

# INREBIC®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

**WARNING:** Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

## 1. Why am I using INREBIC?

INREBIC contains the active ingredient fedratinib. INREBIC is used to treat the disease-related symptoms of myelofibrosis in adult patients, such as enlarged spleen and other related myelofibrosis symptoms. For more information, see Section [1. Why am I using INREBIC?](#) in the full CMI.

## **2. What should I know before I use INREBIC?**

Do not use if you have ever had an allergic reaction to fedratinib or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use INREBIC?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with INREBIC and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## **4. How do I use INREBIC?**

Take INREBIC once a day. Your doctor will tell you how many capsules to take.

Swallow the capsule whole with a full glass of water. Do not open, break or chew the capsule. INREBIC capsules can be taken either with or without food. Taking INREBIC with food may reduce nausea or vomiting.

More instructions can be found in Section [4. How do I use INREBIC?](#) in the full CMI.

## 5. What should I know while using INREBIC?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Keep all of your doctor's appointments so that your progress can be checked, including having blood tests.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using INREBIC.</li></ul> <p><b>Call your doctor straight away if you:</b></p> <ul style="list-style-type: none"><li>• get any of the following signs or symptoms before taking these capsules and during treatment: Confusion, memory loss, or difficulty thinking; loss of balance or difficulty walking; eye problems such as random eye movement, double-vision, blurred vision and loss of vision.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly</li></ul>

	without talking to your doctor first.
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how INREBIC affects you. INREBIC may cause dizziness in some people. Do not drive or operate machines if you experience dizziness after taking INREBIC.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 30°C.</li> </ul>

For more information, see Section [5. What should I know while using INREBIC?](#) in the full CMI.

## 6. Are there any side effects?

Serious side effects: Signs of a serious condition which affects the brain called encephalopathy (including Wernicke's encephalopathy): confusion, memory loss or difficulty thinking; loss of balance or difficulty walking; eye problems such as double-vision, blurred vision loss of vision or random eye movements. Very common side effects include: low levels of red blood cells, blood platelets, changes in blood test results, nausea, vomiting, diarrhoea, headache, tiredness or weakness. For more information, including what to do if

you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

**WARNING: INREBIC may cause a serious and sometimes fatal neurological problem called encephalopathy (including Wernicke's encephalopathy).**

**Wernicke's encephalopathy is a neurologic problem that requires emergency care. It can happen if you do not have enough Vitamin B1 (thiamine) in your body. Follow instructions from your healthcare provider including taking a Vitamin B1 supplement and Vitamin B1 blood tests.**

## **INREBIC** (inn-REH-bik)

**Active ingredient(s):** fedratinib (fe dra' ti nib)

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using INREBIC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].**

**Where to find information in this leaflet:**

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- [1. Why am I using INREBIC?](#)
- [2. What should I know before I use INREBIC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take INREBIC?](#)
- [5. What should I know while using INREBIC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using INREBIC?**

**INREBIC contains the active ingredient fedratinib.** INREBIC belongs to a group of medicines called Janus Kinase (JAK) inhibitors.

**INREBIC is used to treat the disease-related symptoms of myelofibrosis in adult patients, such as enlarged spleen and other related myelofibrosis symptoms.**

An enlarged spleen is one of the characteristics of myelofibrosis. Myelofibrosis is a disorder of the bone marrow, in which the marrow is replaced by scar tissue. The abnormal marrow can no longer produce enough normal blood cells. As a result, the spleen tries to compensate by producing them outside of the bone marrow and hence the spleen can become significantly enlarged. By blocking the action of certain enzymes (called Janus Associated Kinases), Inrebic can reduce the size of the spleen in patients with myelofibrosis and relieve symptoms such as fever, night sweats, bone pain and weight loss in patients with myelofibrosis.

## **2. What should I know before I use INREBIC?**

### **Warnings**

#### **Do not use INREBIC if:**

- you are allergic to fedratinib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

#### **Contact your doctor immediately if you get any of the following signs or symptoms before taking these capsules and during treatment:**

- Confusion, memory loss, or difficulty thinking
- Loss of balance or difficulty walking
- Eye problems such as random eye movement, double-vision, blurred vision and loss of vision

These may be signs of a brain condition called encephalopathy, including Wernicke's encephalopathy, which may lead to death.

#### **Check with your doctor if you:**

- are feeling very tired, being short of breath, pale skin or fast heartbeat – these may be signs of a low red blood cell count
- have unusual bleeding or bruising under the skin, longer than usual bleeding after your blood has been

drawn, or bleeding from your gums – these may be signs of a low blood platelet count

- have nausea, vomiting or diarrhoea
- have or ever had any kidney problems
- have or ever had any liver problems
- have or ever had any problems with your pancreas
- have eye problems, especially an inflammation of the eye called uveitis
- have or have had heart problems
- have or have had blood clots in the veins of your legs, arms or lungs
- have or have had cancer, including skin cancer
- smoked in the past or currently smoke
- have any other medical conditions
- take any medicines for any other condition

### **Blood tests**

Before and during treatment, you will have blood tests to check your blood cell levels (red blood cells, white blood cells and platelets), your vitamin B1 levels and your liver and pancreatic function. Your doctor may adjust the dose or stop treatment based on the results of the blood tests.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Tell your doctor if you are pregnant or intend to become pregnant. Do not take INREBIC if you are pregnant or attempting to become pregnant. Your doctor can discuss with you the risks and benefits involved.

If you are able to become pregnant, use effective birth control during treatment with INREBIC and for at least 1 month after the last dose.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if INREBIC is found in breast milk. Do not breastfeed if you are taking INREBIC and for at least 1 month after the last dose.

## **Use in children or adolescents**

Inrebic should not be used in children or young people under 18 years of age because this medicine has not been studied in this age group.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- medicines used to treat fungal infections, such as ketoconazole or fluconazole

- medicines used to treat depression, such as fluvoxamine
- medicines used to help you sleep or relieve anxiety, such as midazolam
- medicines used to treat viral infections medicines used to treat HIV/AIDS such as ritonavir or efavirenz
- antibiotics used to treat types of bacterial infections, such as rifampicin
- medicines used to treat epilepsy, such as phenytoin
- medicines used to treat high blood pressure and heart rhythm, such as metoprolol
- medicines used to treat stomach problems, such as omeprazole
- medicines used to lower blood sugar levels, such as metformin

These medicines may be affected by INREBIC or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will decide if your dose needs to be changed.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INREBIC.**

## **4. How do I take INREBIC?**

### **How much to take**

- Your doctor will tell you how many capsules to take.

- You will have blood tests before and while you take this medicine to monitor your progress. If you get certain side effects while you are taking INREBIC, your doctor may lower your dose or pause or stop treatment.
- Take INREBIC once a day.
- Swallow the capsule whole with a full glass of water. Do not open, break or chew the capsule.
- INREBIC capsules can be taken either with or without food. Taking INREBIC with food may reduce nausea or vomiting.
- Follow the instructions provided and use INREBIC until your doctor tells you to stop.

## **If you forget to take INREBIC**

INREBIC should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you have taken too much INREBIC**

If you think that you have taken too much INREBIC, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using INREBIC?**

### **Things you should do**

- Keep all of your doctor's appointments so that your progress can be checked, including having blood tests.
- Remind any doctor, dentist or pharmacist you visit that you are using INREBIC.
- Tell your doctor if you are pregnant or attempting to become pregnant. Do not take INREBIC if you are pregnant or attempting to become pregnant.
- If you are able to become pregnant, use effective birth control during treatment with INREBIC and for at least 1 month after the last dose.

### **Call your doctor straight away if you:**

- get any of the following signs or symptoms before taking these capsules and during treatment:  
Confusion, memory loss, or difficulty thinking; loss of balance or difficulty walking; eye problems such as

random eye movement, double-vision, blurred vision and loss of vision.

## **Things you should not do**

- Do not stop using this medicine suddenly without talking to your doctor first.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how INREBIC affects you.**

INREBIC may cause dizziness in some people. Do not drive or operate machines if you experience dizziness after taking INREBIC.

## **Looking after your medicine**

- Store below 30°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Signs of a serious condition which affects the brain called encephalopathy (including Wernicke's encephalopathy):</b></p> <ul style="list-style-type: none"><li>• Confusion, memory loss or difficulty thinking</li><li>• Loss of balance or difficulty walking</li><li>• Eye problems such as double-vision, blurred vision, loss of vision or random eye movements.</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

## Other side effects

<b>Very common side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● Low levels of red blood cells which may cause tiredness, shortness of breath, pale skin or a fast heartbeat (anaemia).</li><li>● Reduction in blood platelets, which can make you bleed or bruise easily (thrombocytopenia).</li><li>● Nausea or vomiting</li><li>● Diarrhoea</li></ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>
<b>Common side effects</b>	
<ul style="list-style-type: none"><li>● Reduction in white blood cells (neutropenia), which can reduce your ability to fight off infections</li><li>● Headache</li><li>● Dizziness</li><li>● Indigestion</li><li>● Muscle spasms</li></ul>	

<b>Very common side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Pain in limbs, hands or feet</li> <li>● Weight gain</li> <li>● Tiredness or weakness</li> <li>● Changes in blood test results (alanine amino transferase increased, aspartate aminotransferase increased, increase in blood creatinine, increase in amylase and lipase levels, Vitamin B1). These may be signs of liver, kidney or pancreas problems.</li> <li>● Inflammation of the eye (uveitis, which causes pain and redness, vision problems or blurry vision)</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What INREBIC contains

<b>Active ingredient (main ingredient)</b>	Fedratinib (as dihydrochloride monohydrate)
<b>Other ingredients (inactive ingredients)</b>	silicified microcrystalline cellulose sodium stearyl fumarate Capsule shell: Gelatin, titanium dioxide, iron oxide red

Printing ink: OPACODE monogramming ink S-1-18086 White
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What INREBIC looks like**

INREBIC 100 mg capsule is reddish brown, size 0 opaque capsule, with "FEDR" on cap and "100 mg" on body in white ink (AUST R 433750).

Each bottle contains 120 capsules.

## **Who distributes INREBIC**

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: [MedInfo.Australia@bms.com](mailto:MedInfo.Australia@bms.com)

This leaflet was prepared in February 2025.

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