

DAURISMO™ (glasdegib) is a prescription medicine that is used with the medicine cytarabine to treat newly diagnosed acute myeloid leukemia (AML) in patients who:

- are 75 years of age or older, or
- have other medical conditions that prevent the use of standard chemotherapy

It is not known if DAURISMO is safe and effective in children.

# LONGER LIFE MAY BE POSSIBLE

In a clinical study, patients taking DAURISMO and low-dose chemotherapy (cytarabine) lived for a median\* of 8.3 months after starting treatment, compared with 4.3 months for patients taking low-dose chemotherapy alone.

\*The median is the midpoint in a range of numbers, where exactly half of the numbers are smaller and half of the numbers are larger than that point.

DAURISMO in combination with low-dose chemotherapy (cytarabine) was studied in 115 patients with newly diagnosed AML who were 75 years of age or older, **or** had other medical conditions that prevented the use of standard chemotherapy. In this study, 77 patients received DAURISMO plus low-dose chemotherapy (cytarabine), and 38 patients received low-dose chemotherapy alone.

DAURISMO MAY HELP YOU LIVE LONGER AND CAN BE TAKEN AT HOME.

#### **SELECTED SAFETY INFORMATION**

WARNING: DAURISMO can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.

For females who can become pregnant: Talk to your healthcare provider about the risks of DAURISMO to your unborn child. Your healthcare provider will do a pregnancy test within 7 days before you start taking DAURISMO. Do not use DAURISMO during pregnancy. Use effective birth control during treatment and for at least 30 days after your last dose of DAURISMO. Talk with your healthcare provider about what birth control method is right for you during this time. Talk to your healthcare provider right away if you have unprotected sex or if you think that your birth control has failed. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.



# Understanding AML

## What is acute myeloid leukemia (AML)?

AML is a blood cancer in which the bone marrow makes too many abnormal blood cells, called leukemic blasts.

AML blocks the production of regular blood cells and can lead to lower numbers of healthy blood cells than normal, including:

- Low red blood cells (anemia)
- Low white blood cells (neutropenia)
- Low platelets (thrombocytopenia)

## What are the approaches to treating AML?

The main treatment for patients with AML is chemotherapy. There are different types of chemotherapy, which work in different ways. Doctors carefully consider which type of chemotherapy to use for each patient. Several factors play a role in this decision:

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

#### **SELECTED SAFETY INFORMATION**

For males: DAURISMO may affect fertility in males. Talk to your healthcare provider if this is a concern for you. It is not known if DAURISMO is present in semen. Do not donate semen during treatment with DAURISMO and for at least 30 days after your last dose. You should always use effective birth control, including a condom, even if you have had a vasectomy, during sex with female partners who are pregnant or who are able to become pregnant, during treatment with DAURISMO and for at least 30 days after your last dose to protect your female partner from being exposed to DAURISMO. Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking DAURISMO.



# **Understanding DAURISMO**

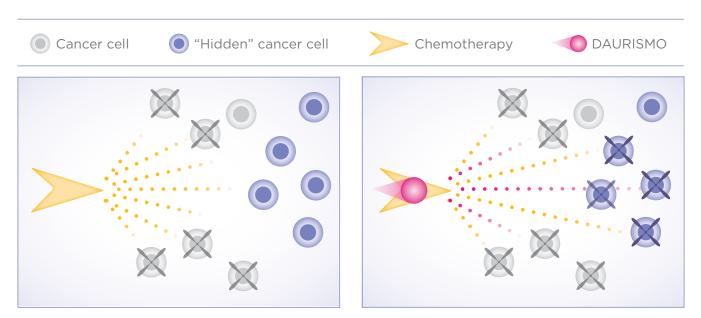
#### What is DAURISMO?

DAURISMO is a prescription medicine that is used with the medicine cytarabine to treat newly diagnosed AML in adults who are 75 years of age or older **or** have other medical conditions that prevent the use of standard chemotherapy.

## How does DAURISMO work together with chemotherapy?

Although chemotherapy destroys most cancer cells, some cancer cells may be able to "hide" and escape from chemotherapy. It is thought that these cells remain after treatment and can survive and grow.

DAURISMO is thought to work by getting cancer cells out of hiding so that chemotherapy can detect and destroy them. DAURISMO and low-dose chemotherapy work together to treat AML by reducing the number of cancer cells.



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.

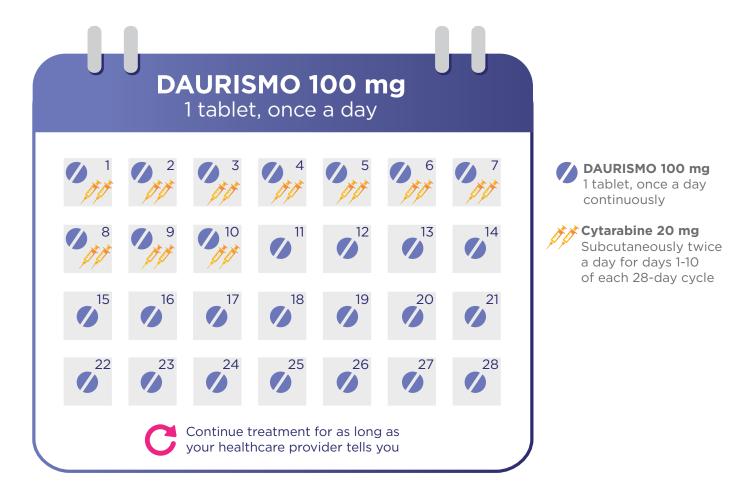
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**Exposure to DAURISMO during pregnancy:** If you think that you or your female partner may have been exposed to DAURISMO during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with DAURISMO, you or your healthcare provider should report your pregnancy to Pfizer at 1-800-438-1985.



# How should I take DAURISMO?

DAURISMO is a tablet that is taken by mouth once daily. It is taken with low-dose chemotherapy (cytarabine) via a subcutaneous injection.



## **SELECTED SAFETY INFORMATION**

**Blood donation:** Do not donate blood or blood products during treatment with DAURISMO and for at least 30 days after the last dose.





# How should I take DAURISMO? (cont'd)



- Take DAURISMO with the medicine cytarabine exactly as your healthcare provider tells you
- Take DAURISMO at about the same time each day
- If you miss a dose, take it as soon as you remember. If it is less than 12 hours before your next dose, just skip the missed dose and take your next dose at your regular time. Do not take 2 doses of DAURISMO within 12 hours



- Take DAURISMO with or without food
- Do not chew, split, or crush DAURISMO tablets
- If you vomit after taking a dose of DAURISMO, do not take an extra dose, just take your next dose at your regular time



- Your healthcare provider will perform certain tests to check you for side effects before and during treatment with DAURISMO
- Your healthcare provider may change your dose or temporarily or permanently stop treatment with DAURISMO if you have certain side effects
- Do not change your dose or stop taking DAURISMO unless your healthcare provider tells you

### **SELECTED SAFETY INFORMATION**

**QT prolongation:** DAURISMO can cause serious side effects, including changes in the electrical activity of your heart called QT prolongation. This can cause irregular heartbeats that can be life-threatening. Tell your healthcare provider right away if you feel faint, light-headed, dizzy, or feel your heart beating irregularly or fast during treatment with DAURISMO.



# More time is possible with DAURISMO

## What were the results from the DAURISMO clinical study?

The efficacy of DAURISMO, in combination with low-dose chemotherapy (cytarabine), was evaluated in the BRIGHT AML study. This study included 115 patients with AML who were 75 years of age or older, **or** had other medical conditions that prevented the use of standard chemotherapy. All patients included in the study were older than 55 years of age, and most had other preexisting health conditions, such as heart disease or mild-to-moderate kidney disease.

In this study, 77 patients received DAURISMO plus low-dose chemotherapy (cytarabine) and 38 patients received low-dose chemotherapy alone.

The addition of DAURISMO to low-dose chemotherapy (cytarabine) helped patients live longer than those treated with low-dose chemotherapy alone.

# Median\* overall survival was:

with DAURISMO + low-dose chemotherapy (cytarabine)

**4.3** 

with low-dose chemotherapy alone

#### **SELECTED SAFETY INFORMATION**

**Side effects:** The most common side effects of DAURISMO with cytarabine include:

- Low red blood cell count (anemia)
- Tiredness
- Bleeding
- Fever with low white blood cell count
- Muscle pain
- Nausea
- Swelling of arms or legs

- Low platelet count
- Shortness of breath
- Decreased appetite
- Changes in taste
- Pain or sores in your mouth or throat
- Constipation
- Rash

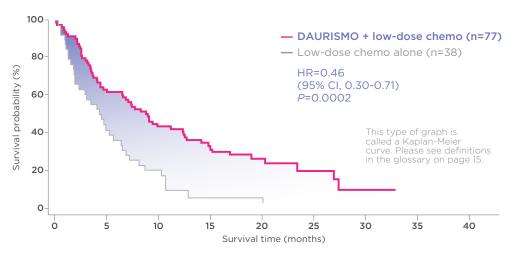
These are not all of the possible side effects of DAURISMO. Call your doctor for medical advice about side effects. Your healthcare provider will perform certain tests to check for side effects before and during treatment with DAURISMO and may change your dose, temporarily stop, or permanently stop treatment with DAURISMO if you have certain side effects. Do not change your dose or stop taking DAURISMO unless your healthcare provider tells you.



<sup>\*</sup>The median is the midpoint in a range of numbers, where exactly half of the numbers are smaller and half of the numbers are larger than that point.

# More time is possible with DAURISMO (cont'd)

# Survival analysis in the BRIGHT AML study



Some patients in the trial were removed from the survival analysis because information about their survival time was incomplete.

CI=confidence interval; HR=hazard ratio.



with DAURISMO + low-dose chemotherapy (cytarabine)

with low-dose chemotherapy alone

The study included a plan to look at how many patients were still alive at 1 year. However, the plan did not strictly control for the possibility that these results may be due to chance.

## **SELECTED SAFETY INFORMATION**

Before you take DAURISMO: Tell your healthcare provider about all of your medical conditions. Tell them if you:

- Have heart problems including a condition called long QT syndrome
- Have abnormal blood salt (electrolytes) levels
- Are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.



# What do I need to know about DAURISMO?

DAURISMO interferes with the cellular pathway that is essential to the way babies develop during pregnancy. Because of this, DAURISMO can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects. Do not use DAURISMO during pregnancy.

## For females who can become pregnant:

- You should talk to your healthcare provider about the risks of DAURISMO to your unborn child
- Your healthcare provider will do a pregnancy test within 7 days before you start taking DAURISMO
- You should not use DAURISMO during pregnancy
- You should use effective birth control during treatment and for at least 30 days after your last dose of DAURISMO. Talk with your healthcare provider about what birth control method is right for you during this time
- Talk to your healthcare provider right away if you have unprotected sex or if you think that your birth control has failed
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant

#### SELECTED SAFETY INFORMATION

**Breastfeeding:** It is not known if DAURISMO passes into your breast milk. Do not breastfeed or provide breast milk to infants or children during treatment with DAURISMO and for at least 30 days after the last dose. Talk to your healthcare provider about the best way to feed your baby during this time.

WARNING: DAURISMO can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.





# What do I need to know about DAURISMO? (cont'd)

### For males:

- It is not known if DAURISMO is present in semen. Do not donate semen during treatment with DAURISMO and for at least 30 days after your last dose
- You should always use effective birth control, including a condom, even if you have had a vasectomy, during sex with female partners who are pregnant or who are able to become pregnant, during treatment with DAURISMO and for at least 30 days after your last dose to protect your female partner from being exposed to DAURISMO
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking DAURISMO

## Exposure to DAURISMO during pregnancy:

If you think that you or your female partner may have been exposed to DAURISMO during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with DAURISMO, you or your healthcare provider should report your pregnancy to Pfizer at 1-800-438-1985.

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# What do I need to know about DAURISMO? (cont'd)

#### Other serious side effects

DAURISMO may cause changes in the electrical activity of your heart, called QT prolongation. QT prolongation can cause irregular heartbeats that can be life-threatening. Tell your healthcare provider right away if you feel faint, lightheaded, dizzy, or feel your heart beating irregularly or fast during treatment with DAURISMO.

The most frequent serious side effects (occurring in 5% or more of patients) associated with DAURISMO treatment were fever with low white blood cell count (29%), pneumonia (23%), bleeding (12%), low red blood cell count (7%), and overwhelming immune response to an infection (7%).

#### **SELECTED SAFETY INFORMATION**

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# What do I need to know about DAURISMO? (cont'd)

#### Common side effects

The most common side effects of DAURISMO with low-dose chemotherapy (cytarabine) include:

- Low red blood cell count (anemia)
- Tiredness
- Bleeding
- Fever with low white blood cell count
- Muscle pain
- Nausea
- Swelling of arms or legs

- Low platelet count
- Shortness of breath
- Decreased appetite
- Changes in taste
- Pain or sores in your mouth or throat
- Constipation
- Rash

DAURISMO may affect fertility in males. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of DAURISMO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

## **SELECTED SAFETY INFORMATION**

**Exposure to DAURISMO during pregnancy:** If you think that you or your female partner may have been exposed to DAURISMO during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with DAURISMO, you or your healthcare provider should report your pregnancy to Pfizer at 1-800-438-1985.

**Blood donation:** Do not donate blood or blood products during treatment with DAURISMO and for at least 30 days after the last dose.



# DAURISMO is given with subcutaneous injections of chemotherapy

## How to give a subcutaneous injection

#### Have all of your supplies ready

It's important to have all of the materials you need handy before you inject

## Choose an appropriate space

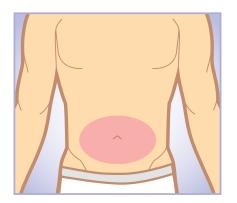
- It is important that you work in an area where you will not be distracted
- The work surface should be clean and no food products should be within reach

### Prepare the space and supplies

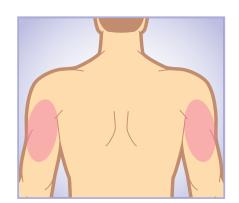
- You will need to wash and dry your hands thoroughly and clean your preparation area
- You should collect all necessary supplies and place them onto your cleaned area

### Administer the subcutaneous injection

• Choose the area on your body where you will give the injection. You can choose to inject into the abdomen, back or sides of the arms, or the thighs. It's important to rotate injection sites to keep the skin healthy







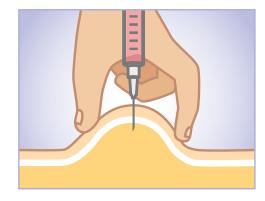
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# DAURISMO is given with subcutaneous injections of chemotherapy (cont'd)

- Clean the area you intend to inject with the alcohol swab and wait 30 seconds for the area to dry
- With your free hand, pinch the skin where you are going to inject and insert the needle at a right angle (90 degrees). The needle will deliver the injection just below the skin
- 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. Leave the needle in place for 10 seconds
- Remove the needle from your skin and place it directly into the sharps bin for safe disposal. Place tissue on your skin firmly over the injection site and remove when there is no leaking fluid or blood from the skin



This information is intended as a quick reference and does not replace discussions with your doctor. Please speak with your doctor about the proper way to administer a subcutaneous injection and do not attempt the injection before discussing it with a doctor or healthcare provider first.

#### SELECTED SAFETY INFORMATION

Side effects: The most common side effects of DAURISMO with cytarabine include:

- Low red blood cell count (anemia)
- Tiredness
- Bleeding
- Fever with low white blood cell count
- Muscle pain
- Nausea
- Swelling of arms or legs

- Low platelet count
- Shortness of breath
- Decreased appetite
- Changes in taste
- Pain or sores in your mouth or throat
- Constipation
- Rash

These are not all of the possible side effects of DAURISMO. Call your doctor for medical advice about side effects. Your healthcare provider will perform certain tests to check for side effects before and during treatment with DAURISMO and may change your dose, temporarily stop, or permanently stop treatment with DAURISMO if you have certain side effects. Do not change your dose or stop taking DAURISMO unless your healthcare provider tells you.



# 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 ANY ADDITIONAL QUESTIONS YOU MAY HAVE.

## **SELECTED SAFETY INFORMATION**

Before you take DAURISMO: Tell your healthcare provider about all of your medical conditions. Tell them if you:

- Have heart problems including a condition called long QT syndrome
- Have abnormal blood salt (electrolytes) levels
- Are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.



# Glossary

**Acute myeloid leukemia (AML):** AML is a blood cancer in which the bone marrow makes too many abnormal blood cells, called leukemic blasts. AML blocks the production of regular blood cells and can lead to lower numbers of healthy blood cells than normal, including low red blood cells, low white blood cells, and low platelets.

Confidence interval (CI): A reflection of accuracy of the study results.

**Hazard ratio:** Compares the chances of an event occurring at any given time between the 2 treatment groups in the study.

Kaplan-Meier curve: A Kaplan-Meier curve uses information about patients in a clinical trial to determine the chance of events over time. In this case, the curves represent patients treated with DAURISMO plus chemotherapy vs patients who received chemotherapy alone. The "y," or vertical axis, measures the percentage of patients estimated to be alive in the clinical trial. The "x," or horizontal axis, tracks time, in this case, measured in months. All patients enter the study alive, so the curves start at 100% for month 0 and decline over time.

**Median:** The midpoint in a range of numbers, where exactly half of the numbers are below and half of the numbers are above that point.

Newly diagnosed AML: You have never been treated for AML.

P value: Shows how likely it is that the difference in results between the groups occurred by chance alone.

**Subcutaneous injection:** An injection given just under the skin.

#### **SELECTED SAFETY INFORMATION**

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# Pfizer Oncology together

# Finding financial support options. Together.



### **COMMERCIALLY INSURED**

Resources for eligible patients with commercial, private, employer, or state health insurance marketplace coverage:

- Co-pay assistance: Eligible, commercially insured patients may pay as little as \$0 per month for DAURISMO. Limits, terms, and conditions apply\*
- There are no income requirements, forms, or faxing to enroll

#### MEDICARE/GOVERNMENT INSURED

Help identifying resources for eligible patients with Medicare/Medicare Part D, Medicaid, and other government insurance plans:

- Assistance with searching for financial support that may be available from independent charitable foundations.
   These foundations exist independently of Pfizer and have their own eligibility criteria and application processes.
   Availability of support from the foundations is determined solely by the foundations
- Financial assistance through Extra Help, a Medicare Part D Low-Income Subsidy (LIS) program
- Free medicine<sup>†</sup>

### **UNINSURED**

Help identifying resources for eligible patients without any form of healthcare coverage:

- Help finding coverage
- Free medicine through the Pfizer Patient Assistance Program, or at a savings through the Pfizer Savings Program<sup>†</sup>

†If support from independent charitable foundations or Medicare Extra Help is not available, Pfizer Oncology Together will provide eligible patients with medication for free through the Pfizer Patient Assistance Program. The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation™. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc. with distinct legal restrictions

<sup>‡</sup>The Pfizer Savings Program is not health insurance. For more information, call the toll-free number 1-877-744-5675. There are no membership fees to participate in this program. Estimated savings are 50% and depend on such factors as the particular drug purchased, amount purchased, and the pharmacy where purchased.

# Pfizer Oncology together™

# Making your support needs a priority. Together.

At Pfizer Oncology Together, we treat your individual needs as a priority. We'll help you identify financial assistance options so you can get your prescribed DAURISMO. We can also connect you with a dedicated Care Champion who has social work experience and will offer resources that may help with some of your day-to-day challenges. Because when it comes to support, we're in this together.

# Care Champion Support

At Pfizer Oncology Together, our Care Champions, who have social work experience, can provide you resources that may help with some of your day-to-day challenges\*:

### **EMOTIONAL SUPPORT**

We can connect you to diagnosis-specific support groups, an independent organization that offers short-term counseling, and a free app, developed by Pfizer Oncology, to help patients connect with loved ones and ask for the support they need.



#### **EDUCATIONAL SUPPORT**

To help support your overall health and well-being, we've created resources about physical and mental health, as well as nutrition tips and healthy recipes developed in partnership with dietitians who specialize in oncology nutrition. We can also provide you with information to help you understand your prescribed DAURISMO.

## PRACTICAL SUPPORT

If you need assistance with transportation or lodging for treatment-related appointments, we'll connect you to independent organizations that offer these services for free to qualifying patients.

And if you're leaving work for a period of time during treatment, or preparing to return to work, we can send you information to help make the transition easier.



### FOR LIVE, PERSONALIZED SUPPORT

Call 1-877-744-5675 (Monday-Friday 8 AM-8 PM ET)

#### **VISIT**

PfizerOncologyTogether.com

<sup>\*</sup>Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

# Important Safety Information and Indication

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- Low red blood cell count (anemia)
- Tiredness
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- Fever with low white blood cell count
- Muscle pain
- Nausea
- Swelling of arms or legs

- Low platelet count
- Shortness of breath
- Decreased appetite
- Changes in taste
- Pain or sores in your mouth or throat
- Constipation
- Rash



# Important Safety Information and Indication (cont'd)

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#### Indication:

DAURISMO is a prescription medicine that is used with the medicine cytarabine to treat newly diagnosed acute myeloid leukemia (AML) in adults who:

- are 75 years of age or older, or
- have other medical conditions that prevent the use of standard chemotherapy

It is not known if DAURISMO is safe and effective in children.





Visit **DAURISMO.com** to learn more

For additional support, visit PfizerOncologyTogether.com or call 1-877-744-5675.

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Please see Important Safety Information on pages 18 and 19 and click <u>here</u> for full Prescribing Information, including **BOXED WARNING** and Medication Guide.

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