

ORAL CHEMOTHERAPY EDUCATION



National Community Oncology
Dispensing Association, Inc.
PASSION FOR PATIENTS



ENASIDENIB

Name of your medication

Generic name — enasidenib (EH-nuh-SIH-deh-nib)

Brand name — Idhifa® (ide-HEE-fuh)

Approved uses

Enasidenib is used to treat patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 (IDH-2) mutation.

Dose and schedule

Taking enasidenib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of enasidenib is 100 milligrams (100 mg) to be taken by mouth once daily. The dose may be adjusted by your care provider based upon your individual needs.
- Enasidenib can be taken with or without food, but at the same time each day.
- Enasidenib should be swallowed whole with 1 cup (8 ounces) of water. Do not crush, cut, or dissolve the tablet. If you are unable to swallow enasidenib, talk to your care provider or pharmacist for possible options.
- If you miss or vomit immediately after a dose of enasidenib, take an extra dose as soon as possible and return to your normal schedule the following day. **Do not** take two doses at one time.
- Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Enasidenib has the potential for drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle enasidenib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store enasidenib at room temperature (68°F–77°F) in a dry location away from light in its original bottle with the desiccant canister (i.e., moisture controller).
- Keep enasidenib out of reach of children and pets.
- Leave enasidenib in the provided packaging until it is ready to be taken.
- Whenever possible, give enasidenib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give enasidenib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)

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3. Gently transfer the enasidenib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box is **not** recommended to be used with enasidenib. You should keep the medication in the original bottle.
 - If you have any unused enasidenib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of enasidenib.
 - If you are traveling, put your enasidenib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Enasidenib

Below are common side effects that have been known to happen in about one third or more of patients taking enasidenib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Changes in liver function	<p>Your liver function should be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
Changes in electrolytes and other laboratory values <ul style="list-style-type: none"> • Low calcium levels • Low potassium levels 	<p>Changes in some laboratory values may occur and should be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine

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Possible Side Effect	Management
<p>Nausea or vomiting</p>	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
<p>Decreased appetite or weight loss</p>	<p>Talk to your care provider if you notice a decrease in weight while taking this medication.</p> <p>When you do not feel like eating, try the following:</p> <ul style="list-style-type: none"> • Eat small, frequent meals instead of 3 large meals each day. • Keep snacks nearby so you can eat when you feel hungry. • Take liquid nutritional supplements. • Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.

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Serious side effects of enasidenib

- Differentiation syndrome is a condition that affects your blood cells and may be life-threatening or lead to death if not treated. Go to the nearest hospital emergency room or call 911 if you develop any of these symptoms: fever, cough, shortness of breath, bone pain, fast weight gain (10 lbs within one week), or swelling of arms and legs, around the neck, groin, or underarm.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Enasidenib remains in your body for several days after it is taken, so some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take enasidenib, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or enasidenib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking enasidenib. Women of childbearing age and potential should use effective contraception during therapy and for a minimum of two months after the last dose of enasidenib. Men of reproductive age and potential should use effective contraception during therapy and for a minimum of two months after the last dose of enasidenib.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking enasidenib and for two months after the last dose of enasidenib.
- Inform your care provider if you become pregnant.

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- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on enasidenib, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about the process for obtaining your enasidenib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.idhifa.com>

Product prescribing information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209606s004lbl.pdf

Product resources: <https://www.idhifa.com/resources-and-financial-support>

Updated — October 1, 2021

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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