MF

Your guide to Jakavi® (ruxolitinib)

Information about your treatment

This booklet is not intended to replace the patient information leaflet or guidance from your healthcare team. For the full information on your treatment please refer to the patient information leaflet.
This booklet is intended for patients with myelofibrosis who have been prescribed Jakavi® (ruxolitinib).
This booklet has been funded and developed by Novartis Pharmaceuticals UK Ltd.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

JAKAVI® ruxolitinib

306221 | November 2023

Welcome to your Jakavi® essential guide

Starting an unfamiliar treatment can be a bit daunting and you've probably got lots of questions, so this guide has been developed to support you throughout your treatment journey.

Within it, you can learn more about your condition, how Jakavi® (ruxolitinib) works and how it can help you and the different support networks available.

What is MF?

‘my-eh-lo-fy-bro-sis’

Myelofibrosis, or MF, is a rare blood cancer that 2–3 people per 100,000 are diagnosed with every year. It is classified as a myeloproliferative neoplasm (MPN). MPNs are conditions that cause an increase in the amount of blood cells. In MF, in particular, the bone marrow (myelo) develops scar tissue (fibrosis).

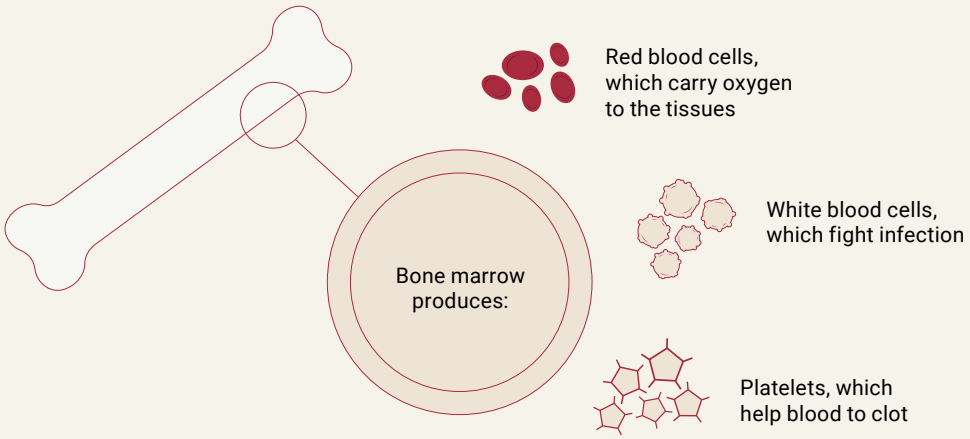
A cancer diagnosis can be frightening, and you may be feeling anxious. But try to remember, every case of MF is different and how each person’s body responds to treatment will vary. Your doctor will always give you advice and provide you with the most suitable treatment for you.

What causes MF?

The exact causes of MF are unknown, but researchers have discovered that many patients have a genetic mutation for a protein called JAK2 – short for Janus kinase 2. A genetic mutation for another protein known as JAK1 – or Janus kinase 1 – has also been associated with MF.

The JAK1 and JAK2 proteins help regulate blood cell production. If JAK1 or JAK2 become overactive, our bone marrow – the soft tissue inside our bones – can start to produce too many abnormal blood cells that can’t function properly. During this process, the bone marrow also builds up scar tissue.

Blood cells made by the bone marrow:



Why does MF develop?

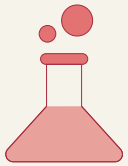
You are not born with the genetic changes that cause MF; they happen over your lifetime. This means it is unlikely for it to be passed to your children or to have been inherited from your parents. However, some families do seem to get MF more frequently than others.

There are other factors that can increase your risk of developing MF, including:

Age:
While people of any age can have MF, it’s usually diagnosed in those over the age of 50

Another blood disorder:
Some people with MF develop it from another condition, such as essential thrombocythaemia (ET) or polycythaemia vera (PV)

Exposure to radiation:
People who’ve been exposed to radioactive material may have an increased risk of developing MF



Exposure to chemicals:
MF has been associated with exposure to certain industrial chemicals, including toluene and benzene

Understanding your symptoms

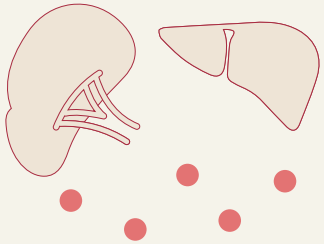
MF develops slowly and in its very early stages it can be difficult to notice any symptoms. Some people are diagnosed early from abnormal blood test results. As the condition progresses, symptoms tend to become more noticeable.

Common MF symptoms include:

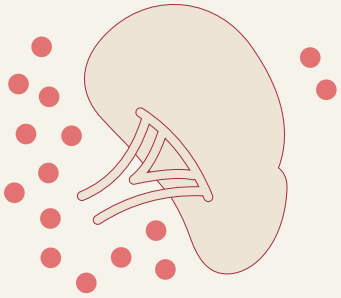
- Abdominal discomfort
- Bone pain
- Itching (pruritus)
- Concentration problems
- Inactivity
- General fatigue
- Night sweats
- Fever
- Weight loss
- Filling up quickly when you eat (early satiety)

How does MF cause symptoms?

When MF causes problems with blood cell production in your bone marrow, your spleen and liver try to make up for the lack of healthy blood cells. Unfortunately, they are not as good at producing blood cells as your bone marrow was. Overall, this can lead to anaemia (low red blood cell count), thrombocytopenia (low platelet count), neutropenia (low white blood cell count) and your spleen and liver may become enlarged. An enlarged spleen can cause symptoms such as abdominal discomfort and early satiety resulting in weight loss.



Your spleen and liver are able to make a small amount of red blood cells

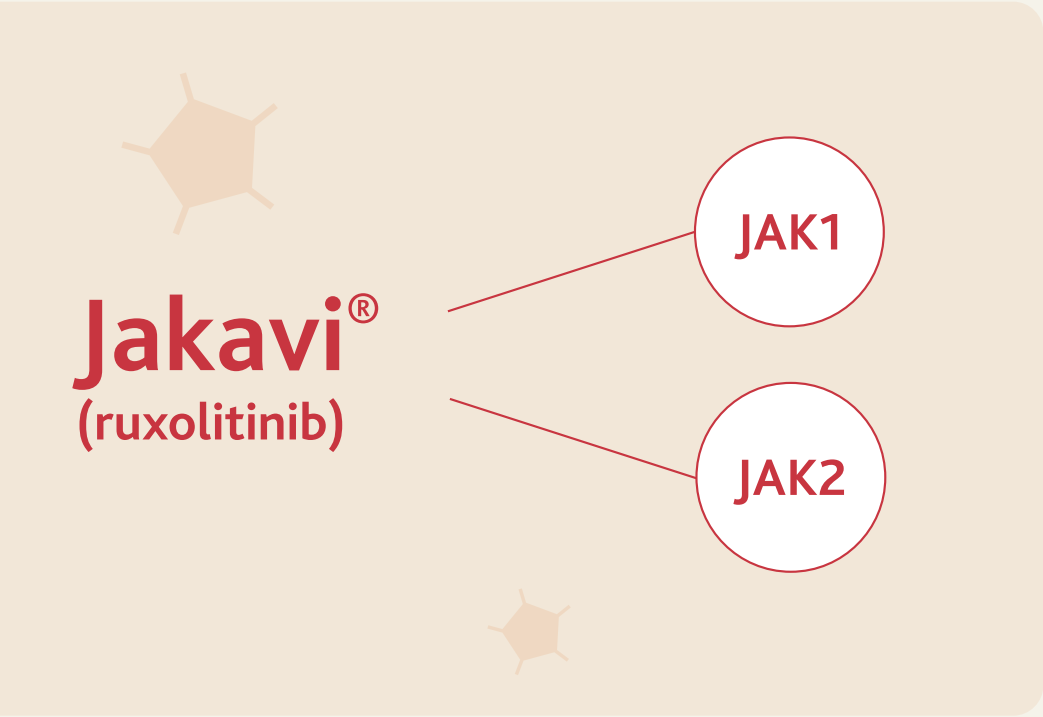


The spleen tries to compensate for the bone marrow not working correctly by producing more red blood cells than it usually would. As it tries to keep up, it can become enlarged

What is Jakavi® (ruxolitinib) and how does it work?

Your doctor has prescribed you Jakavi®, also called ruxolitinib. Ruxolitinib is a medicine used to treat some MPNs including MF.

Ruxolitinib is an inhibitor which blocks the activity of the JAK1 and JAK2 proteins. As these proteins are overactive in MF, reducing their activity helps regulate blood cell production and reduce the number of abnormal blood cells.



By blocking the action of JAK1 and JAK2, ruxolitinib can help reduce the size of the spleen in patients with myelofibrosis and relieve symptoms such as:

Fever | Night sweats | Bone pain | Weight loss

Tracking your treatment

Medications affect people differently, which is why it's important for your doctor to be aware of how you're feeling while you're taking ruxolitinib.

If you notice that your symptoms are improving or getting worse, or if you're feeling more and more unwell, it's important to let your doctor or another member of your healthcare team know. You don't have to suffer with your symptoms in silence.

You can track your symptoms with the MPN tracker website to help you and your doctor record your progress and get the most from your treatment.

Scan the QR code to access the website:

This website has been sponsored and developed by Novartis Pharmaceuticals UK Ltd to support people living with MPNs.

What to expect from treatment with Jakavi® (ruxolitinib)

Remember to take your treatment journey day-by-day and stay on top of your medication. You may start seeing improvements within the first month of treatment but don't be discouraged if it takes longer.

If you have not seen any improvements after around 6 months of ruxolitinib treatment, your doctor may discontinue therapy.

Do not take ruxolitinib:

- If you are allergic to ruxolitinib or any of the other ingredients of this medicine
- If you are pregnant or breastfeeding

If either of the above applies to you, tell your doctor who will then decide whether you should start treatment with ruxolitinib.

Warnings and precautions

Talk to your doctor or pharmacist before taking ruxolitinib:

- If you have any infections. It may be necessary to treat your infection before starting ruxolitinib. It is important that you tell your doctor if you have ever had tuberculosis or if you have been in close contact with someone who has or has had tuberculosis. Your doctor may perform tests to see if you have tuberculosis or any other infections. It is important that you tell your doctor if you have ever had hepatitis B
- If you have any kidney problems. Your doctor may need to prescribe a different dose of ruxolitinib
- If you have or have ever had any liver problems. Your doctor may need to prescribe a different dose of ruxolitinib
- If you are taking other medicines
- If you have ever had tuberculosis
- If you have ever had skin cancer

Talk to your doctor or pharmacist during your treatment with ruxolitinib:

- If you experience unexpected bruising and/or bleeding, unusual tiredness, shortness of breath during exercise or at rest, unusually pale skin or frequent infections (these are signs of blood disorders)
- If you experience fever, chills or other symptoms of infections
- If you experience chronic coughing with blood-tinged sputum, fever, night sweats and weight loss (these can be signs of tuberculosis)
- If you have any of the following or if anyone close to you notices you have: confusion or difficulty thinking, loss of balance or difficulty walking, clumsiness, difficulty speaking, decreased strength or weakness on one side of your body, blurred and/or loss of vision. These may be signs of a serious brain infection and your doctor may suggest further testing and follow-up
- If you develop a painful skin rash with blisters (this is a sign of shingles)
- If you notice skin changes. These may require further observation as certain types of skin cancer (non-melanoma) have been reported

Please see the patient information leaflet for further information.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may increase the risk of side effects with ruxolitinib.

Your doctor may need to adjust your ruxolitinib dose if you take any of the following medicines:

- Ketoconazole, itraconazole, posaconazole, fluconazole and voriconazole (used to treat fungal disease)
- Clarithromycin, telithromycin, ciprofloxacin, or erythromycin (antibiotics used to treat bacterial infections)
- Amprenavir, atazanavir, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir, saquinavir (used to treat viral infections, including HIV/AIDS)
- Boceprevir or telaprevir (used to treat hepatitis C)
- Nefazodone (used to treat depression)
- Mibefradil or diltiazem (used to treat hypertension and chronic angina pectoris)
- Cimetidine (used to treat heartburn)

It is very important to tell your doctor if you take any of the medicines in this list.

Some medicines may reduce the effectiveness of ruxolitinib:

- Avasimibe, a medicine to treat heart disease
- Phenytoin, carbamazepine or phenobarbital and other anti-epileptics used to stop seizures or fits
- Rifabutin or rifampicin, medicines used to treat tuberculosis (TB)
- St. John's wort (Hypericum perforatum), a herbal product used to treat depression

While you are taking ruxolitinib you should never start a new medicine without checking first with the doctor who prescribed ruxolitinib. This includes prescription medicines, non-prescription medicines and herbal or alternative medicines.

Please see the patient information leaflet for further information.

Pregnancy and breastfeeding

Do not take ruxolitinib during pregnancy. Talk to your doctor about how to take appropriate measures to avoid becoming pregnant during your treatment with ruxolitinib.

Do not breastfeed while taking ruxolitinib. Tell your doctor if you are breastfeeding.

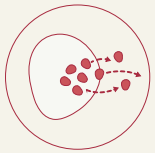
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Some side effects could be serious

Seek medical help **immediately** if you experience any of the following side effects.

Very common (may affect more than 1 in 10 people):

Any sign of bleeding in the stomach or intestine, such as passing black or bloodstained stools, or vomiting blood



Unexpected bruising and/or bleeding, unusual tiredness, shortness of breath during exercise or at rest, unusually pale skin, or frequent infections (possible symptoms of blood disorders)

Painful skin rash with blisters (possible symptoms of shingles (herpes zoster))

Fever, chills or other symptoms of infections

Low level of red blood cells (anaemia), low level of white blood cells (neutropenia) or low level of platelets (thrombocytopenia)

Common (may affect up to 1 in 10 people):

Any sign of bleeding in the brain, such as sudden altered level of consciousness, persistent headache, numbness, tingling, weakness or paralysis

Other side effects with ruxolitinib

If you experience any of the side effects listed below, talk to your doctor or pharmacist.

Very common (may affect more than 1 in 10 people):

- High level of cholesterol or fat in the blood (hypertriglyceridaemia)
- Abnormal liver function test results
- Dizziness
- Headache
- Urinary tract infections
- Weight gain
- Fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia)
- High blood pressure (hypertension), which may also be the cause of dizziness and headaches
- Constipation
- High level of lipase in the blood

Common (may affect up to 1 in 10 people):

- Reduced number of all three types of blood cells – red blood cells, white blood cells, and platelets (pancytopenia)
- Frequently passing wind (flatulence)

Uncommon (may affect up to 1 in 100 people):

- Tuberculosis
- Recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick)

How to take your medication

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose of ruxolitinib depends on the patient's blood cell count. Your doctor will measure the amount of blood cells in your body and find the best dose for you, particularly if you have liver or kidney problems.

- The recommended starting dose in myelofibrosis is 5 mg twice daily, 10 mg twice daily, 15 mg twice daily or 20 mg twice daily, depending on your blood cell count.

Your doctor will always tell you exactly how many ruxolitinib tablets to take.

Ruxolitinib tablets come in the following doses:

5 mg round tablet with 'L5' on one side and 'NVR' on the other

10 mg round tablet with 'L10' on one side and 'NVR' on the other

15 mg oval tablet with 'L15' on one side and 'NVR' on the other

20 mg elongated tablet with 'L20' on one side and 'NVR' on the other

Illustrations not actual size.

Dosing with ruxolitinib

During the treatment your doctor may recommend a lower or higher dose to you if the results of blood tests show that this is necessary, if you have problems with your liver or kidneys, or if you also need treatment with certain other medicines.

If you receive dialysis, take either one single dose or two separate doses of ruxolitinib only on dialysis days, after the dialysis has been completed. Your doctor will tell you if you should take one or two doses and how many tablets to take for each dose.

You should take ruxolitinib every day at the same time, either with or without food.

You should continue taking ruxolitinib for as long as your doctor tells you to. This is a long-term treatment.

Your doctor will regularly monitor your condition to make sure that the treatment is having the desired effect.

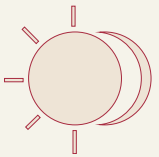
If you have questions about how long to take ruxolitinib, talk to your doctor or pharmacist.

If you experience certain side effects (e.g. blood disorders), your doctor might need to change the amount of ruxolitinib you have to take or tell you to stop taking ruxolitinib for a while.

Making your medication part of your day

To take ruxolitinib twice a day, you could:

Take it every morning with breakfast and every evening at dinner.



Take it when you get up in the morning and go to bed at night.

Use your phone to set yourself a reminder.

If you miss a dose…	If you miss several doses…	If you take more than you should…
Take your dose at the next usual time – do not take a double dose to make up for the missed one.	Contact your doctor or pharmacist so they can get you back on track.	Contact your doctor or pharmacist immediately.

You should not stop taking ruxolitinib or change the dose without discussing it with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Resources and support

Patient support networks

Although MF is a rare disease, you are not alone. There are numerous resources and many patient networks that can give you extra support. Many of them will have local groups that you can join.

Here are a few that you can contact if you'd like to learn more about MF and ruxolitinib:

Blood Cancer UK's vision is to beat blood cancer by funding research and supporting those affected. They provide support and information for people living with any kind of blood cancer.

Find out more about Blood Cancer UK
www.bloodcancer.org.uk

Leukaemia Care is dedicated to ensuring that everyone affected by blood cancer receives the best possible diagnosis, information, advice, treatment and support. They provide information, advice and support to improve the lives of people affected by leukaemia, MDS and MPN.

Find out more about Leukaemia Care
www.leukaemiacare.org.uk

Macmillan Cancer Support helps patients navigate the emotional, practical, physical and financial impact cancer can have on their lives. They help guide patients through every stage of their cancer journey and do whatever it takes to support people living with cancer. They also host an online community so that patients can talk to other people going through a similar experience.

Find out more about Macmillan Cancer Support
www.macmillan.org.uk

MPN Voice provides clear and accurate information and emotional support to anyone living with an MPN, as well as their friends and families. They offer patient forums and peer-to-peer support so that patients know they are not alone and can talk to someone else living with an MPN.

Find out more about MPN Voice
www.mpnvoice.org.uk

MPN Tracker website

The MPN Tracker website helps you monitor how you are feeling, your symptoms and your treatment plan. Recording your MF experience will help your doctor understand your condition and help you get the most out of your treatment.

Scan the QR code to access the website:

This website has been sponsored and developed by Novartis Pharmaceuticals UK Ltd to support people living with MPNs.

Abbreviations

AIDS, acquired immunodeficiency syndrome; ET, essential thrombocythaemia; HIV, human immunodeficiency virus; JAK, janus kinase; MDS, myelodysplastic syndromes; MF, myelofibrosis; MPN, myeloproliferative neoplasm; PV, polycythaemia vera; QR, quick response; TB, tuberculosis.

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