

[Home](#) > New drug targets myelofibrosis, a rare bone marrow disorder

Generic Name:

Fedratinib

Trade Name:

Inrebic

Company:

Celgene Corp.

Notes:

On August 16, FDA [approved](#) fedratinib capsules to treat adult patients with certain types of myelofibrosis.

Approval of fedratinib for intermediate-2 or high-risk primary or secondary (postpolycythemia vera or postessential thrombocythemia) myelofibrosis was based on the results of a clinical trial in which 289 patients with myelofibrosis were randomized to receive two different doses (400 mg/d or 500 mg/d orally) of fedratinib or placebo.

Thirty-five of 96 patients treated with the fedratinib 400-mg daily dose (the dose recommended in the approved label) experienced a significant therapeutic effect, measured by greater than or equal to a 35% reduction from baseline in spleen volume at the end of cycle 6 (week 24) as measured by an MRI or CT scan with a follow-up scan 4 weeks later.

As a result of treatment, 36 patients experienced 50% or greater reduction in myelofibrosis-related symptoms, such as night sweats, itching, abdominal discomfort, feeling full sooner than normal, pain under ribs on left side, and bone or muscle pain.

The fedratinib prescribing information includes a boxed warning about the risk of serious and fatal encephalopathy, including Wernicke's, a neurologic emergency related to a thiamine deficiency. Health professionals are advised to assess thiamine levels in all patients before starting fedratinib, during treatment, and as clinically indicated. If encephalopathy is suspected, fedratinib should be immediately discontinued.

Common adverse effects are diarrhea, nausea, vomiting, fatigue, and muscle spasms. Health professionals are cautioned that patients may experience severe anemia and thrombocytopenia. Patients should be monitored for GI toxicity and for hepatic toxicity. The dose should be reduced or stopped if a patient develops severe diarrhea, nausea, or vomiting, and treatment with antidiarrhea medications may be recommended.

Patients may develop high levels of amylase and lipase in their blood and should be managed by dose reduction or stopping the medication.

Fedratinib must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks.

Medication Monitor Categories:

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