MEDICATION GUIDE

INREBIC® (inn-REH-bik)

(fedratinib)

capsules, for oral use

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

INREBIC may cause serious side effects, including:

- **Encephalopathy (including Wernicke's encephalopathy).** A serious and sometimes fatal neurological problem called encephalopathy (including Wernicke's encephalopathy) has happened in some people who take INREBIC.

  Wernicke's encephalopathy is a neurologic emergency that can happen if you do not have enough Vitamin B1 (thiamine) in your body. Your healthcare provider will do a blood test to check your Vitamin B1 level and treat you with Vitamin B1 if your level is too low before starting treatment with INREBIC. Your healthcare provider may also check your Vitamin B1 level during treatment with INREBIC. You should take a Vitamin B1 supplement (100 mg of thiamine) during treatment with INREBIC.
  Your healthcare provider may tell you to stop taking INREBIC if you develop side effects during treatment with INREBIC.

  Get emergency medical help right away if you develop the following:

  - confusion, memory problems or drowsiness
  - problems with balance and movement, such as difficulty walking
  - eye problems, such as double or blurred vision or abnormal eye movements

  Call your healthcare provider right away if you experience diarrhea, nausea, vomiting, and weight loss that does not get better with treatment.

See **"What are the possible side effects of INREBIC"** for more information about side effects**.**

What is INREBIC?

INREBIC is a prescription medicine used to treat adults with certain types of myelofibrosis (MF).

It is not known if INREBIC is safe and effective in children.

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

- have low Vitamin B1 (thiamine) levels
- have low red blood cell or platelet counts
- have or have had liver problems
- have or have had kidney problems
- are a current or past smoker
- have had a blood clot, heart attack, other heart problems, or stroke
- have or have had any other cancer
- are pregnant or plan to become pregnant. It is not known if INREBIC may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if INREBIC passes into your breast milk. You should not breastfeed during treatment with INREBIC and for at least 1 month after your last dose. Talk to your healthcare provider about the best way to feed your baby during treatment with INREBIC.

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

Taking INREBIC with certain other medicines may cause side effects from INREBIC or from the other medicine and may affect the way that INREBIC works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take INREBIC?

- Take INREBIC exactly as your healthcare provider tells you to. Do not change your dose or stop taking INREBIC unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with INREBIC if you develop side effects.
- Take INREBIC 1 time each day.
- Take INREBIC with or without food. Taking INREBIC with a high fat meal may help to reduce nausea and vomiting symptoms.

- Take Vitamin B1 (thiamine 100 mg) by mouth daily to prevent low Vitamin B1 levels during treatment with INREBIC.
- If you miss a dose of INREBIC, skip the missed dose and take your usual dose the next day at your regularly scheduled time. Do not take 2 doses to make up for the missed dose.

What are the possible side effects of INREBIC?

INREBIC may cause serious side effects, including:

- See **"What is the most important information I should know about INREBIC?"**
- **Low blood cell counts.** INREBIC may cause new or worsening low red blood cell counts (anemia) and low platelet counts (thrombocytopenia) in some people. You may need a blood transfusion if your blood counts drop too low. Your healthcare provider will do blood tests to check your blood counts before you start and during treatment with INREBIC. Tell your healthcare provider if you develop any bleeding or bruising during treatment with INREBIC.
- **Diarrhea, nausea, and vomiting.** Your healthcare provider may give you certain medicines to help treat your diarrhea, nausea, and vomiting. Call your healthcare provider or get emergency medical help right away if you have diarrhea, nausea, or vomiting that does not get better with treatment.
- **Liver problems.** INREBIC may cause increased liver enzymes. Your healthcare provider will do blood tests to check your liver function before starting and during treatment with INREBIC.
- **Amylase and lipase increases.** You may have increases in your blood amylase or lipase levels that may indicate a problem with your pancreas. Your healthcare provider will do blood tests to check your amylase or lipase levels before starting and during treatment with INREBIC.
- **Major cardiac events such as heart attack, stroke, or death**. An increased risk of major cardiac events has happened in people, especially those who have cardiovascular risk factors and who are current or past smokers, while taking another Janus Kinase (JAK)-inhibitor to treat rheumatoid arthritis.

  Get emergency help right away if you have any symptoms of a heart attack or stroke while taking INREBIC, including:
  - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
  - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
  - pain or discomfort in your arms, back, neck, jaw, or stomach
  - shortness of breath with or without chest discomfort
  - breaking out in a cold sweat
  - nausea or vomiting
  - feeling lightheaded
  - weakness in one part or on one side of your body
  - slurred speech
- **Blood clots.** Increased risk of blood clots in the veins of the legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) have happened in people taking another JAK-inhibitor for rheumatoid arthritis and may be life-threatening.

  Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with INREBIC, including:
  - swelling, pain, or tenderness in one or both legs
  - sudden unexplained chest or upper back pain
  - shortness of breath or difficulty breathing
- **New (secondary) cancers.** People who take another JAK-inhibitor for rheumatoid arthritis have an increased risk of new (secondary) cancers, including lymphoma and other cancers, except nonmelanoma skin cancer. People who smoke or who smoked in the past have an added increased risk of new cancers.

The most common side effects of INREBIC include:

- diarrhea
- nausea
- low red blood cell counts (anemia)
- vomiting

These are not all of the possible side effects of INREBIC.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INREBIC?

- Store INREBIC below 86°F (30°C).

Keep INREBIC and all medicines out of the reach of children.

General information about the safe and effective use of INREBIC.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INREBIC for conditions for which it was not prescribed. Do not give INREBIC 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 INREBIC that is written for health professionals.

What are the ingredients in INREBIC?

Active ingredient: fedratinib

Inactive ingredients: silicified microcrystalline cellulose and sodium stearyl fumarate. The capsule shell contains gelatin, red iron oxide, titanium dioxide and white ink.

Marketed by:
Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

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For more information go to www.INREBIC.com or call 1-800-721-5072.

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