells, or platelets are also called leukemic blasts. These cells can build up in the bone marrow and blood, meaning there is less room for healthy blood cells (see graphic below)³



Normal blood



Leukemia

For further information on AML, please visit *[Note to countries: please include the URL of a local patient organization website that patients can visit to obtain further information]*

What are secondary and de novo AML?

AML can be divided into 2 main groups based on how the leukemia has developed:

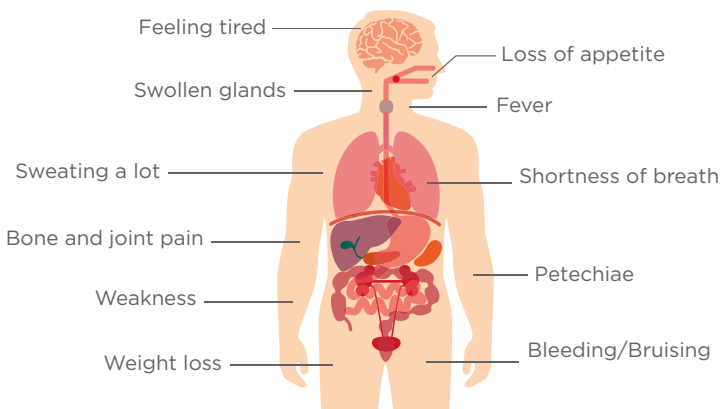
- Secondary AML can develop from the progression of prior blood disorders, or as a result of prior treatment with therapies such as chemotherapy or radiation (also called therapy-related AML)^{5,6}
- De novo AML develops randomly, without any of these known causes⁵

How common is AML?

AML is the most common type of acute leukemia in adults.³ Although AML can affect both adults and children, it is most often diagnosed in older people.^{4,7} The average age of people when they are diagnosed with AML is 68 years.⁸

What are the signs and symptoms of AML?

Many of the signs and symptoms of AML are caused by the reduced number of healthy (normal) blood cells which happens when leukemic blasts (abnormal cells) overcrowd the healthy cells.^{3,4} A person with AML may sweat a lot, experience fever, frequent infections, or shortness of breath.^{3,9} They may bruise or bleed easily (eg bleeding gums or nose bleeds) and have flat, pinpoint red spots under the skin caused by bleeding (otherwise known as petechiae).^{3,9} They may also have a pale complexion, feel weak or tired, have bone and joint pain, swollen glands, or experience unexplained weight loss or loss of appetite.^{3,9}



INTRODUCTION (CONTINUED)

How is AML diagnosed?

AML is diagnosed by blood and bone marrow tests.³ After diagnosis, your doctor will talk to you about your treatment options.



Please ask your doctor if you would like an explanation of any of these procedures

How is AML treated?

One of the standard treatments for AML is chemotherapy.³ Chemotherapy uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from reproducing.³ There are different types of chemotherapy which work in different ways.^{10,11}

Doctors carefully consider which type of chemotherapy to use for each patient, and may decide that standard chemotherapy, which is also known as intensive chemotherapy, is not the best treatment option for some patients.^{10,11} For these patients, doctors may recommend a reduced intensity chemotherapy, which is also known as nonintensive chemotherapy.¹⁰

- **Standard (intensive) chemotherapy uses high-dose chemotherapy and is carried out in hospital or in a specialist center¹⁰**

- **Reduced intensity (nonintensive) chemotherapy is an alternative option to standard chemotherapy.¹⁰ Medications used during reduced intensity treatment can often be given on an outpatient basis¹⁰**

Several factors play a role in the decision to use standard (intensive) or reduced intensity (nonintensive) chemotherapy^{10,11}:

- The patient's other medical conditions
- The patient's physical ability to handle the treatment
- The patient's age
- The patient's goals for treatment

What are the different phases of AML treatment?

Treatment of AML usually has 2 phases^{3,10}:

1. Remission induction therapy
 - The goal of induction therapy is to kill the leukemia cells in the blood and bone marrow. This can put the leukemia into remission (a decrease in, or disappearance of, signs and symptoms of leukemia)
2. Post-remission or remission continuation/consolidation therapy
 - This phase begins after remission occurs. The goal of post-remission therapy is to kill any remaining leukemia cells that may not be active but could still regrow and cause AML to return (relapse)



Throughout your treatment, your doctor will discuss your treatment options with you, and you will be able to ask questions, give your opinion, and discuss your treatment preferences

UNDERSTANDING DAURISMO

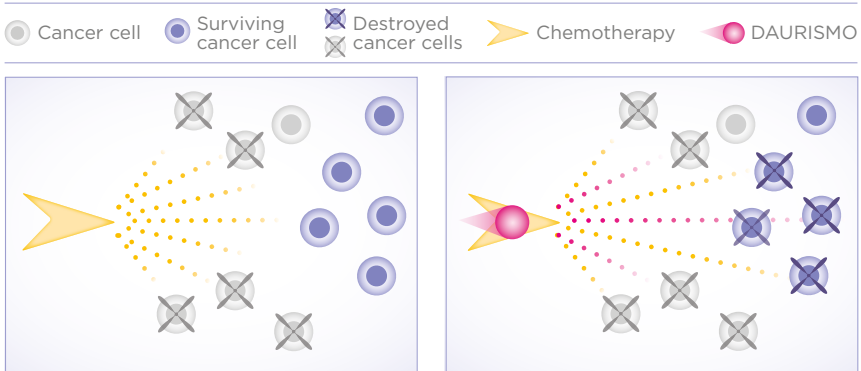
What is DAURISMO?

DAURISMO is a prescription medicine used to treat adults who have been newly diagnosed with a blood cancer called AML, and who are not able to receive standard induction chemotherapy. DAURISMO is used with another cancer medicine: a chemotherapy called cytarabine, which is given at a low dose.¹

How does DAURISMO work together with chemotherapy against AML?

Although chemotherapy destroys most cancer cells, some cancer cells may be able to escape from chemotherapy.^{3,10}

It is thought that these cells remain after treatment and can survive and grow.^{3,10,11} DAURISMO is thought to work by making these cancer cells more sensitive to chemotherapy.¹² DAURISMO and low-dose chemotherapy work together to treat AML by reducing the number of cancer cells.¹



It is thought that chemotherapy works by destroying most cancer cells. Some cancer cells may not get exposed to chemotherapy and may remain after treatment.

Adding DAURISMO may help low-dose chemotherapy destroy cancer cells. It is thought that DAURISMO does this by blocking a signal that helps protect cancer cells from chemotherapy.



If you have any questions about how DAURISMO works, or why this medicine has been prescribed for you, ask your doctor

IMPORTANT: WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAURISMO



Review this section carefully. If you have any questions, talk with your doctor, pharmacist, or nurse

You should not take DAURISMO if you are allergic to the active substance glasdegib or any of the other ingredients of this medicine (sodium starch glycolate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, magnesium stearate, lactose monohydrate, hypromellose, titanium dioxide, macrogol, triacetin, iron oxide yellow, and iron oxide red (100 mg tablets only)).¹



DAURISMO present in semen (sperm) may cause harm or death to an unborn child.¹ If you are male, please read your alert card carefully before taking DAURISMO.

Warnings and precautions



Before taking DAURISMO, talk to your doctor, pharmacist, or nurse if:



You or your partner are able to become pregnant¹ (please see the pregnancy, contraception, breastfeeding, and fertility section on page 11)



You have ever had QT interval prolongation (a change in the electrical activity of the heart that can cause serious irregular heart rhythms) or know you are in danger of the condition¹



You take other medicines that you have been told can prolong the QT interval.¹ Certain cardiac drugs, antidepressants, antipsychotics, antihistamines, antimicrobials, and some other drugs can cause QT interval prolongation.¹³ Tell your doctor about any medication you take

IMPORTANT: WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAURISMO (CONTINUED)



Your blood tests show you have abnormal levels of electrolytes (eg calcium, magnesium, or potassium)¹



You have kidney problems¹



You have a history of muscle cramps or weakness¹

While you are taking DAURISMO, tell your doctor immediately if:



Your muscles hurt or you have unexplained muscle cramps or weakness. If this is the case, your doctor may need to change your dose or stop your treatment temporarily or permanently¹

Taking food, drink, and other medicines with DAURISMO¹



Tell your doctor, pharmacist, or nurse about all of the medicines you are taking, have recently taken, or might take. This includes medicines obtained without a prescription and herbal medicines. This is because DAURISMO can affect the way some other medicines work and because some medicines can affect the way DAURISMO works



Do not drink grapefruit juice or eat grapefruit while you're being treated with DAURISMO, because they may change the amount of DAURISMO in your body

Driving and using machines¹



If you feel tired or get muscle cramps, pain, or nausea (feeling sick) while on treatment with DAURISMO, take special care when driving and using machines

DAURISMO contains sodium and lactose¹



DAURISMO is essentially 'sodium-free' (because it contains less than 23 mg of sodium per tablet)



DAURISMO contains lactose (found in milk and dairy products)



If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine

Pregnancy, contraception, breastfeeding, and fertility¹

Pregnancy



You must not become pregnant while taking DAURISMO and you must not take it if you are pregnant. DAURISMO can cause severe defects in babies or lead to the death of an unborn baby



Your doctor will give you more information about the effects of DAURISMO on the unborn baby, and will carry out a pregnancy test before you start taking the medicine



You must talk to your doctor immediately if you or your partner becomes pregnant, or if you suspect you or your partner could be pregnant, during your treatment and for 30 days after your last dose of DAURISMO



If you are pregnant, think you may be pregnant, or are planning to get pregnant, ask your doctor or pharmacist for advice before taking this medicine

IMPORTANT: WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAURISMO (CONTINUED)

Contraception

Women



You should always use effective birth control (contraception) while taking DAURISMO and for at least 30 days after your last dose of DAURISMO



Talk to your doctor about birth control methods that are right for you and your partner

Men

DAURISMO present in semen (sperm) may cause harm or death to an unborn child.



You should always use effective contraception, including condoms (with spermicide, if available), even if you have had a vasectomy, while taking DAURISMO and for at least 30 days after your last dose of DAURISMO



You should not donate semen at any time while you are taking DAURISMO and for at least 30 days after your last dose

Breastfeeding



Do not breastfeed while taking DAURISMO or during the 1 week after your last dose of DAURISMO. It is not known if DAURISMO passes into your breast milk and harms your baby

Fertility



DAURISMO may affect male and female fertility



Talk to your doctor about fertility preservation before taking DAURISMO

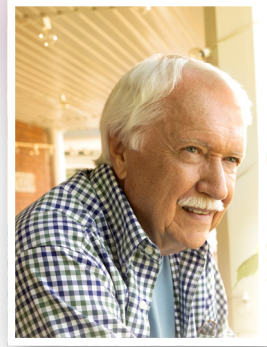
HOW SHOULD I TAKE DAURISMO?

DAURISMO treatment schedule^{1,12}

DAURISMO is taken by mouth once daily, every day. For the first 10 days of each 28-day cycle, DAURISMO is taken with low-dose chemotherapy (cytarabine), which is given by subcutaneous injection twice daily.

What does subcutaneous mean?¹⁴

Subcutaneous means giving the injection into the fatty tissue layer just under the skin. You use a short needle to perform a subcutaneous injection and inject under the skin into the tissue layer between the skin and the muscle.



DAURISMO 100 mg
1 tablet, once a day continuously for the duration of treatment

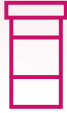
Cytarabine 20 mg
Subcutaneously twice a day for days 1-10 of each 28-day cycle



If you are not sure how to take DAURISMO, check with your pharmacist or doctor

HOW SHOULD I TAKE DAURISMO? (CONTINUED)

With or without



- Take DAURISMO with the medicine cytarabine **exactly** as your doctor or pharmacist has told you
- Take DAURISMO once a day at about **the same time every day**
- Take DAURISMO **with or without food**
- You should not drink grapefruit juice or eat grapefruit while on treatment with DAURISMO, because they may change the amount of DAURISMO in your body
- If you get certain side effects while you are taking DAURISMO, your doctor may lower your dose or stop your treatment, either temporarily or permanently
- It is important to take DAURISMO every day for as long as your doctor prescribes it to you



Do not stop taking DAURISMO unless your doctor tells you to

What should I do if I forget to take DAURISMO?¹



If less than 10 hours have passed since your scheduled dose time

- Take your missed dose **as soon as possible**
- Take your next dose at your usual time



If more than 10 hours have passed since your scheduled dose time

- **Skip this dose**
- Take your next dose at your usual time
- **Do not take a double dose to make up for a forgotten dose**

What should I do if I vomit after taking DAURISMO?¹

- If you vomit after taking a dose of DAURISMO, **do not take an extra dose.** Take your next dose at your usual time
-



If you accidentally take too many tablets, tell your doctor, pharmacist, or nurse straight away. You may require urgent medical attention



If you cannot take DAURISMO as your doctor has prescribed, or you feel you do not need it any more, speak with your doctor right away

POSSIBLE SIDE EFFECTS WITH DAURISMO¹

Like all medicines, DAURISMO can cause side effects. Not everyone will respond to DAURISMO in the same way and some people may experience more side effects than others.

Please read the important information in the **Package leaflet: Information for the user** that came with your medicine. If you do not have this leaflet, please ask your doctor, pharmacist, or nurse for a copy.

DAURISMO may cause severe birth defects. It may also lead to the death of a baby before it is born or shortly after being born. You must not become pregnant while taking this medicine (please see page 9 in this booklet for more information).

Very common side effects with DAURISMO in combination with cytarabine

Very common side effects that may affect more than 1 in 10 people:

- Low hemoglobin
- Bleeding
- Fever
- Nausea
- Loss of appetite
- Muscle pain
- Feeling tired
- Decrease in the number of platelets in the blood
- Diarrhea
- Pneumonia
- Changes in taste
- Swelling of the arms and legs
- Constipation
- Abdominal (belly) pain
- Rash
- Shortness of breath
- Vomiting
- Weight loss
- Decrease in the number of white blood cells
- Decrease in the number of neutrophils (a type of white blood cell)
- Joint pain
- Hair loss

Common side effects with DAURISMO in combination with cytarabine

Common side effects that may affect up to 1 in 10 people:

- Changes in the electrical activity of the heart
- Heart palpitations
- Blood infection
- Burning sensation during urination, and frequent and urgent need to urinate (which may be symptoms of a urinary tract infection)
- Irritation in the mouth

Reporting of side effects



Speak to your doctor, pharmacist, or nurse if you experience any side effects. This includes any side effects not listed in this booklet or in the packaging leaflet that came with your medicine

You can report side effects directly to *[Countries to insert contact details for local reporting system]*. By reporting side effects, you can help provide more information on the safety of this medicine.

DAURISMO IS GIVEN WITH A SUBCUTANEOUS INJECTION OF CHEMOTHERAPY

DAURISMO is taken with low-dose chemotherapy (cytarabine), which is given by subcutaneous injection and may be administered in hospital or at home.^{1,14}

What happens if you inject cytarabine at home?

If you and your doctor decide that you will receive cytarabine injections at home, you and your carer will be provided with guidance and advice. The information given below is a quick reference guide for injecting cytarabine and is an example of the type of information you will receive from, and discuss with, your care team. This information is intended as a quick reference guide and is not intended to replace discussions with your doctor.

Cytarabine injections are given twice daily, 12 hours apart, for 10 days, and the course is repeated in 28-day intervals (cycles).^{1,14}

How to give a subcutaneous injection

Have all of your supplies ready¹⁴

- It is important to have all the materials you need handy before you inject

Choose an appropriate space¹⁴

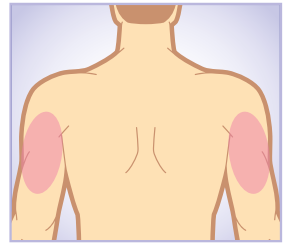
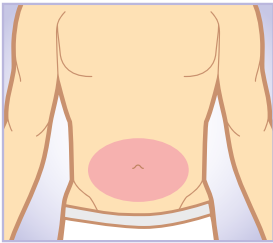
- It is important that you choose an area where you will not be distracted
- To avoid distractions and inadvertent exposure, only people who are helping you should be in the room
- The work surface should be clean, and no food products should be within reach

Prepare the space and supplies¹⁴

- You will need to wash and dry your hands thoroughly and clean your preparation area and tray
- You should collect all necessary supplies and place them onto your cleaned area

Administer the subcutaneous injection

Choose the area on your body where you will give the injection. You can choose to inject into the abdomen (belly), thighs, or the back or sides of the arms¹⁵



- It is important to rotate the injection sites each time you give an injection, to keep the skin healthy and reduce bruising^{14,15}
- Clean the area you intend to inject with the alcohol swab and leave enough time for the area to dry¹⁴
- With your free hand, pinch the skin where you are going to inject and insert the needle at a right angle (90°). The needle will deliver the injection just below the skin¹⁴
- Once the prepared needle is in place, release the pinch on the skin if you need both hands. Use one hand to support the syringe and the other hand to push the plunger down slowly until all the drug has gone in.¹⁴ Leave the needle in place for 10 seconds¹⁵
- Remove the needle from your skin and place it directly into the sharps bin for safe disposal (please see 'what to do after the injection' for further guidance). Place tissue on your skin firmly over the injection site and remove when there is no fluid or blood leaking from the skin¹⁴
- Subcutaneous injections should not be given if the skin is burned, hardened, inflamed, swollen, bruised, or damaged by a previous injection¹⁴

DAURISMO IS GIVEN WITH A SUBCUTANEOUS INJECTION OF CHEMOTHERAPY (CONTINUED)

What to do after the injection

- Discard all used items (syringe, tissue, screw top, packaging, gloves, and apron) into the sharps bin¹⁴
- Wash and dry your hands¹⁴
- The bin must be stored out of sight and reach of children and pets¹⁴

Dealing with a spillage

- If there is a chemotherapy spillage, keep everyone out of the area (especially children and pregnant women) except the minimum number of people required to clear up¹⁴
- After clearing up, return your spillage waste to your local chemotherapy unit for disposal¹⁴

Spillage onto the **skin**¹⁴:



- Immediately hold the affected area under cool water for 10 minutes and do not scrub the skin
- Contact your doctor or nurse if your skin becomes irritated after the spillage

Spillage into the **eyes**¹⁴:



- Wash the eye(s) with plenty of water for at least 10 minutes
- Contact your doctor or nurse immediately for further advice

Spillage onto a **surface**¹⁴:



- Put on protective clothing (gloves and apron)
- Use absorbent material to wipe up any spillage, and then dispose of it in the sharps bin
- When the spill area has dried, wash the area with water only, and leave to dry. Do not add any cleaning agent to the area. If the spillage is on carpet, wash, allow to dry, and then vacuum
- When all the spillage has been cleared and the remaining chemotherapy contained, the protective clothing should be removed, placed in a plastic bag, and sealed

Spillage onto **clothes**¹⁴:



- Wear protective clothing (gloves and apron) when handling the contaminated item(s)
- If a small amount of the chemotherapy has spilled onto clothes, wash them twice in a washing machine on the hottest wash available. They should be washed separately from noncontaminated clothing
- If a large amount of the chemotherapy has spilled, the clothing should be disposed of immediately in a plastic disposal bag



If you or your carer accidentally stick yourself with the needle, it is important to make the puncture site bleed, then wash the area with lots of running water and cover with a plaster. Contact your doctor or nurse immediately for advice

TALKING TO YOUR DOCTOR ABOUT CHEMOTHERAPY

A successful injection starts with a conversation

Asking the following questions can help you prepare for your injection:



- How do I store my chemotherapy properly?
- How do I check to make sure the medicine in the needle is good to inject?
- What supplies do I need for the injection?
- What do I do if I'm missing any supplies?
- What is the proper way to take the injection?
- What is the proper way to dispose of the needle after the injection?
- How do I handle any spills?
- What should I do if I have any problems during or after the injection?
- When should I call my doctor?



Be sure to ask your doctor, pharmacist, or nurse any additional questions you may have. There are some pages for notes at the end of this booklet where you can keep a record of any other questions you may want to ask

GETTING THE SUPPORT YOU NEED

General resources and information

- Local support groups for blood cancers can provide you with resources, information, and general support. These include ***[section to be completed by countries for local use]***
- It is important to be aware of the possible side effects of DAURISMO
 - Some side effects may only be mild and short-lived
 - Others may come and go
 - Some might be more serious and require medical attention




















































Please speak to your doctor, pharmacist, or nurse if you experience any side effects with DAURISMO treatment, including any that are not listed in this guide

KEEPING A DIARY OF YOUR MEDICATION

















































28-day dosing schedule for DAURISMO tablets and cytarabine injections: Weeks 1-2

Date of first DAURISMO dose: _____ Time of DAURISMO dose: _____ AM | PM

Record your start date and mark every date you take your treatment

	Day of the week	Date	DAURISMO once daily 	Twice-daily cytarabine injections		Injection site			How I feel today			
				 AM	 PM	Abd	Thigh	Arm				
												
Week 1												
												
												
												
												
												
												
Week 2												
												
												
												
												
												
												
				Rest days								

28-day dosing schedule for DAURISMO tablets and cytarabine injections: Weeks 3-4

	Day of the week	Date	DAURISMO once daily 	Twice-daily cytarabine injections		Injection site			How I feel today		
				 AM	 PM	Abd	Thigh	Arm			
Week 3											
											
											
											
											
											
											
Week 4				Rest days							
				Rest days							
				Rest days							
				Rest days							
				Rest days							
				Rest days							
				Rest days							
				Rest days							



Please ask your doctor for an A4 version of this diary, which is available separately for your use

KEEPING A DIARY OF YOUR MEDICATION (CONTINUED)

Checklist

- Before you fill anything in, photocopy your diary and this checklist so you can keep track of your medication beyond 4 weeks
- Record the date you first start taking DAURISMO
- Make a note of the time you usually take DAURISMO
- For the first 10 days, take DAURISMO once daily and subcutaneous cytarabine injections twice a day. On Days 11-28, take DAURISMO once daily, and don't use cytarabine
- Check off your daily doses in the table
- Make a note of where you inject cytarabine (abdomen [abd], arm, or thigh), and remember to change where you are injecting each time
- Make a note of how you are feeling each day by circling the face icon which best describes your mood
- Always follow the instructions you have received from your doctor, pharmacist, or nurse

FREQUENTLY ASKED QUESTIONS

Why am I receiving DAURISMO?

- DAURISMO is a cancer medicine containing the active substance glasdegib¹
- DAURISMO is used with another cancer medicine, cytarabine, to treat adults newly diagnosed with AML who are not candidates for standard induction chemotherapy¹
- Your doctor has decided to give you DAURISMO because they consider it to be the most appropriate treatment for you

How long will I need to be treated with DAURISMO?

- DAURISMO is a tablet that is taken by mouth once a day continuously.¹ It is taken with low-dose chemotherapy (cytarabine) via a subcutaneous injection twice a day for Days 1-10 of each 28-day cycle¹
 - A 28-day cycle means that you will have cytarabine injections for 10 days and then have some time without cytarabine injections (18 days) so that your body can rest.^{1,16} The treatment time and rest time make up 1 treatment cycle¹⁶
- You should continue your treatment cycles for as long as your doctor tells you¹

Can I take DAURISMO at home?

- **Yes.** DAURISMO is a tablet that is taken by mouth once a day continuously.¹ It is taken with low-dose chemotherapy (cytarabine) via a subcutaneous injection that can be administered at home^{1,14}
- Cytarabine injections are given twice a day for Days 1-10 of 28-day treatment cycles.^{1,12} If you decide to inject cytarabine at home, you and your carer will be provided with guidance and advice from your doctor

How should I store DAURISMO?¹

- DAURISMO does not require any special storage conditions
- DAURISMO should be stored out of sight and reach of children

FREQUENTLY ASKED QUESTIONS (CONTINUED)

Where should I inject cytarabine?

- You can choose to inject cytarabine into the abdomen, back or sides of the arms, or the thighs¹⁵
- Cytarabine is injected subcutaneously, which means giving the injection into the fatty tissue layer just under the skin¹⁴
- It is important to rotate the injection sites each time you give an injection to keep the skin healthy and reduce bruising^{14,15}

Is there anything I cannot eat, drink, or take when being treated with DAURISMO?¹

- **Yes.** You should not drink grapefruit juice or eat grapefruit while on treatment with DAURISMO, because they may change the amount of DAURISMO in your body, which may also increase the risk of side effects with DAURISMO

Are there any medicines I cannot take while being treated with DAURISMO?¹

- **Yes.** It is important that you tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because DAURISMO can affect the way some medicines work. Some other medicines can affect the way DAURISMO works
- A list of medicines that may increase the risk of side effects with DAURISMO, and a list of medicines that may reduce the effectiveness of DAURISMO, can be found in the **Package leaflet: Information for the user** that came with your medicine. If you do not have this leaflet, please ask your doctor, pharmacist, or nurse for a copy

What should I do if I miss a dose of DAURISMO?¹

- If you forget to take a tablet, and less than 10 hours have passed since your scheduled dose time, then take it as soon as you remember
- If you forget to take a tablet and more than 10 hours have passed since your last scheduled dose time, you should skip the dose
- **You should not take a double dose to make up for a forgotten dose**

What should I do if I vomit after taking DAURISMO?¹

- If you vomit after taking a dose of DAURISMO, do not take an extra dose – just take your next dose at the usual time

Will I experience any side effects when I take DAURISMO?

- Like all medicines, DAURISMO can cause side effects, although not everybody experiences them.¹ If you experience any side effects, please talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the package leaflet that came with your medicine, or in the side effects section of this guide¹

What if my doctor says I need to change my dose of DAURISMO?¹

- If you have certain side effects, your doctor may lower your dose of DAURISMO or stop treatment, either temporarily or permanently

How will I know if DAURISMO is working?

- Your doctor will take blood or bone marrow samples for testing during your treatment to check if DAURISMO is working.³ If you are able to tolerate and are benefiting from treatment, your treatment with DAURISMO will continue^{1,3}

Why does DAURISMO sometimes not work?

- Not everyone will respond to treatment with DAURISMO in the same way. Your doctor will check your response to treatment and how well you are able to tolerate it³
- Nonintensive therapies, like DAURISMO, may take longer to work than intensive chemotherapies¹⁷
- Your doctor may recommend stopping the treatment if your cancer is not responding to DAURISMO and you are not benefiting from treatment^{1,3}
- If DAURISMO does not work for you, your doctor will talk to you about other available treatment options

FREQUENTLY ASKED QUESTIONS (CONTINUED)

What happens if my doctor says I need to stop taking DAURISMO?

- Not everyone will respond to DAURISMO in the same way
- If your blood cancer does not respond to DAURISMO, your treatment will be stopped.¹ Your doctor may also completely stop treatment with DAURISMO if you have certain side effects.¹ If this happens, your doctor will talk to you about other available treatment options



Ask your doctor, pharmacist, or nurse if you have any questions about your treatment with DAURISMO that are not covered in this frequently asked questions section. There are some pages for notes at the end of this booklet where you can keep a record of any other questions you may want to ask

GLOSSARY

Acute myeloid leukemia (AML)	AML is a fast-growing type of blood cancer. In AML the bone marrow makes abnormal myeloblasts (immature white blood cells), red blood cells, or platelets ^{2,3}
Active substance	The substance responsible for the activity of a medicine ¹⁸
Blood stem cell	An immature cell that can develop into all types of blood cells, including white blood cells, red blood cells, and platelets. Blood stem cells are found in the peripheral blood and the bone marrow. These are also called hematopoietic stem cells ²
Bone marrow	Soft, sponge-like tissue in the center of most bones. It produces white blood cells, red blood cells, and platelets ³
Chemotherapy	Treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from reproducing ²
Continuation/consolidation therapy	Treatment that is given after cancer has disappeared following the initial therapy. Continuation/consolidation therapy is used to kill any cancer cells that may be left in the body ^{3,10}
Cytarabine	A chemotherapy drug used in combination with other drugs to treat leukemia. Cytarabine blocks cells from making DNA and may kill cancer cells ²
DAURISMO	DAURISMO is a cancer medicine containing the active substance glasdegib. In AML, cancer cells called stem cells constantly make new leukemic cancer cells. DAURISMO works by blocking a key process in these cells called the Hedgehog pathway. This reduces their ability to make new cancer cells. By blocking the Hedgehog pathway, DAURISMO can also make cancer cells more sensitive to the cancer medicine, cytarabine, used to treat AML ¹

GLOSSARY (CONTINUED)

Induction therapy	The first treatment given for a disease ^{3,10}
Myeloblast	A type of immature white blood cell that forms in the bone marrow ³
Nausea	A feeling of sickness or discomfort in the stomach that may come with an urge to vomit ²
Petechiae	Pinpoint, unraised, round red spots under the skin caused by bleeding ²
Platelet	A type of blood cell that helps to form blood clots which slow or stop bleeding and help wounds heal ²
QT interval prolongation	A change in the electrical activity of the heart that can cause serious irregular heart rhythms ¹
Red blood cell	A type of blood cell that is made in the bone marrow and contains a protein called hemoglobin that carries oxygen from the lungs to all parts of the body ³
Subcutaneous injection	A method of injecting medicine into the body (into the fatty tissue layer just under the skin) ¹⁴
White blood cell	A type of blood cell that is made in the bone marrow and found in the blood and lymph tissue. White blood cells are part of the body's immune system and help to fight infection and disease ²

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