



## WHAT IS INREBIC® FEDRATINIB?

- A targeted therapy used to treat some blood cancers.
- Prescribed and renewed by your haematologist.
- Available from community pharmacies on presentation of your prescription.



- **100 mg** reddish-brown opaque capsule printed with “FEDR” on the cap and “100 mg” on the body in white ink



- Do not store above 25°C, and keep out of the sight and reach of children.





- Do not take the capsules out of the vial to put them in a pillbox.



- Wash your hands carefully before and after handling the capsules.

- Do not throw away opened vials, please return them to your pharmacist.

## HOW TO TAKE THIS MEDICINE

When?	.....:.....	<b>= 1 dose per day at a set time</b> <b>With or without a meal</b> <i>Taking this medicine with food can reduce nausea and vomiting.</i>
How?		Swallow the capsules whole, with water, at the same time every day. Do not chew, cut, crush or dissolve them. 

You can use your **medical diary\*** and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

*This leaflet is not a prescription, please refer to your most recent prescription.*

## IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- **If you forget to take your medicine**, do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary\*.
- **If you throw up**, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary\*.

## INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit, St. John's Wort, Seville orange, liquorice, milk thistle**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.









- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 1 month after the last dose**.
- Stop breastfeeding during treatment **and for 1 month after the last dose**.

\*Patient diary available (in French) at [www.omeditbretagne.fr](http://www.omeditbretagne.fr) or [www.omedit-paysdelaloire.fr](http://www.omedit-paysdelaloire.fr)

# WHAT SIDE EFFECTS CAN OCCUR WITH INREBIC® FEDRATINIB?

Like all medicines, fedratinib may cause side effects, although not everybody gets them.

Side effects	Prevention
 Headache, tiredness	Drink sufficient quantities (1.5 to 2 L water per day) and eat healthily, at regular intervals. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Rest during the day, while maintaining up to moderate levels of activity. Establish a sleep schedule; avoid going to bed and getting up late. Take care when driving.
 Digestive effects: constipation or diarrhoea, nausea, vomiting	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). <b>In case of constipation</b> , eat foods rich in fibre (bran, grains, wholemeal bread, green vegetables, fruit and nuts) and exercise regularly. <b>In case of diarrhoea</b> , eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). <b>In case of nausea/vomiting</b> , divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.
 Low red blood cells, white blood cells and platelets	<b>Low red blood cells</b> : contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches. <b>Low white blood cells</b> : contact your doctor in case of temperature > 38°C, chills, sweating, cough, shortness of breath/pain when breathing, a burning sensation when urinating, diarrhoea accompanied by fever or any other signs suggesting infection. <b>Low platelets</b> : contact your doctor in case of small red dots on your skin, bruising, nosebleeds, bleeding eyes or gums, or blood in your urine or faeces.
 Unusual bleeding	Use a soft toothbrush. Do not use rectal thermometers. Do not take aspirin, anti-inflammatories (e.g. ibuprofen), or herbal products (that can increase bleeding) without medical guidance: consult a healthcare professional. In case of bruising, apply cold (compress or ice pack) or a suitable cream/gel (e.g. arnica) if the skin is not broken.
 High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 5 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.
	<p>Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.</p> <p>You can also ask your <a href="#">Regional Pharmacovigilance Centre</a> and report any side effects online: <a href="#">signalement-sante-gouv-fr</a></p>



Remember to go for the lab tests prescribed by your doctor.

## WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

**Contact your doctor rapidly** in case of:

- Extreme tiredness, shortness of breath, paleness
- Signs of infection (fever, cough, chills, burning sensation when urinating, etc.)
- Bleeding
- Any persistent or worsening side effect



**Useful contacts:**

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**Note:**

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