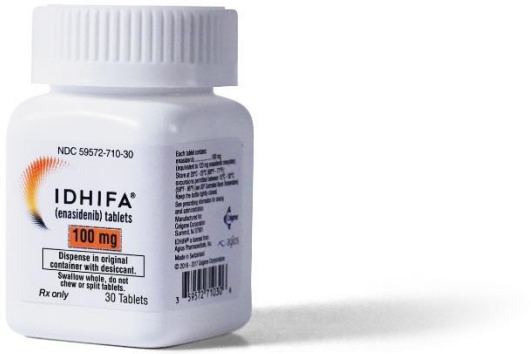
Idhifa (enasidenib)



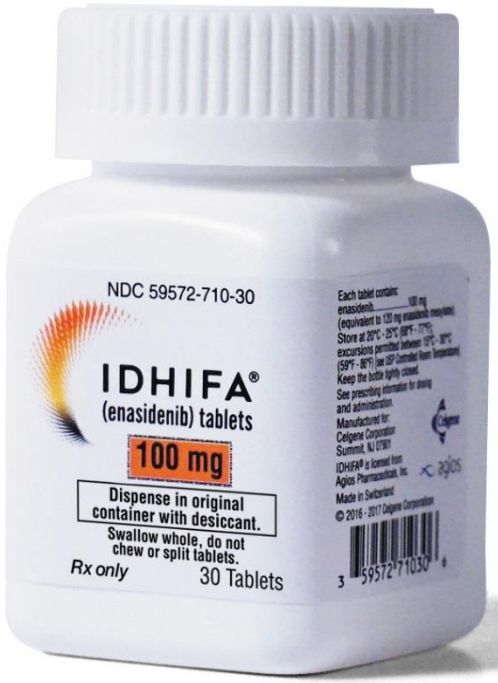
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Idhifa
- **Generic name:** Enasidenib
- **Pharmacological class:** Isocitrate dehydrogenase-2 (IDH2) inhibitor
- **Strength and Formulation:** 50mg, 100mg; tabs
- **Manufacturer:** Celgene
- **How supplied:** Bottle—30
- **Legal Classification:** Rx

IDHIFA


NDC 59572-710-30
IDHIFA®
(enasidenib) tablets
100 mg
Dispense in original container with desiccant.
Swallow whole, do not chew or split tablets.
Rx only
30 Tablets
Each tablet contains:
enasidenib 100 mg
(equivalent to 130 mg enasidenib mesylate)
Store at 20°C - 25°C (68°F - 77°F);
excursions permitted between 15°C - 30°C
(59°F - 86°F) [see USP Controlled Room Temperature].
Keep the bottle tightly closed.
See prescribing information for dosing and administration.
Manufactured for:
Celgene Corporation
Summit, NJ 07901
IDHIFA® is licensed from
Agios Pharmaceuticals, Inc.
Made in Switzerland
© 2016 - 2017 Celgene Corporation
agios
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Indications

- Treatment of adults with **relapsed or refractory acute myeloid leukemia (AML)** with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test

Dosage & Administration

- Swallow whole
- Take at same time each day
- Initially 100mg once daily until disease progression or unacceptable toxicity; treat for a minimum of 6 months for response
- Dose modifications for toxicities: see full labeling

Considerations for Special Populations

- **Pregnancy:** Exclude status prior to initiation
- **Nursing mothers:** Not recommended during and for at least 1 month after final dose
- **Pediatric:** Not established
- **Elderly:** No overall differences in safety or efficacy were observed

Warnings/Precautions

- Risk of **differentiation syndrome** (may be fatal if not treated)
- If suspected, initiate oral or IV corticosteroids and hemodynamic monitoring until resolution; interrupt dose if severe pulmonary symptoms requiring intubation or ventilator support, and/or renal dysfunction persist >48hrs after corticosteroid initiation

Warnings/Precautions

- Assess blood counts/chemistries for **leukocytosis** and **tumor lysis syndrome** prior to initiation; monitor at minimum of every 2 weeks for at least the first 3 months during therapy

Warnings/Precautions

- Embryo-fetal toxicity
- Females of reproductive potential and males (with female partners) should **use effective contraception** during and for at least 1 month after final dose

Interactions

- May affect concomitant combination hormonal contraceptives

Adverse Reactions

- Nausea
- Vomiting
- Diarrhea
- Elevated bilirubin
- Decreased appetite
- Differentiation syndrome
- Leukocytosis
- Tumor lysis syndrome

Mechanism of Action

- Enasidenib is a small molecule inhibitor of the IDH2 enzyme
- In blood samples from patients with AML with mutated IDH2, enasidenib decreased 2-HG levels, reduced blast counts, and increased percentages of mature myeloid cells

Clinical Studies

- Idhifa was evaluated in an open-label, single-arm, multicenter, 2-cohort clinical trial (Study AG221-C-001) of adults with relapsed or refractory AML and an IDH2 mutation (n=199)
- Patients were assigned to receive Idhifa 100mg daily until disease progression or unacceptable toxicity

Clinical Studies

- Efficacy was determined by:
  - Rate of complete response (CR)/complete response with partial hematologic recovery (CRh)
  - Duration of CR/CRh
  - Rate of conversion from transfusion dependence to transfusion independence
- Median follow-up was 6.6 months

Clinical Studies

- The data showed similar rates of CR/CRh in patients with either R140 or R172 mutation
- **CR** was seen in 19% of patients (95% CI: 13, 25) with a median duration of response (DOR) of 8.2 months (95% CI: 4.7, 19.4)

Clinical Studies

- **CRh** was seen in 4% of patients (95% CI: 2, 8) with a median DOR of 9.6 months (95% CI: 0.7, NA)
- **CR/CRh** was seen in 23% of patients (95% CI: 18, 30) with a median DOR or 8.2 months (95% CI: 4.3, 19.4)
  - Median time to first response was 1.9 months
  - Median time to best response was 3.7 months

Clinical Studies

- Of the patients who were dependent on red blood cell (RBC) and/or platelet transfusions at baseline, **34%** became independent during any 56-day post-baseline period

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/idhifa/drug/34735/