

fedratinib

Pronunciation: fed RA ti nib
Other Name(s): Inrebic®

Appearance: reddish brown capsule

This handout gives general information about this cancer medication.

You will learn:

- who to contact for help
- · what the medication is
- how it is given
- what to expect while on medication



This handout was created by Ontario Health (Cancer Care Ontario) together with patients and their caregivers who have also gone through cancer treatment. It is meant to help support you through your cancer treatment and answer some of your questions.

This information does not replace the advice of your health care team. Always talk to your health care team about your treatment.

Who do I contact if I have questions or need help?			
My cancer health care provider is:			
During the day I should contact:			
Evenings, weekends and holidays:			

What is this treatment for?

For treating a type of blood cancer called myelofibrosis

What should I do before I start this treatment?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- kidney or liver problems,
- low thiamine (vitamin B1),
- a blood clot, stroke or heart problems, or
- any allergies

If you smoke or used to smoke, talk to your health care team. It may increase your risk of serious side effects.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the <u>Hepatitis B and Cancer Medications</u> pamphlet for more information.

How is this treatment given?

- This medication is usually taken once a day by mouth. Talk to your health care team about how and when to take your medication.
- Fedratinib may be taken with or without food. If you experience nausea or vomiting, taking fedratinib with food (especially a high-fat meal) in the evening may help.
- Swallow capsules whole. Do not open, break, or chew capsules.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of medication in your blood and increase side effects.
- If you forget to take a dose, skip this dose and take your next dose as scheduled. Do not take an extra dose (double up) to make up for the forgotten dose.
- If you vomit (throw up) after taking your medication, talk to your health care team about what to do.

Warning: If you take too much of this medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

Other medications you may be given with this treatment

To Prevent Low Thiamine (Vitamin B1) Levels

Low thiamine levels may lead to a rare but severe side effect on the brain. You will be given a medication called thiamine to help prevent low thiamine levels.

To Prevent or Treat Nausea and Vomiting

You may be given medications to prevent or stop nausea (feeling like throwing up) and vomiting (throwing up) before they start. These are called anti-nausea medications.

 Medications to prevent nausea and vomiting before they start include ondansetron (Zofran®), granisetron (Kytril®), or others.

If you already have nausea and/or vomiting, some anti-nausea medications can stop them from getting worse. You may be given these medications to have at home in case you start to feel nausea or if you vomit.

• Medications to stop nausea and vomiting include prochlorperazine (Stemetil®), metoclopramide (Maxeran®), or others.

To Treat Diarrhea

Fedratinib can cause diarrhea. Diarrhea is when you have loose bowel movements (watery poo) or you need to go poo (have bowel movements) more often than usual. Diarrhea may start a few days after your treatment.

You may be given a medication called loperamide (Imodium®) to help treat your diarrhea. Take this medication only if you need it. Keep your loperamide with you all the time. When diarrhea starts, take the loperamide right away.

Talk to your health care team if you haven't been given any instructions on how to manage diarrhea.

DO this while on treatment

- ✓ DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- ✓ DO talk to your health care team about your risk of getting other cancers and heart problems after this treatment.

DO NOT do this while on treatment



- X DO NOT use tobacco products (such as smoking cigarettes or vaping) or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- X DO NOT start any complementary or alternative therapies, such as acupuncture or homeopathic medications, without checking with your health care team.
- X DO NOT take any other medications, such as vitamins, over-the-counter (nonprescription) drugs, or natural health products without checking with your health care team.
- X DO NOT eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. These may increase the quantity of the medication in your blood and increase the side effects.

Will this treatment interact with other medications or natural health products?

Yes, this medication can interact with other medications, vitamins, foods and natural health products. Interactions can make this medication not work as well or cause severe side effects.

Tell your health care team about all of your:

- prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
- natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements

Check with your health care team before starting or stopping any of them.



Talk to your health care team BEFORE taking or using these :

- Anti-inflammatory medications such as ibuprofen (Advil[®] or Motrin[®]), naproxen (Aleve[®]) or Aspirin[®].
- Over-the-counter products such as dimenhydrinate (Gravol[®])
- Natural health products such as St. John's Wort
- Supplements such as vitamin C
- Grapefruit juice
- Alcoholic drinks
- Tobacco
- All other drugs, such as marijuana or cannabis (medical or recreational)

What to do if you feel unwell, have pain, a headache or a fever

- ✓ **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time

OR

• 38.0°C (100.4°F) or higher for at least one hour.



If you do have a fever:

- ✓ Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.
- ✓ Ask your health care team for the <u>Fever</u> pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

✓ Ask your health care team about the right medication for you. Acetaminophen (Tylenol®) is a safe choice for most people.



Talk to your health care team before you start taking ibuprofen (Advil[®], Motrin[®]), naproxen (Aleve[®]) or ASA (Aspirin[®]), as they may increase your chance of bleeding or interact with your cancer treatment.



Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

How will this treatment affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until at least **1 month** after your last dose. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication until at least 1 month after your last dose.

How to safely store and handle this medication

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.

How to safely touch oral anti-cancer medication

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills .

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.

What to do if anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

 Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this treatment?

The following table lists side effects that you may have when getting fedratinib. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on fedratinib.

Very Common Side Effects (50 or more out of 100 people)		
Side effects and what to do	When to contact health care team	
What to look for? Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. What to do?	Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day).	
If you have diarrhea:		
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol, until your diarrhea has stopped. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. Ask your health care team for the Diarrhea pamphlet for more information. 		

Very Common Side Effects (50 or more out of 100 people)		
Side effects and what to do	When to contact health care team	
 Nausea and vomiting What to look for? Nausea is feeling like you need to throw up. You may also feel lightheaded. You may feel nausea within hours to days after your treatment. What to do? 	Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe.	
 It is easier to prevent nausea than to treat it once it happens. If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (like coffee, tea) and avoid alcohol. If you have nausea or vomiting:		
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the Nausea & Vomiting pamphlet for more information. Talk to your health care team if: nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe 		

Common Side Effects (25 to 49 out of 100 people)		
Side effects and what to do	When to contact health care team	
Anemia (low red blood cells)	Talk to your	
(May be severe)	health care team if it does not	
What to look for?	improve or if it is severe.	
You may feel more tired or weaker than normal.		
Pale skin and cold hands and feet.		
You may feel short of breath, dizzy or lightheaded.		
 This may occur in days to weeks after your treatment starts. 		

Common Side Effects (25 to 49 out of 100 people)		
Side effects and what to do	When to contact health care team	
What to do?		
If your health care team has told you that you have anemia (low red blood cells):		
 Rest often and eat well. Light exercise, such as walking may help. You may need medication or a blood transfusion. 		
If it is very bad, your doctor may need to make changes to your treatment regimen.		

Less Common Side Effects (10 to 24 out of 100 people)		
Side effects and what to do	When to contact health care team	
 Fatigue What to look for? Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. 	Talk to your health care team if it does not improve or if it is severe.	
 What to do? Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Ask family or friends to help you with things like housework, shopping, and child or pet care. Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. Ask your health care team for the <u>Fatigue</u> pamphlet for more information.		

Less Common Side Effects (10 to 24 out of 100 people)			
Side effects and what to do	When to contact health care team		
Low neutrophils (white blood cells) in the blood (neutropenia)	If you have a fever,		
(May be severe)	try to contact your health care team. If you are unable to		
When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.	talk to the team for advice, you MUST get emergency medical help right away.		
What to look for?			
 If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol® (acetaminophen), or Advil® 			
 (ibuprofen)). Do not eat or drink anything hot or cold right before taking your temperature. 			
You have a fever if your temperature taken in your mouth (oral temperature) is:			
38.3°C (100.9°F) or higher at any time OR			
38.0°C (100.4°F) or higher for at least one hour.			
What to do?			
If your health care team has told you that you have low neutrophils:			
 Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 			
If you have a fever:			
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.			

Side effects and what to do	When to contact health care tear
Low platelets in the blood	Talk to your health
(Mary has a suggest)	care team if you
(May be severe)	have any signs of bleeding. If you
When your platelets are low, you are at risk for bleeding and bruising. Ask your	have bleeding that
health care team for the <u>Low Platelet Count</u> pamphlet for more information.	doesn't stop or is
	severe (very heavy), you MUS
What to look for?	get emergency
Watch for signs of bleeding:	help right away.
 bleeding from your gums 	
 unusual or heavy nosebleeds 	
 bruising easily or more than normal 	
 black coloured stools (poo) or blood in your stools (poo) 	
coughing up red or brown coloured mucus dizziness, constant boodcohe or changes in your vision.	
dizziness, constant headache or changes in your visionheavy vaginal bleeding	
NW 44 1 0	
What to do?	
If your health care team has told you that you have low platelets:	
Tell your pharmacist that your platelet count may be low before taking any	
prescriptions or over-the-counter medication.	
Check with your healthcare team before you go to the dentist. Take a read to a set to attribute the set of the set	
 Take care of your mouth and use a soft toothbrush. Try to prevent cuts and bruises. 	
 Ask your health care team what activities are safe for you. 	
Your treatment may have to be delayed if you have low platelets. Your	
health care team may recommend a blood transfusion.	
If you have signs of bleeding:	
If you have a small bleed, clean the area with soap and water or a saline	
(saltwater) rinse. Apply pressure for at least 10 minutes.	
If you have bleeding that does not stop or is severe (very heavy), you	

Less Common Side Effects (10 to 24 out of 100 people)			
Side effects and what to do	When to contact health care team		
Constipation What to look for? • Having bowel movements (going poo) less often than normal.	Talk to your health care team if it does not improve or if it is severe.		
 Small hard stools (poo) that look like pellets. The need to push hard and strain to have any stool (poo) come out. Stomach ache or cramps. A bloated belly, feeling of fullness, or discomfort. Leaking of watery stools (poo). Lots of gas or burping. Nausea or vomiting. 			
What to do?			
To help prevent constipation:			
 Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. 			
 Be active. Exercise can help to keep you regular. If you take opioid pain medication, ask your health care team if eating more fibre is right for you. 			
To help treat constipation:			
 If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. 			
Ask your health care team for the Constipation Pamphlet for more information.			
Kidney problems	Get emergency medical help right		
(May be severe)	away.		
Your health care team may check your kidney function regularly with a blood test. You may have blood in your urine.			
What to look for?			
Swelling in your hands, ankles, feet or other areas of your body.Weight gain that is not normal for you.			

Less Common Side Effects (10 to 24 out of 100 people)		
When to contact health care team		
Talk to your health care team if it		
does not improve or if it is severe.		
or in it is severe.		
Talk to your health care team if it		
does not improve or if it is severe.		
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Less Common Side Effects (10 to 24 out of 100 people)			
Side effects and what to do	When to contact health care team		
Higher than normal levels of pancreas enzymes in your blood (lipase, amylase) (May be severe) What to look for? • These changes usually do not cause any symptoms. • In some cases, you may feel pain in the centre of your belly that may spread to your back.	If you have any symptoms, get emergency medical help right away.		
 What to do? Your health care team may do blood tests to watch your levels of enzymes in the pancreas. If you have any symptoms, get emergency medical help right away. 			

Other rare, but serious side effects are possible with this treatment.

If you have **any** of the following, talk to your cancer health care team or get emergency medical help right away:

- irregular heartbeat, shortness of breath, chest pain or fainting spells,
- new or worsening cough, problems breathing, or coughing up blood,
- trouble seeing, speaking, or using your arms and legs,
- pain, swelling and hardening of a vein in the body,
- new swelling in your legs, ankles, feet or other areas of your body,
- drowsiness, confusion or problems with your memory,
- problems with your balance such as difficulty walking,
- eye problems such as seeing double or blurry eyesight, or eye movements that you cannot control.

For more information on how to manage your symptoms ask your health care provider, or visit: https://www.cancercareontario.ca/symptoms.

Notes			
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January 2025 Updated/revised information sheet

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.