(_____)

Generic Name:
Enasidenib
Trade Name:
Idhifa
Company:
Celgene
Notes:

FDA is warning that signs and symptoms of a life-threatening adverse effect called differentiation syndrome are not being recognized in patients receiving the acute myeloid leukemia medicine enasidenib. The enasidenib prescribing information and patient Medication Guide already contain a warning about differentiation syndrome. However, the agency said it has become aware of cases of differentiation syndrome not being recognized and patients not receiving the necessary treatment.

As a result, FDA is alerting health professionals and patients about the need for early recognition and aggressive management of differentiation syndrome to lessen the likelihood of serious illness and death. The agency is continuing to monitor this safety concern.

Health professionals should describe to patients the symptoms of differentiation syndrome listed in the Medication Guide when starting enasidenib and at follow-up visits, and inform them to call their health professional if such symptoms occur. Differentiation syndrome has occurred as early as 10 days and up to 5 months after starting the medicine. If patients experience unexplained respiratory distress or other symptoms, consider a diagnosis of differentiation syndrome, and treat promptly with oral or I.V. corticosteroids.

Patients should contact their health professional or go to the nearest hospital emergency department right away if they develop any of the following symptoms of differentiation syndrome while taking enasidenib: fever; cough; shortness of breath; swelling of arms and legs; swelling around the neck, groin, or underarm area; fast weight gain of more than 10 pounds within a week; bone pain; or feeling dizzy or lightheaded.

Enasidenib was approved in August 2017 to treat patients with acute myeloid leukemia (AML) with a specific genetic mutation called isocitrate dehydrogenase (IDH)-2 whose disease has come back or has not improved after treatment with other chemotherapy medicines. Enasidenib works by blocking several enzymes that promote this abnormal blood cell growth.

In the clinical trial conducted for enasidenib's approval, at least 14% of patients experienced differentiation syndrome. The manufacturer?s safety report, which included the period of May 1, 2018, to July 31, 2018, reported five cases of death associated with differentiation syndrome in patients taking the drug.

Medication Monitor Categories:
Alerts and Recalls