

Your guide to

Ruxolitinib (Jakavi®)

Information and advice



MPN voice



Supporting patients and families affected by MPN

Established by a group of MPN patients over 10 years ago, MPN Voice, registered under the auspices of Guy's and St Thomas' Charity, has a website with a lively online community and up to date information on essential thrombocythaemia (ET), polycythemia vera (PV), and myelofibrosis (MF).

Backed by leading healthcare professionals, MPN Voice also publishes a newsletter, MPN disease leaflets and drug leaflets, runs regular regional patient forums, funds MPN research and offers a buddy scheme.

For more information visit the website www.mpnvoice.org.uk

Email info@mpnvoice.org.uk

MPN Voice previously known as MPD Voice



Name: _____
I have the following MPD: _____
Medication: _____
Hospital contact number is: _____



What is this leaflet about?

This leaflet is for people with myeloproliferative neoplasms (MPNs), also known as myeloproliferative disorders, (MPDs).

It offers information about the medicine ruxolitinib or Jakavi®.

In this leaflet you will learn:

- How ruxolitinib works
- The benefits and drawbacks of taking ruxolitinib
- How to take and store ruxolitinib
- Answers to frequently asked questions
- How to feel your best while taking ruxolitinib

The leaflet provides information that can aid your decision about taking ruxolitinib, and is a reference for people already taking this medication. It is important that in addition to reading this leaflet you also read the information provided with your medicine.

What is ruxolitinib?

Ruxolitinib is a medication used to treat myeloproliferative neoplasms (MPNs). It is licensed for the treatment of patients with myelofibrosis (MF) either primary or occurring after polycythaemia vera (PV) or essential thrombocythaemia (ET). It is under investigation in clinical trials for patients with PV and ET.

The drug is known by several names. It goes under the brand name Jakavi® and the molecule is called ruxolitinib. Before this it was known as INC18424 or INC424.

If you need more information about JAK2 mutation or the types of MPN or myelofibrosis you can learn more on our website at www.mprnvoice.org.uk

Ruxolitinib comes as a capsule and is taken by mouth. Ruxolitinib is currently available in 5mg, 15mg or 20mg white capsules.

How does ruxolitinib work?

Blood cells originate from stem cells. Stem cells are master cells which divide and mature into the different types of blood cells: red blood cells, white blood cells and platelets. The marrow in our bones acts as a factory for the division and maturation of these stem cells into blood cells. Each new blood cell contains DNA which carries all the instructions the cell needs to grow and function. Once the blood cells have matured they leave the bone marrow and enter our blood stream. In MPNs the processes involved in controlling blood cell production are disordered and for most patients this is thought to be due to over activation of JAK2 a protein found in most cells. For about 75% of patients with MPN this over activation is due to a mutation or change in the genetic sequence of JAK known as JAK2V617F.

Ruxolitinib works by interfering with the function of JAK2 and its relation JAK1. This slows down blood cell production and also the production of signalling chemicals known as cytokines.

When you take ruxolitinib the number of blood cells being made decreases so that your bloodstream will be less crowded, your blood will flow more freely, and you will be less likely to suffer a blood clot or thrombosis. Treatment with ruxolitinib also reduces the size of most patients' spleens towards a more normal size. In addition many of the symptoms, for example sweating, itching, tiredness and pain and fullness after eating which with MF and other MPN patients suffer, improve with ruxolitinib therapy.

You may be asked to sign a consent to treatment form before you start taking ruxolitinib.

Are there any drawbacks?

As with all medications you may experience side effects whilst taking ruxolitinib. These are listed in the side effects section below.

You will need frequent blood tests and monitoring whilst taking ruxolitinib to ensure that the dose is correct for you.

A small number of people develop a resistance to ruxolitinib, (so that it no longer works) over a period of years, requiring a switch to another treatment.

Are there any side effects?

Most people taking this drug tolerate it well and have few side effects. However, it is important that you inform your doctor or nurse if you are experiencing any of the side effects listed below or any develop any new symptoms, even if mild.

Common side effects

Approximately one person in 100 up to one person in five (1-20%) of people taking ruxolitinib will experience some of these common side effects:

- *Reduced red blood cells* If your red blood cells drop too low (anaemia) you may notice that you are becoming breathless and tire easily.
- *Reduced platelets* If your platelet count drops too low you may experience nose bleeds, bleeding gums when you clean your teeth, a rash of tiny red spots or increased bruising.
- *Reduced white blood cells* If your white blood cells drop too low you may have an increased risk of developing infections. You may experience a high temperature, fever, shivers or chills.

If you experience any of the symptoms above you must contact your hospital immediately. Sudden and unexpected changes in blood cell levels may occur, although this is uncommon. Therefore it is important to attend appointments to have your blood counts checked and to discuss any symptoms with your haematologist.

Other common side effects

- painful skin rash with blisters (possible symptoms of shingles (*herpes zoster*))
- high level of cholesterol
- abnormal liver function test results
- dizziness
- headache
- weight gain
- frequently passing wind (*flatulence*)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed here.

Ruxolitinib and infections

Ruxolitinib treatment has been shown to be associated with increased risk of infections varying from simple chest and urine infections to reactivation or occurrence of more serious infections such as shingles, hepatitis, TB and rare infections including a disease called Progressive Multifocal Leucoencephalopathy.

Taking ruxolitinib

How to take ruxolitinib

- Take either before or after food, usually twice daily.
- Wash your hands thoroughly before and after taking the tablets.
- Swallow whole with plenty of water.

Dosage

Your doctor, nurse or pharmacist will give dosage instructions. He or she may recommend that you take the medication every day, on alternate days of the week or that you vary the amount by day. Please be sure to follow the directions precisely.

Keeping track

It may be helpful to keep a record to remember when to take your tablets and to record any side effects. You may be given a diary or booklet for this purpose.

Storage and disposal of Ruxolitinib

- Store in a dry place at room temperature and definitely less than 30°C
- Ruxolitinib can be dangerous to others. Keep your capsules in a secure location, well out of the reach of children and pets
- Return any unused medication to your local pharmacy or hospital.
- Do not dispose of them in the bin or flush them down the toilet.

What should I expect?

How fast does it work?

Ruxolitinib may take several weeks to begin having an effect on your cells, but often its effects on spleen and symptoms occur in 2-4 weeks. Your blood cell counts may not stabilise for up to 16 weeks.

How will I feel?

You will hopefully notice a reduction in your MPN-related symptoms. It may help to keep track of these so you can monitor how you are feeling. Most people taking this drug tolerate it well and have relatively few side effects.

Will I need follow up?

You will need more frequent blood tests during the first weeks of treatment to determine how your body is responding to the medication. Once your body has adjusted to the medication you will attend for checks less frequently, perhaps every two to three months. Your kidney and liver function may also be checked with blood tests.

Important tips for taking ruxolitinib

Ruxolitinib works fast to reduce spleen and symptoms but these benefits are rapidly lost when the medication is stopped. This relapse of symptoms and spleen size can occur rapidly and can make patients very ill.

For this reason it is important not to stop this medication suddenly and generally your medical team will slowly reduce the dose before stopping this drug.

Can I take other medicines?

Whenever you take ruxolitinib (or in fact any medication), it is important to inform your medical advisors about all other medications you are taking: this includes medicines prescribed for you as well as any vitamins, herbal supplements or remedies bought in chemists. Always provide the names of these medications and remedies to the hospital doctors, GPs, nurses and pharmacists who are treating you, prescribing additional medications or giving you advice. It can be very helpful to carry a list of the names and dosages of all your medicines to show to your doctor or nurse at appointments.

Some medicines may interact with ruxolitinib because the drug is broken down by an enzyme called CYP3A4. These include:

- Medicines used to treat fungal diseases (such as ketoconazole, itraconazole, posaconazole, fluconazole and voriconazole).
- Medicines used to treat certain types of bacterial infections (antibiotics such as clarithromycin, telithromycin, ciprofloxacin, or erythromycin).
- Medicines to treat HIV infection/AIDS (such as apranavir, atazanavir, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir, saquinavir).
- Medicines 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.
- FOOD such as grapefruit and Seville oranges (note these are used in making marmalade).

The following 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

What if I have other medical conditions?

Ruxolitinib should be used under supervision if you have now or have had any of the following conditions:

- Allergies to any of the ingredients in the medicine (these will be listed on the information leaflet that came with your tablets)
- HIV infection or AIDS
- Previous infections such as TB (tuberculosis) or hepatitis B
- Kidney problems
- If you are planning pregnancy
- If you have radiation therapy planned

If you think you may have or have had one of these conditions please discuss this with your doctor.

Frequently asked questions

Can I eat and drink normally?

Yes. We recommend that you eat a normal, healthy diet and drink plenty of water.

Can I drink alcohol?

While it is safe to drink alcohol in moderation whilst taking ruxolitinib, we recommend you do not exceed the recommended weekly limits of 21 units of alcohol per week for a man and 14 units for a woman. Alcohol can cause dehydration, and it is important to avoid becoming dehydrated if you have an MPN. Please ask your nurse or doctor if you require more information regarding alcohol consumption.

What if I want to have a child?

- We strongly recommend that you use contraception whilst taking ruxolitinib, because this medication can be harmful to a developing foetus.
- When planning to conceive or to father a child, you should stop taking Ruxolitinib AFTER discussion with your doctor.

- It is imperative to discuss your plans together with your haematologist prior to becoming pregnant or fathering a child. Your doctor can recommend treatment options for you that will not cause harm to your developing baby and will increase your chance of a successful pregnancy.
- If you or your partner becomes pregnant while taking this drug please contact your doctor immediately for further advice.

Can I breastfeed while taking ruxolitinib?

Breastfeeding while taking ruxolitinib is not recommended.

Who will prescribe ruxolitinib for me?

Your doctor, specially trained nurse or hospital pharmacist will prescribe your medication.

Can I drive?

There is no evidence that taking ruxolitinib would stop you from driving.

Do I need to take any special precautions?

It is important not to stop taking ruxolitinib suddenly as this can cause a withdrawal type syndrome which consists of a return of symptoms and growth of your spleen which may be very sudden and have sometimes made patients very unwell.

Can I have vaccinations such as the flu jab while taking ruxolitinib?

Yes, you can have most vaccinations including the flu vaccine whilst taking ruxolitinib. Some vaccinations are live vaccines and these should not be taken with ruxolitinib. It is important you tell the person giving you the vaccine that you are taking ruxolitinib so they can verify it is safe for you to be vaccinated.

What to do if...

You have taken too much medicine/someone else has taken your medicine

If you have taken extra tablets or if another person has taken your medication please contact your nurse or doctor as soon as possible.

You were sick shortly after taking your tablets

If this happens just once, take your next dose as usual. If you are sick over a number of days contact your doctor.

You forget to take a dose

If you have forgotten to take a dose, do not take any extra but take your next dose as normal. If you have forgotten to take a few doses, start taking them again and contact your doctor.

You need to have a medical procedure or operation

You may occasionally be required to adjust or stop your ruxolitinib if you need an operation. It is important that you inform the doctor or dentist planning the procedure or operation that you are taking ruxolitinib and that they coordinate your treatment with your haematology doctor or nurse. We always recommend that you inform your haematology doctor or nurse if you have any procedures or operations planned. It is very important not to STOP taking ruxolitinib without a discussion with your haematology team.

You feel anxious about taking ruxolitinib

If you have concerns, please discuss this with your doctor or nurse. You can also visit the Living with MPN section of our website www.mpnvoice.org.uk

If you do not want to take this medication

Whether or not to take ruxolitinib is entirely your decision. If after talking things over with your haematologist you still feel uncertain or prefer not to take this medication, you can choose not to take it.

Keep your doctor or nurse in the loop

If you decide not to take ruxolitinib or if you want to stop after you begin treatment, it is important to inform your doctor or nurse of your decision. He or she can recommend alternatives or other suggestions if necessary to safeguard your health. It is important not to stop taking ruxolitinib suddenly as this can cause a withdrawal type syndrome which consists of a return of symptoms and growth of your spleen which may be very sudden and have sometimes made patients very unwell.

Is there an alternative?

There are other treatment alternatives available and you can discuss additional options with your haematologist. If you wish to read up about them, please visit our website at www.mpnvoice.org.uk and click on “Treatments”.

Consent

Your doctor will generally ask you to sign a consent form when you begin treatment. This confirms that you know why ruxolitinib has been recommended for you, and that you understand the risks and benefits of this treatment.

How to help yourself

If you have an MPN it's important to take good care of yourself. There are many things you can do to feel better.

- Good nutrition is important. Eat a balanced diet including lots of fresh fruit and vegetables, lean protein and whole grains. Drink plenty of water and be careful to prevent dehydration by avoiding excessive alcohol and caffeinated drinks.
- Maintain a normal weight and maintain your muscle mass to help keep your cholesterol and blood sugar within normal limits. This is important if you are taking a drug like ruxolitinib which can cause weight gain!
- Exercise is very beneficial for all MPN patients and helps fight fatigue. Be sure to check with your GP and haematologist before launching on any new programme and start slowly and gently if you have not exercised before.
- Stop smoking. Ask your GP if you need help.

Making the adjustment

It can be disconcerting to start a new medication or find you must increase your dosage. You may feel that your MPN is getting worse or that you are at greater risk of serious medical problems. You may also feel concerned about the long and short term risks of taking this medication. It is normal to feel this way and many people with MPNs have had similar experiences. You may want to discuss your concerns with a family member or friend. MPN Voice also offers a "buddy" programme for interested patients. Please email us at buddies@mpnvoice.org.uk for more information.

It's worth bearing in mind that many people with MPNs have a long life expectancy, and that the treatments are very effective at controlling cell production. You can read more about the psychological aspects of MPN treatment on our website at www.mpnvoice.org.uk under "Living with MPNs".

Medical exemptions for treatment

MPN patients in England are entitled to an exemption certificate and should obtain a FP92A form from their GP or haematologist. Further details can be found on our website at www.mpnvoice.org.uk in the living-with MPNs, everyday challenges/cost of medication section.

Resources for patients and families

MPN Voice

Registered under the auspices of Guy's and St Thomas' charity, MPN Voice provides patients and families affected by MPNs with a comprehensive range of disease and medication publications, regular newsletters, a buddy scheme and runs regional patient forums as well as funding research into MPNs and drugs trials. The website also offers access to an online community of MPN patients as well as the latest news and reports from leading healthcare professionals.

www.mpnvoice.org.uk

Anthony Nolan

It's vision is to save the lives of everyone who needs a bone marrow or stem cell transplant. Established in 1974, the Anthony Nolan Bone Marrow Register was the founding member of Bone Marrows Worldwide in 1988. Today the register has almost ½ million potential donors on it.

Tel: 0303 303 0303

www.anthonynolan.org

British Heart Foundation

Founded over 50 years ago by a group of medical professionals who wanted to fund extra research into the causes, diagnosis, treatment and prevention of heart and circulatory disease. The website offers health advice to prevent heart disease and practical tips for healthy living.

www.bhf.org.uk

Leukaemia Care

Offers a helpline and website which provides support to anyone affected by a blood or lymphatic cancer.

Tel: 08088 010 444

www.leukaemiacare.org.uk

Leukaemia and Lymphoma Research

The charity focuses on improving the lives of patients with all types of blood cancer, including leukaemia, lymphoma and myeloma. It does this through dedicated research focused on finding the causes, improving diagnosis and treatments as well as investment in groundbreaking clinical trials for all blood cancer patients.

www.leukaemialymphomaresearch.org.uk

Medicines.org

A website run in collaboration with the NHS providing up to date, reliable and understandable information about medicines. A great resource for all medicines.

www.medicines.org.uk

Macmillan Cancer Support

Offers a comprehensive website with information about MPNs, chemotherapy drugs, side effects and how best to manage side effects.

Tel: 0808 808 0000

www.macmillan.org.uk

Spotlight on MPN

An international website on myeloproliferative neoplasms, intended for patients and caregivers. Produced by Novartis Oncology.

www.spotlightonmpn.com

Stroke Association

Offering help and advice for people and families affected by stroke. The website offers tips on recognising the signs of a stroke as well as the preventative lifestyle measures everyone should consider if at high risk of a stroke.

Tel: 0303 3033 100

www.stroke.org.uk

Could you help us?

Your support will enable us to help many more MPN patients and their families



If you have an MPN or know someone with this condition **MPN Voice** aims to offer support and advice.

Visit www.mpnvoice.org.uk to find out more about our

- Buddy System
- Medical Alert Cards
- Newsletters
- Treatment and drug leaflets
- Regional patient forums
- Online community of MPN patients
- Funding of some of the latest MPN research
- Backing by leading health professionals

www.mpnvoice.org.uk

email info@mpnvoice.org.uk



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If you can help, please complete the donation form on the next page

Donations

MPN Voice is funded by donations made by generous supporters. All money raised goes towards providing better information for patients and their families e.g booklets such as this, as well as investing in research to investigate why some people develop MPNs. Any donation will make a difference so thank you for your kind support.

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For further information please call 0207 848 4701
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If you are a UK taxpayer, Guy's and St Thomas' Charity, on behalf of MPN Voice, can reclaim the tax on your donation and receive an extra 25p for every £1 donated.

You need to have paid at least as much UK Income and/or Capital Gains Tax as the amount to be reclaimed on all your charitable donations in the appropriate tax year. Please inform us if you no longer pay UK tax at any time after the date of this declaration.

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About this publication and MPN Voice

This document was written by Yvonne Francis, an NHS MPN specialist nurse, with input from consultant haematologists, specialist nurses, psychologists and volunteers of MPN Voice.

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We welcome your feedback. Please write with your suggestions to our postal address or email us at info@mpnvoice.org.uk

You can also contact the Guy's and St Thomas' Charity at info@gsttcharity.org.uk or visit their website for more information at www.gsttcharity.org.uk



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- Online community of MPN patients
- Funding of some of the latest MPN research

www.mpnvoice.org.uk



Supporting people
and families affected
by MPN