

BE IN COMMAND

Ask your doctor about INREBIC® (fedratinib), and take an active approach to your primary or secondary myelofibrosis (MF) journey.



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.

IMPORTANT SAFETY INFORMATION

WARNING: ENCEPHALOPATHY INCLUDING WERNICKE'S

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 before starting and during treatment with INREBIC. Your healthcare provider may tell you to stop taking INREBIC and take a vitamin B1 supplement if you develop side effects during treatment with INREBIC.

Call your healthcare provider right away if you develop diarrhea, nausea, or vomiting that does not respond to treatment.

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 if you experience rapid weight loss or weight loss that does not get better with treatment.



INREBIC[®]
(fedratinib) capsules

100mg

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).



What is INREBIC® (fedratinib)?

INREBIC is a prescription medicine used to treat adults with intermediate-2 or high-risk myelofibrosis (MF).* It is not known if INREBIC is safe and effective in children.

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

*See definitions in the Glossary of Terms on back cover.

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

In this brochure, read about:	Page
Clinical data	4-7
Potential side effects	8-11
How to take INREBIC	12-13
Financial assistance and support	14-15
Support organizations and groups.....	16-17
Indication and Important Safety Information	18-19
Glossary of terms	back cover

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)

Learn about the clinical data

The clinical trial* of INREBIC® was called JAKARTA. The JAKARTA study looked at whether INREBIC was safe and effective in treating adult patients with intermediate-2 or high-risk primary* or secondary* MF with splenomegaly.*

The study included 289 patients who had intermediate-2 or high-risk primary or secondary MF. INREBIC users were compared with a group given a placebo.* In the study, 97 patients took a 500 mg dose, 96 patients took a 400 mg dose, and 96 patients took a placebo. The recommended daily dose is 400 mg, so only data from the group of patients that took the 400 mg dose are shown.

Study goals

- ① The main study goal, or primary endpoint* of the study, was to measure the number of patients who had a **35% reduction or more in the volume of their spleen**. This was measured after patients took 6 cycles* of INREBIC and then had follow-up scans 4 weeks later.

To measure the change in spleen volume, patients had an MRI* or CT* scan after Cycle 3 and Cycle 6.

- ② Also in this clinical trial, an additional goal, or a secondary endpoint, of the study was to measure the percentage of people who had a **50% or greater reduction in their Total Symptom Score (TSS)** after 6 cycles of taking INREBIC. The TSS tallied symptom scores for each patient and looked at the following symptoms:



Night sweats



Itching



Early satiety*



Bone or muscle pain



Pain under ribs on left side



Abdominal discomfort



In the JAKARTA study:

- Patients had never taken ruxolitinib
- Some of the patients had low platelet counts (50 to $<100 \times 10^9/L$)

In the JAKARTA trial, symptoms were measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0 diary.

The modified MFSAF v2.0 is a patient diary that looked at 6 core symptoms of MF: night sweats, itching, abdominal discomfort, early satiety, pain under the ribs on the left side, and bone or muscle pain. The modified MFSAF diary was filled out daily during the week prior to Day 1 of each treatment cycle, and at the end of Cycle 6. Symptom scores ranged from 0 ("absent") to 10 ("worst imaginable"). These scores were added together to create the Total Symptom Score (TSS).

IMPORTANT SAFETY INFORMATION (cont.)

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

- have low red blood cell or platelet counts
- have or have had liver problems
- have or have had kidney problems
- have had cancer in the past
- are a current or past smoker
- have had a blood clot, heart attack, other heart problems, or stroke
- 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.

INREBIC and other medicines may affect each other causing unwanted side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

*See definitions in the Glossary of Terms on back cover.

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)

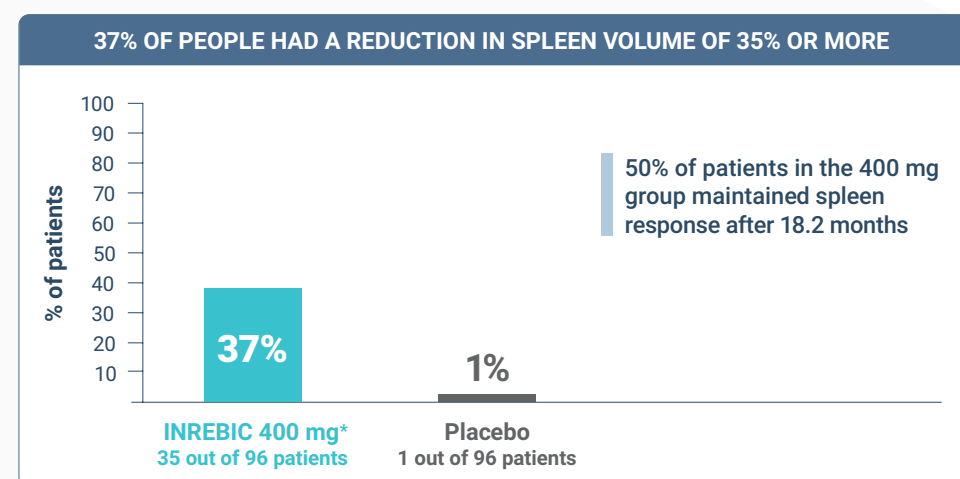


INREBIC
(fedratinib) capsules
100mg

The results of the study showed:

Reduced spleen volume

In the JAKARTA study, 37% of patients had greater than or equal to 35% reduction in spleen volume after taking INREBIC® for 6 cycles, with a follow-up scan 4 weeks later.



*Out of the 289 patients, 97 patients received 500 mg dose, 96 patients 400 mg dose, and 96 patients a placebo. The recommended daily dose is 400 mg. That is why the 500 mg dose arm of the study is not shown in the chart.

IMPORTANT SAFETY INFORMATION (cont.)

The most common side effects of INREBIC include:

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

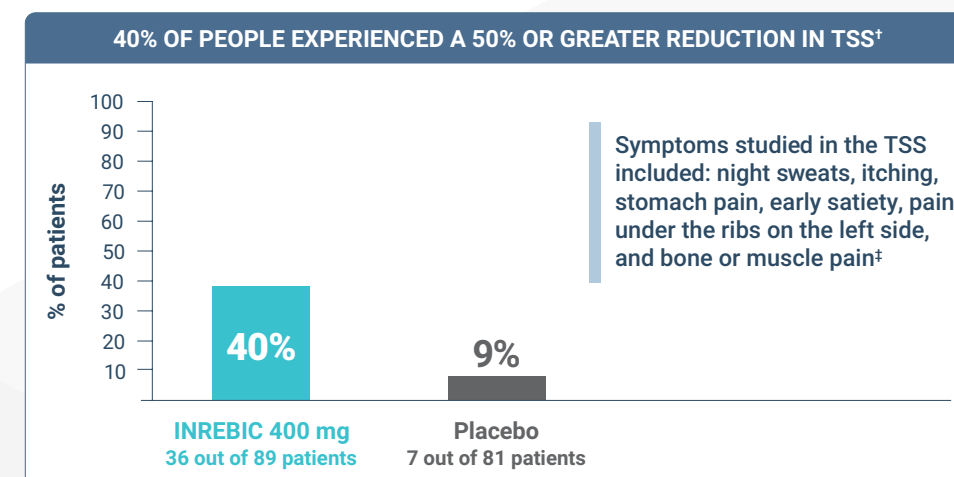
These are not all of the possible side effects of INREBIC.

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

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

MF symptoms studied

INREBIC showed reduction in MF symptoms as measured by the Total Symptom Score (TSS) calculation at the end of Cycle 6.



†A total of 89 patients receiving INREBIC 400 mg and 81 patients receiving placebo were evaluated in the study for this endpoint.

‡Some symptoms had significant reduction, but that does not mean that they went away.

Selected safety findings

Most common side effects (reported in >20% of patients taking INREBIC).

Side Effect	INREBIC 400 mg (n=96)	Placebo (n=95)
Diarrhea	66%	16%
Nausea	62%	15%
Low red blood cell counts (anemia)	40%	14%
Vomiting	39%	5%

These are not all the possible side effects of INREBIC.

Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.

See the next page to read about INREBIC side effects.

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)



INREBIC
(fedratinib) capsules
100mg



Learn about potential side effects

It's important to understand the possible side effects of treatment. Talk to your doctor about any side effects that you may experience.

INREBIC® may cause serious side effects, such as 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 before starting and during treatment with INREBIC. Your healthcare provider may tell you to stop taking INREBIC and take a B1 vitamin if you develop side effects during treatment with INREBIC.

Call your healthcare provider right away if you develop diarrhea, nausea, or vomiting that does not respond to treatment.

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 if you experience rapid weight loss or weight loss that does not get better with treatment.

These are not all the possible side effects of INREBIC. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)


INREBIC®
(fedratinib) capsules
100mg



Learn about potential side effects (cont.)

INREBIC® can cause other serious side effects, including:

Low blood cell counts. INREBIC may cause 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.

Nausea, vomiting, and diarrhea. Your healthcare provider may give you certain medicines to help treat your nausea, vomiting, and diarrhea. Call your healthcare provider or get emergency medical help right away if you have nausea, vomiting, or diarrhea that does not get better with treatment.

Liver problems. 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 changes 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.

Increased risk of major cardiac events such as heart attack, stroke, or death in people who have cardiovascular risk factors and who are current or past smokers while using another JAK inhibitor to treat rheumatoid arthritis

Get emergency medical 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

Increased risk of blood clots

Blood clots in the veins of your 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

Possible increased risk of 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. People who smoke or who smoked in the past have an added 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 the possible side effects of INREBIC.

Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)










INREBIC®
(fedratinib) capsules
100mg



How to take INREBIC®

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

-  have low red blood cell or platelet counts
-  have or have had liver problems
-  have or have had kidney problems
-  have had cancer in the past
-  are a current or past smoker
-  have had a blood clot, heart attack, other heart problems, or stroke
-  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.

INREBIC and other medicines may affect each other, causing unwanted side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full Prescribing Information, including Boxed WARNING and Medication Guide.

How once-daily INREBIC should be taken:

- 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
- 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
- If you miss a dose of INREBIC, skip the missed dose and take your next dose at your regular time. Do not take 2 doses to make up for the missed dose

Who can take INREBIC?

Adults with primary or secondary intermediate-2 or high-risk myelofibrosis (MF) may be able to take INREBIC. That includes patients:

- Who have and haven't been treated with ruxolitinib
- With low platelet counts ($\geq 50 \times 10^9/L$)

How to store INREBIC:

- Store INREBIC below 86 °F (30 °C)
- Keep INREBIC and all medicines out of the reach of children



Capsules shown are not actual size.



INREBIC®
(fedratinib) capsules
100mg

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)



BMS Access Support® Can Provide Patient Access and Reimbursement Assistance

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer BMS Access Support. BMS Access Support provides resources to help patients understand their insurance coverage. In addition, we can share information on sources of financial support, including co-pay assistance for eligible commercially insured patients.



How BMS Access Support May Help

Find out how BMS can work with patients and their healthcare providers to help access a prescribed BMS medication.



Financial Support Options

There may be programs and services that could help with the cost of treatment. Learn about what options are available.



Additional Resources

We provide videos, tools, and other resources that may help with your access and reimbursement needs.

Have Questions About Our Program or Possible Financial Support?

If you have questions about coverage for a prescribed BMS medication, BMS Access Support may be able to help. Patients and their healthcare provider can complete an enrollment form to learn about programs that may be of assistance. Visit our website or contact BMS Access Support to learn more.



Call Bristol Myers Squibb Access Support at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday



Visit www.BMSAccessSupport.com

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.





Support organizations and advocacy groups

Independent organizations offer support and information related to MF for both patients and caregivers.



The MPN Research Foundation, a resource for information on research and clinical trials, also offers a monthly newsletter on the latest developments in the field.
mpnresearchfoundation.org



MPN Advocacy & Education International educates patients with MPNs and their entire healthcare teams by hosting daylong seminars featuring patients and doctors.
mpnadvocacy.com



Patient Power is an organization that connects patients and their care partners to an active and knowledgeable community of cancer experts and patient advocates across a wide range of cancers, including myelofibrosis.
patientpower.info



The Cancer Support Community (CSC) is a global nonprofit network of 175 locations that deliver free support services to patients and families.
cancersupportcommunity.org

This list of independent organizations is provided as an additional resource for obtaining information related to MF. This list does not indicate endorsement by Bristol-Myers Squibb Company of an organization or its communications.

Please see INREBIC Important Safety Information throughout and on pages 18-19, as well as full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#).

LEARN MORE AT INREBIC.COM



INREBIC[®]
(fedratinib) capsules
100mg

Indication and Important Safety Information

INDICATION

What is INREBIC® (fedratinib)?

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.

IMPORTANT SAFETY INFORMATION

WARNING: ENCEPHALOPATHY INCLUDING WERNICKE'S

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 before starting and during treatment with INREBIC. Your healthcare provider may tell you to stop taking INREBIC and take a vitamin B1 supplement if you develop side effects during treatment with INREBIC.

Call your healthcare provider right away if you develop diarrhea, nausea, or vomiting that does not respond to treatment.

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 if you experience rapid weight loss or weight loss that does not get better with treatment.

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

- have low red blood cell or platelet counts
- have or have had liver problems
- have or have had kidney problems
- have had cancer in the past
- are a current or past smoker
- have had a blood clot, heart attack, other heart problems, or stroke
- 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.

INREBIC and other medicines may affect each other causing unwanted side effects. 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.
- 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.
- If you miss a dose of INREBIC, skip the missed dose and take your next dose at your regular time. Do not take 2 doses to make up for the missed dose.

What are the possible side effects of INREBIC?

INREBIC can cause serious side effects, including:

- **Low blood cell counts.** INREBIC may cause 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.
- **Nausea, vomiting, and diarrhea.** Your healthcare provider may give you certain medicines to help treat your nausea, vomiting, and diarrhea. Call your healthcare provider or get emergency medical help right away if you have nausea, vomiting, or diarrhea that does not get better with treatment.
- **Liver problems.** 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 changes 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.
- **Increased risk of major cardiac events such as heart attack, stroke, or death in people who have cardiovascular risk factors and who are current or past smokers while using another 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
- **Increased risk of blood clots.** Blood clots in the veins of your 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
- **Possible increased risk of 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. People who smoke or who smoked in the past have an added 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.

Please see INREBIC Important Safety Information throughout and on page 18, as well as full Prescribing Information, including Boxed WARNING and Medication Guide.

LEARN MORE AT [INREBIC.COM](https://www.inrebic.com)

GLOSSARY OF TERMS

Clinical trial: a research study involving human volunteers (also called participants) that is intended to add to medical knowledge.

CT: computer tomography scan. A procedure that uses a computer linked to an x-ray machine to make a detailed picture of what's inside the body.

Cycle: a period of treatment followed by a period of rest (no treatment) that may be repeated.

Endpoint: in clinical trials, an event or outcome that can be measured to determine if the intervention being studied is beneficial.

MRI: magnetic resonance imaging. A procedure in which radio waves and a powerful magnet linked to a computer are used to create pictures of areas inside the body.

Myelofibrosis (MF): a disorder in which the bone marrow is replaced by fibrous tissue.

Placebo: an inactive substance that has no therapeutic effect but may be used to compare the effects of an active drug.

Primary MF: when the disease occurs in the absence of another cancer.

Early Satiety: feeling full after a small meal.

Secondary MF: when MF occurs as the result of another known disease.

Splenomegaly: a larger-than-normal spleen.

TSS: Total Symptom Score, calculated as the mean score for 10 items focused on fatigue, concentration, early satiety, inactivity, night sweats, itching, bone pain, abdominal discomfort, weight loss, and fevers.



INREBIC[®]
(fedratinib) capsules
100mg

READ MORE AT [INREBIC.COM](https://www.inrebic.com)

IMPORTANT SAFETY INFORMATION

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 before starting and during treatment with INREBIC. Your healthcare provider may tell you to stop taking INREBIC and take a vitamin B1 supplement if you develop side effects during treatment with INREBIC.

Call your healthcare provider right away if you develop diarrhea, nausea, or vomiting that does not respond to treatment.

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 if you experience rapid weight loss or weight loss that does not get better with treatment.

Please see **INREBIC Important Safety Information** throughout and on pages 18-19, as well as full **Prescribing Information**, including **Boxed WARNING** and **Medication Guide**.



© 2023 Impact Biomedicines, Inc.

INREBIC[®] and its logo are registered trademarks of Impact Biomedicines, Inc.

Access Support[®] is a registered trademark of Bristol-Myers Squibb Company.

03/23 2010-US-2300016