A GUIDE TO STARTING TREATMENT
IDHIFA® (enasidenib) is a prescription medicine used to treat people with acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation whose disease has come back or has not improved after previous treatment(s). It is not known if IDHIFA is safe and effective in children.

What is the most important information I should know about IDHIFA?

IDHIFA may cause serious side effects including:

- **Differentiation Syndrome.** Differentiation syndrome is a condition that affects your blood cells which may be life-threatening or lead to death if not treated. Differentiation syndrome has happened within 10 days and up to 5 months after starting IDHIFA. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome while taking IDHIFA:
  - Fever
  - Cough
  - Shortness of breath
  - Swelling of arms and legs
  - Swelling around neck, groin, or underarm area
  - Fast weight gain (greater than 10 pounds within a week)
  - Bone pain

If you develop any of these symptoms of differentiation syndrome, your healthcare provider may start you on a medicine taken by mouth or given through a vein (intravenous) called corticosteroids and may monitor you in the hospital.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
You and your doctor have decided that IDHIFA is right for you

This guide will help explain AML and your course of treatment with IDHIFA. Here’s what you’ll find inside:

RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA:
WHAT YOU SHOULD KNOW

What is AML?
What is relapsed or refractory AML?

UNDERSTANDING TREATMENT WITH IDHIFA

What is IDHIFA and what is an IDH2 mutation?
What should I tell my healthcare provider before taking IDHIFA?
How does IDHIFA work?
What are the possible benefits of IDHIFA?

UNDERSTANDING SAFETY AND SIDE EFFECTS WITH IDHIFA

What are the possible side effects of IDHIFA?

TAKING AND STORING IDHIFA

How should I take IDHIFA?
How long should I take IDHIFA?
How should I store IDHIFA?

RESOURCES

Important questions to ask your healthcare provider
Learn about financial help through Celgene Patient Support®
Appointment tracker
Dosing calendar

For more information on IDHIFA and to access helpful resources, visit www.IDHIFA.com/discover

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
What is AML?

AML is a blood cancer that starts in the bone marrow. Bone marrow typically produces platelets (which help with blood clotting), red blood cells (which transport oxygen throughout the body), and white blood cells (which help fight infection). In most cases, AML can quickly move from the bone marrow into the blood and can sometimes spread to other parts of the body.

With 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 can.

As the bone marrow continues to produce more and more blasts, there becomes no 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.

What is relapsed or refractory AML?

The term “relapsed” means that the signs and symptoms of AML have returned after a period of being symptom free after initial therapy. It is also possible for AML to be “refractory,” which means that it does not respond to a particular treatment. It is common for a person with relapsed or refractory AML to go through periods of treatment, response, and relapse over time.
What is IDHIFA and what is an IDH2 mutation?

IDHIFA® (enasidenib) is a prescription medicine used to treat people with acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation whose disease has come back or has not improved after previous treatment(s).

Your doctor has determined that IDHIFA is an appropriate treatment choice for you because you have a specific type of mutation known as IDH2. The IDH2 mutation blocks blasts from maturing into healthy adult blood cells. Approximately 8% to 19% of people with AML have this mutation. IDHIFA is not a traditional chemotherapy, it is the first and only medication in a class called IDH2 inhibitors that is specifically used for people with relapsed or refractory AML with an IDH2 mutation. The following information may help you understand your treatment with IDHIFA.

What should I tell my healthcare provider before taking IDHIFA?

Before taking IDHIFA, tell your healthcare provider about all of your medical conditions, including if you:

• Are pregnant or plan to become pregnant. IDHIFA can cause harm to your unborn baby if taken during pregnancy
  — If you are able to become pregnant, your healthcare provider will do a pregnancy test before you start taking IDHIFA
  — **Females** who are able to become pregnant and who take IDHIFA should use effective birth control (contraception) during treatment with IDHIFA and for at least 1 month after your last dose of IDHIFA
  — **Males** who have female partners that are able to become pregnant should use effective birth control during treatment with IDHIFA and for at least 1 month after your last dose of IDHIFA
  — IDHIFA may affect how hormonal contraceptives work and may cause them to not work as well
  — Talk to your healthcare provider about birth control methods that may be right for you while taking IDHIFA
  — IDHIFA may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility

• Are breastfeeding or plan to breastfeed. It is not known if IDHIFA passes into your breast milk.
  You should not breastfeed during your treatment with IDHIFA and for at least 1 month after your last dose of IDHIFA

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
How does IDHIFA work?

Bone marrow with AML
With your type of AML, the IDH2 mutation blocks young blood cells in the bone marrow from growing into healthy adult red blood cells, white blood cells, and platelets. When there are too many young blood cells and not enough healthy cells in the bone marrow, the symptoms of AML begin to occur.

Bone marrow after treatment with IDHIFA
IDHIFA works by inhibiting IDH2 and releasing the block on maturation of young blood cells. This means that the young cells in the marrow can grow up to be normally functioning healthy red blood cells, white blood cells, and platelets. This also helps relieve overcrowding of immature blood cells in the marrow.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
What are the possible benefits of IDHIFA?

A clinical trial was done to determine the effectiveness and safety of IDHIFA in patients with relapsed or refractory AML with an IDH2 mutation. To study the effectiveness of IDHIFA, 199 patients were started on the 100-mg oral dose of IDHIFA every day until disease progression or unacceptable toxicity. Dose reductions were allowed to manage side effects.

IDHIFA helped patients achieve different levels of response.

Nearly 1 in 4 patients (46 out of 199, or 23%) responded to IDHIFA treatment. Achieving a “response” means that IDHIFA helped patients achieve a complete remission (CR) or complete remission with partial hematologic recovery (CRh). A CR occurs when a patient’s blood counts and bone marrow return to normal. A CRh means that no signs of the cancer were seen, but certain blood counts did not completely return to normal.

37 patients out of the 199 studied (19%) achieved a CR.

- Half of patients who achieved a CR saw the benefit of IDHIFA last for more than 8.2 months, while half saw the benefit last for less than that

9 patients out of the 199 studied (4%) achieved a CRh.

- Half of patients who achieved a CRh saw the benefit of IDHIFA last for more than 9.6 months, while half saw the benefit last for less than that

IDHIFA helped patients reduce the need for red blood cell or platelet transfusions.

More than 1 in 3 patients (53 out of 157, or 34%) became transfusion free. This means that patients who needed red blood cell and/or platelet transfusions when the clinical trial began became transfusion free for a period of 8 weeks or more.

32 out of 42 patients (76%) remained transfusion free. This means that patients who did not need red blood cell and/or platelet transfusions when the clinical trial began remained transfusion free for a period of 8 weeks or more.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
What are the possible side effects of IDHIFA?

To study the safety of IDHIFA, 214 patients with relapsed or refractory AML with an IDH2 mutation were assigned to receive the 100-mg oral dose of IDHIFA every day and were monitored for the appearance of side effects.

You may experience side effects while taking IDHIFA. In the clinical trial, 92 out of 214 patients (43%) had their dose of IDHIFA interrupted, 10 out of 214 patients (5%) had their dose reduced, and 36 out of 214 patients (17%) had their dose discontinued due to side effects.

**IDHIFA may cause serious side effects, including:**

- Differentiation syndrome

For more information, please see page 2 of this brochure.

**The most common side effects of IDHIFA include:**

- Nausea
- Vomiting
- Diarrhea
- Jaundice
- Decreased appetite

Tell your healthcare provider if you have any changes to the color of your skin or the whites of your eyes.

These are not all the possible side effects of IDHIFA. Tell your doctor if you are experiencing any of the side effects listed on this page.

- Your healthcare provider will monitor you for side effects during treatment and may tell you to stop taking IDHIFA if you develop certain side effects
  - Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088

Learn about financial help for IDHIFA:

- [www.celgenepatientsupport.com](http://www.celgenepatientsupport.com)
- 1-800-931-8691
How should I take IDHIFA?

IDHIFA is an oral medication that you can take at home

• Take IDHIFA exactly as your healthcare provider tells you to

- Take IDHIFA 1 time a day at the same time each day
- Swallow IDHIFA tablets whole with 8 ounces (1 cup) of water. Do not chew or split the tablet
- IDHIFA can be taken with or without food

• If you miss a dose of IDHIFA or vomit after taking a dose of IDHIFA, take the dose of IDHIFA as soon as possible on the same day. Then take your next dose the next day at your regularly scheduled time. Do not take 2 doses at the same time to make up for the missed dose

• Your healthcare provider should do blood tests to check your blood counts before you start IDHIFA treatment and at a minimum of every 2 weeks for at least the first 3 months during treatment to check for side effects

How long should I take IDHIFA?

• In the clinical trial, half of the 214 patients evaluated for safety took IDHIFA for more than 4.3 months, while half took it for less than that (range of 0.3 months to 23.6 months)

• In patients evaluated for efficacy and for whom IDHIFA worked (46 out of 199) the amount of time it took to see a response varied:
  — Half of patients saw their first response after taking IDHIFA for 1.9 months (range of 0.5 months to 7.5 months), while for other half it took longer
  — Half of patients saw their best response after taking IDHIFA for 3.7 months (range of 0.6 months to 11.2 months), while for other half it took longer

• Your doctor will decide how long you will take IDHIFA, so be sure to follow his or her instructions about treatment schedule and dose

IDHIFA may cause serious side effects, including:

Differentiation syndrome: Differentiation syndrome is a condition that affects your blood cells which may be life-threatening or lead to death if not treated. Differentiation syndrome has happened within 10 days and up to 5 months after starting IDHIFA. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the symptoms of differentiation syndrome listed on page 2 of this brochure.

If you develop any of these symptoms of differentiation syndrome, your healthcare provider may start you on a medicine taken by mouth or given through a vein (intravenous) called corticosteroids and may monitor you in the hospital.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
How should I store IDHIFA?

- Store IDHIFA at room temperature, 68°F to 77°F (20°C to 25°C)
- Keep IDHIFA in the original container
- Keep the container tightly closed with desiccant canister (drying agent) inside to protect the tablets from moisture

Keep IDHIFA and all medicines out of reach of children.

General information about the safe and effective use of IDHIFA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take IDHIFA for conditions for which it was not prescribed. Do not give IDHIFA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about IDHIFA that is written for health professionals.

IDHIFA is available in two tablet strengths:
Tablets shown are actual size

- 100 mg
- 50 mg
Important questions to ask your healthcare provider

One of the best ways to learn about your treatment with IDHIFA is to talk to your healthcare team. Speaking with your doctor or nurse can help make you feel more at ease and comfortable with your treatment. Some questions you may want to ask are:

Why is IDHIFA right for me?

What are the most important things I need to know about IDHIFA?

What should I expect while taking IDHIFA? Are there side effects that I should watch out for?

Are there things that I should not do while taking IDHIFA?

How do I take IDHIFA? What if I miss a dose of IDHIFA?

Where and how do I get IDHIFA?

How do I store and handle IDHIFA?

How often should I come in for follow-up visits while taking IDHIFA?

How long will it take for IDHIFA to start working? How will I know if it’s working?

How long will I stay on IDHIFA?

Are there any medicines I can’t take while I’m taking IDHIFA?

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
Celgene Patient Support®

Learn about financial help for IDHIFA

At Celgene Patient Support®, we believe nothing should come between you and your prescribed Celgene medicine. Our Specialists are here to help you and your loved ones understand the financial help that may be available for IDHIFA.

Programs that help with the cost of IDHIFA differ by the type of insurance you have. Even if you don’t have insurance or enough coverage to pay for your medicine, financial help may be available.

**Celgene Commercial Co-Pay Program**
For eligible patients with commercial or private insurance (including healthcare exchanges)*

**Independent Third-Party Organizations**
For patients who are unable to afford their medication (including patients with Medicare, Medicaid, or other government-sponsored insurance)†

Independent third-party organizations† may also be able to help with travel costs to and from your doctor’s office, including gas, tolls, parking, and taxi, bus, or train fare

**Celgene Patient Assistance Program (PAP)**
For qualified patients who are uninsured or underinsured‡

Contact Celgene Patient Support® to learn more. Enrollment is simple—choose the option that is best for you.

- Enroll online at [www.celgenepatientsupport.com](http://www.celgenepatientsupport.com)
- Call us at **1-800-931-8691**
  Monday – Thursday 8 AM – 7 PM ET, Friday 8 AM – 6 PM ET (translation services available)
- Download the English or Spanish enrollment form at [www.celgenepatientsupport.com](http://www.celgenepatientsupport.com) and return it to us by e-mail at patientsupport@celgene.com or fax it to us at **1-800-822-2496**

*Other eligibility requirements and restrictions apply. Please see Full Terms and Conditions on the Celgene Patient Support® website.
†Financial and medical eligibility requirements vary by organization.
‡Patients must meet specified financial and eligibility requirements to qualify for assistance.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.
My healthcare appointments

Keep track of your visits with the healthcare team. Make a note of appointment dates, which members of the healthcare team you met with, and what you talked about.

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My dosing calendar

Use this calendar to keep track of the IDHIFA that you take and what time you take it. Be sure to follow your doctor’s instructions.

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I take IDHIFA at this time: AM/PM

My notes

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