PV

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 eligible patients with polycythaemia vera 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

414252 | March 2024

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, how it can help you and the different support networks available.

What is PV?

‘polly-sigh-thee-me-ah’ ‘veer-uh’

Polycythaemia vera (PV) is a blood cancer with a prevalence (estimated number of people in a population with a diagnosis of the disease) of 22 per 100,000 people. It is classified as a “myeloproliferative neoplasm” (MPN). MPNs are conditions that cause an increase in the amount of blood cells.

PV is a chronic disease primarily characterised by an increased number of red blood cells. Patients may also have an increased number of white blood cells and platelets.

A cancer diagnosis can be frightening, and you may be feeling anxious. But try to remember, every case of PV 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.

Unless it’s properly treated and controlled, the overproduction of blood cells in PV can lead to a higher risk of developing serious health problems, including thrombosis (blood clots). PV affects people differently, but symptoms can include tiredness (fatigue), itching (pruritus), night sweats and bone pain.

In PV, you may also have an enlarged spleen, which can cause abdominal discomfort and a feeling of fullness, which can result in weight loss.

See page 6 for more on understanding your symptoms.

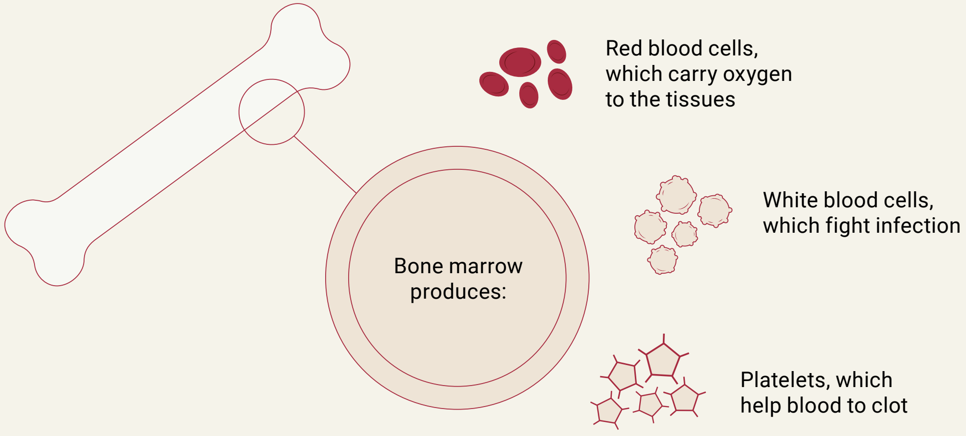
What causes PV?

The cause of PV is unknown. However, researchers have discovered that 95% of patients with the disorder have a mutation of a protein that is involved in blood cell production in the bone marrow.

This protein is known as JAK2 – short for Janus kinase 2.

You are not born with the genetic changes, they happen over your lifetime. It is also important to note that PV is not usually passed on from parent to child, although some families do seem to develop PV more frequently than others.

Blood cells made by the bone marrow:



Understanding your symptoms

PV symptoms vary from person to person, and can range in severity and frequency.

Common PV symptoms include:

- Fatigue
- Feeling full after a small amount of food
- Itching
- Bone pain
- Abdominal discomfort
- Inactivity
- Fever
- Weight loss
- Concentration problems
- Night sweats

What is the goal of treating PV?

The goal of PV treatment is to reduce the risk of cardiovascular complications, manage symptoms and to minimise the chances of the disease progressing to myelofibrosis or acute myeloid leukaemia.

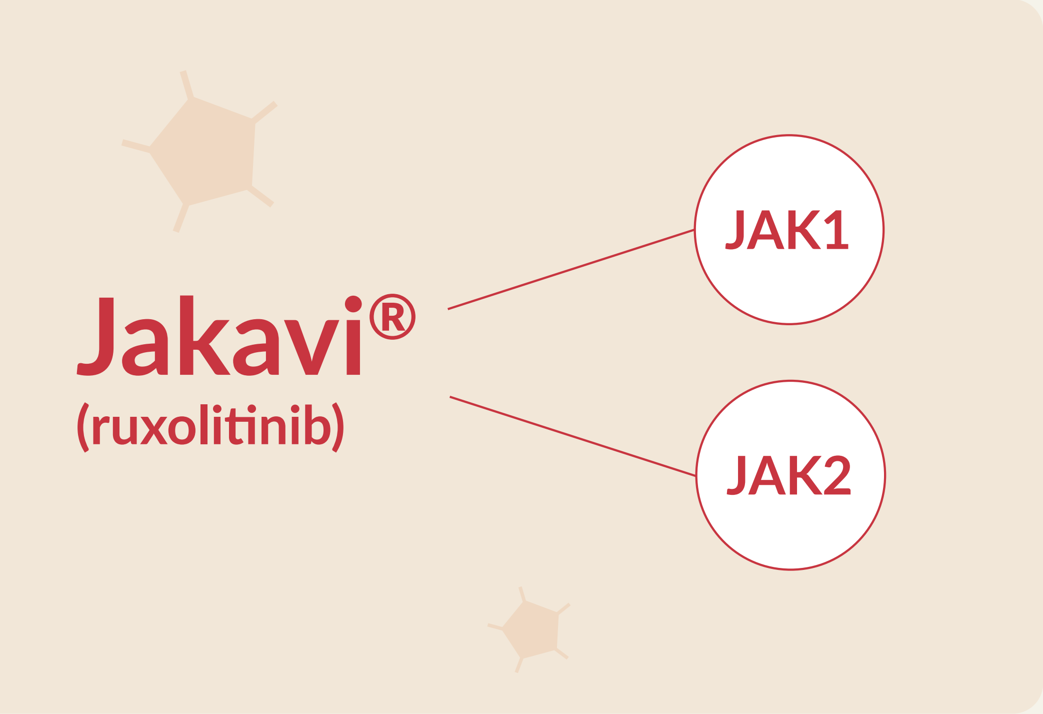
To determine whether your PV is being managed by your treatment, your haematologists will consider:

- **Red blood cell count**
- **Platelet count**
- **White blood cell count**
- **Spleen size**
- **Disease-related symptoms**

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 eligible patients with PV.

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



By blocking the action of JAK1 and JAK2, ruxolitinib can help treat PV by reducing:

- Spleen size
- Symptoms
- Volume of blood cells

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.

What you need to know before you take ruxolitinib:

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Do not take ruxolitinib:

- If you are allergic to ruxolitinib or any of the other ingredients of this medicine (these can found in section 6 of the patient information leaflet)
- 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 (refer to pages 12 and 13)
- 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

Not an exhaustive list of what you need to know before taking ruxolitinib. Please see the patient information leaflet for the full guidance.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to adjust the ruxolitinib dose if you take any of the following medicines.

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

- Medicines to treat fungal infections such as ketoconazole, itraconazole, posaconazole, fluconazole and voriconazole
- Antibiotics to treat bacterial infections such as clarithromycin, telithromycin, ciprofloxacin and erythromycin
- Medicines to treat viral infections, including HIV/AIDS, such as amprenavir, atazanavir, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir and saquinavir
- Medicines used to treat hepatitis C (boceprevir, telaprevir)
- Nefazodone, a medicine to treat depression
- Mibefradil or diltiazem, medicines to treat hypertension and chronic angina pectoris
- Cimetidine, a medicine 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:

- Medicine used to treat heart disease (avasimibe)
- Anti-epileptics used to stop seizures or fits such as phenytoin, carbamazepine and phenobarbital
- Medicines used to treat tuberculosis such as rifabutin and rifampicin
- 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.

Possible side effects

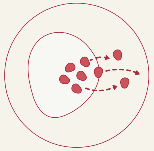
Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the side effects of ruxolitinib are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Some side effects could be serious

Seek medical help immediately prior to the next scheduled dose if you experience any of the following side effects.

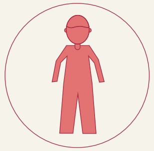
Very common (may affect more than 1 in 10 people):

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 recommended starting dose for PV is 10 mg twice daily

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 stop taking ruxolitinib...**	**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.

How to store ruxolitinib:

Do not use this medicine after the expiry date which is stated on the carton or blister after “EXP”. Do not store above 30°C.

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 PV 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 PV 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

These are non-Novartis websites and Novartis are not responsible for the content of the websites.

MPN Tracker website

The MPN Tracker website helps you monitor how you are feeling, your symptoms and your treatment plan. Recording your PV 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; HIV, human immunodeficiency virus; JAK, janus kinase; MDS, myelodysplastic syndromes; MPN, myeloproliferative neoplasm; PV, polycythaemia vera; QR, quick response.

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414252 | March 2024