

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr<sup>DAURISMO</sup>®

#### Glasdegib Tablets

Read this carefully before you start taking **DAURISMO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DAURISMO**.

Your acute myeloid leukemia (AML) will be treated with **DAURISMO** in combination with another drug called cytarabine. Read the Patient Information leaflets for the other drug as well as this one.

#### Serious Warnings and Precautions

**Only take DAURISMO under the care of a doctor who knows how to use anti-cancer drugs. They should have a full understanding of the risks and monitoring needs of DAURISMO.**

- DAURISMO can cause your baby to die before it is born or cause your baby to have severe birth defects.
- DAURISMO is available only through a controlled distribution program called the DAURISMO Pregnancy Prevention Program (DPPP).
- DAURISMO is not for children or adolescents less than 18 years old.
- DAURISMO may harm fertility in males and females.

#### For female patients:

- Do not use DAURISMO if you are pregnant.
- If you are able to become pregnant, your healthcare professional will do a pregnancy test within 7 days before you start taking DAURISMO, and every month during treatment.
- If you are able to become pregnant, use two highly effective birth control methods while taking DAURISMO (including dose interruptions) and for at least 30 days after your last dose.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant while taking DAURISMO.

#### For male patients:

- It is not known if DAURISMO passes into semen. Sexual partners might be at risk of exposure through semen.
- Do not donate semen while taking DAURISMO and for at least 30 days after your last dose.
- Use a condom that has a sperm killing substance (spermicide) when having sexual intercourse with a woman (even if she is pregnant). The condom must be used:
  - while taking DAURISMO (including dose interruptions), and
  - for 30 days after your last dose of DAURISMO, and
  - even if you had a vasectomy.
- If your female partner is able to become pregnant, she must also use a highly effective method of birth control, while you are taking DAURISMO (including dose interruptions) and for at least 30 days after your last dose.

### **What is DAURISMO used for?**

DAURISMO is used to treat acute myeloid leukemia (AML) that has not been treated before. It is used together with a cancer drug called cytarabine, and they are only used in adults who:

- are 75 years of age or older  
or
- cannot receive intensive chemotherapy.

**DAURISMO can only be given to patients who are registered in and meet all conditions of the DAURISMO Pregnancy Prevention Program (DPPP), which is a controlled distribution program for DAURISMO.**

### **How does DAURISMO work?**

Glasdegib, the medicinal ingredient in DAURISMO, is a type of drug called a hedgehog pathway inhibitor. It works by stopping cancer cells from dividing and growing.

### **What are the ingredients in DAURISMO?**

Medicinal ingredients: glasdegib (as glasdegib maleate)

Non-medicinal ingredients: dibasic calcium phosphate anhydrous, hypromellose, iron oxide yellow (25 mg tablet), iron oxide red and iron oxide yellow (100 mg tablet), lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, sodium starch glycolate; titanium dioxide, triacetin

### **DAURISMO comes in the following dosage forms:**

Tablets, 25 mg, 100 mg

### **Do not use DAURISMO if:**

- you are pregnant or plan to become pregnant.
- you are female that can get pregnant but cannot or are unwilling to use effective birth control.
- you are breastfeeding or plan to breastfeed.
- you are male but cannot or are unwilling to use effective birth control.
- you are allergic to any ingredients in this drug or the container.
- you are a child or adolescent less than 18 years old.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DAURISMO. Talk about any health conditions or problems you may have, including if you:**

- Have heart rhythm problems, including:
  - Long QT interval syndrome (changes in the electrical system of your heart).
  - Heart arrhythmias. This is when heartbeats are not normal and can cause:
    - heart fibrillation (heart shakes instead of pumping blood).
    - heart tachycardia (heart beats faster than normal when resting).
- Have blood salt (electrolyte) levels that are not normal.
- Have liver or kidney problems.

**Other warnings you should know about:**

- Do not donate blood or blood products while taking DAURISMO and for at least 30 days after your last dose. Your blood might be given to a female that can get pregnant.
- DAURISMO may harm fertility in males and females. It may affect the ability for males to father children, and for females to have children. Talk to your healthcare professional about ways to keep your fertility before you start treatment.

**Female Patients: Important Warnings**

- Do not take DAURISMO if you are pregnant or if you are still able to get pregnant and are not using highly effective birth control.
- You must avoid becoming pregnant while you are taking DAURISMO and for at least 30 days after your last dose.
- Your healthcare professional will talk to you about the possible serious risks of DAURISMO to your unborn baby if you become pregnant.
- DAURISMO can cause your baby to die before it is born or cause your baby to have severe birth defects.
- If you can get pregnant, your healthcare professional will do a pregnancy test:
  - within 7 days before you start treatment with DAURISMO, and
  - every month during treatment with DAURISMO.
- You will continue to have pregnancy tests, even if you stop menstruating, during treatment.
- You will not be given DAURISMO if you are pregnant.
- Your healthcare professional will talk to you about what birth control methods are right for you.
- Unless you commit to not having sexual intercourse, you must use two highly effective birth control methods while taking DAURISMO and for at least 30 days after your last dose.
- Talk to your healthcare professional if you committed to not having sexual intercourse but you have changed your mind. You must commit to using two highly effective birth control methods.
- You must use two highly effective birth control methods even if:
  - you have a history of infertility, your periods have stopped, are irregular, or have abnormal menstrual bleeding.
- If you become pregnant or think you are pregnant during treatment with DAURISMO, stop taking DAURISMO and tell your healthcare professional right away. They will explain the risks to you.
- Do not breastfeed during treatment with DAURISMO and for at least 30 days after the final dose. Talk to your healthcare professional about the best way to feed your baby during this time. It is not known if DAURISMO passes into breast milk.

**Male Patients: Important Warnings**

- You must tell your female partner:
  - that you are taking DAURISMO, and
  - the possible serious risks to an unborn baby if she becomes pregnant by you. This could happen during your treatment of DAURISMO (including dose interruptions) or at least 30 days after your last dose.
- Use a condom that has a sperm killing substance (spermicide) when having sexual intercourse with a woman (even if she is pregnant). The condom must be used:
  - while taking DAURISMO (including dose interruptions), and

- for 30 days after your last dose of DAURISMO, and
- even if you had a vasectomy.
- If your female partner is able to become pregnant, she must also use a highly effective method of birth control while you are taking DAURISMO (including dose interruptions) and for at least 30 days after your last dose.
- Do not donate semen while taking DAURISMO (including dose interruptions) and for at least 30 days after your last dose.
- Tell your healthcare professional right away if your female partner is or maybe pregnant.

**Driving and Using Machines:** DAURISMO can cause fatigue. Before you do tasks which may require attention, wait until you know how you respond to DAURISMO.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

DAURISMO and certain other drugs can cause heart rhythm problems. Avoid taking these other drugs with DAURISMO. Taking these drugs together with DAURISMO might make your heart rhythm problems worse. Your healthcare professional will determine if other treatments can be used.

**The following may interact with DAURISMO:**

- Nafcillin, rifampin, and troleandomycin, used to treat bacterial infections (antibiotics)
- Ketoconazole, itraconazole, posaconazole and voriconazole, used to treat fungal infections.
- Ritonavir, indinavir, lopinavir, efavirenz, etravirine, elvitegravir, cobicistat and tipranavir, used to treat HIV.
- Boceprevir, telaprevir, paritaprevir, ombitasvir, dasabuvir and danoprevir, used to treat viral infections like hepatitis C.
- Conivaptan, used to treat blood salt levels.
- Carbamazepine and phenytoin, used to treat epilepsy.
- St. John's Wort, used to treat depression.
- Enzalutamide and mitotane, used to treat cancers.
- Bosentan, used to treat high blood pressure in lung blood vessels.
- Modafinil, used to treat sleepiness.

Ask your healthcare professional if you are not sure whether a drug you are taking is listed. Tell them if you are prescribed any new drugs.

**How to take DAURISMO:**

- Take DAURISMO as your healthcare professional tells you. It is taken with another drug for acute myeloid leukemia (AML).
- Your health care professional will tell you how much, when, and how you will take the other drug.
- Treatment may continue until the cancer gets worse or you get side effects that could prevent treatment continuation.
- Take DAURISMO once a day, at about the same time each day.
- Take DAURISMO with or without food.
- If you vomit after taking a dose of DAURISMO, do not take another dose on that day. Take your next dose at your regular time.

- Do not take more than the recommended dose prescribed by your healthcare professional.
- Do not change the DAURISMO dose or schedule unless your healthcare professional tells you to.

**Usual dose:****Adults:**

- Take 100 mg of DAURISMO once daily, by mouth, with another drug for acute myeloid leukemia (AML).
- Your healthcare professional will monitor your health. They may interrupt, reduce, or stop your dose. This may occur based on your current health, if you take certain other medications or if you have certain side effects.

**Overdose:**

If you think you, or a person you are caring for, have taken too much [Brand name], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If a dose of DAURISMO is missed:

- If you are less than 12 hours late, take the missed dose as soon as you remember. Take the next dose at your regular time.
- If you are more than 12 hours late, skip the dose for that day. Wait until the regular time for your next dose.
- Do not take two doses within 12 hours to make up for a missed dose.

**What are possible side effects from using DAURISMO?**

These are not all the possible side effects you may have when taking DAURISMO. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- feeling tired, weak
- headache
- pain: muscle, limb, joints, bones, stomach, back
- muscle spasms and tightness
- nausea (feeling sick)
- swelling of arms, legs, face
- decreased appetite
- change in taste
- loose tooth, tooth ache
- pain or sores in your mouth or throat
- constipation
- hair loss
- weight loss

DAURISMO can cause heart electrical signal changes and abnormal blood and urine test results. Your healthcare professional will do some tests before, during and after your treatment. These include checking your heart rhythm and blood cell count, salt and enzyme levels. More frequent tests might be needed. They will tell you if your test results are abnormal and if you need treatment.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Eye hemorrhage</b> (eye bleeding): blurred vision, pain when exposed to bright light, a layer of blood may be visible on white part of eye, eye bruising			X
<b>Gastrointestinal (GI) bleeding</b> (bleeding anywhere along the GI tract between mouth and anus): (bleeding in esophagus, stomach or first part of small intestines): blood in vomit, black tarry stool, bright red blood in your stool or coming from rectum, rapid pulse, low blood pressure, low urine flow, confusion, weakness, dizziness;  (bleeding from large intestine, rectum): bright red blood in your stool or coming from rectum, rapid pulse, low blood pressure, low urine flow, confusion, weakness, dizziness			X
<b>Hematuria</b> (blood in the urine): pink, red or very dark urine			X
<b>Hemoptysis:</b> coughing up blood			X
<b>Intracerebral hemorrhage</b> (bleeding in the brain): sudden, severe headache; confusion; nausea and vomiting; seizures; loss of consciousness			X
<b>Pneumonia</b> (infection in the lungs): chest pain when you breathe or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Purpura (bleeding under the skin):</b> bruising, purple spotted spots or rash, discoloration of skin	X		
<b>Febrile neutropenia:</b> infections, fatigue, fever, aches, pains and flu-like symptoms		X	
<b>COMMON</b>			
<b>Acute respiratory failure:</b> blue color on skin, lips, and fingernails; feel sleepy; irregular heartbeats; loss of consciousness; sudden worsening of shortness of breath			X
<b>Acute kidney failure</b> (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain.			X
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		X	
<b>Cardiac arrhythmias</b> (abnormal heart rhythms): irregular pulse, slow pulse, rapid pulse, palpitations, shortness of breath, dizziness			X
<b>Hyponatremia</b> (low sodium in the blood): lethargy, confusion, muscular twitching, achy, stiff or uncoordinated muscles, seizure, coma		X	
<b>Mucositis</b> (inflammation and ulceration of the mucous membranes lining the digestive tract): painful, red, shiny or swollen gums, tongue, mouth or throat sores, blood in the mouth, difficult or painful swallowing or talking, dry mouth, mild burning, or pain when eating food		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Myocardial infarction</b> (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			X
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		X	
<b>Prolongation of QT interval</b> (a heart rhythm condition): Irregular heartbeat, fainting, loss of consciousness, seizures, dizziness, lightheaded			X
<b>Sepsis and septic shock</b> (Infection of the blood): fever or dizziness, chills, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat.		X	
<b>Skin disorders:</b> Rash, painful red lumps, pain in joints and muscles	X		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store DAURISMO at 15°C to 30°C.

**Keep DAURISMO and all medicines out of reach and sight of children.**

### **If you want more information about DAURISMO:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001.

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