JAKAVI® and ME

Supporting you through your treatment

JAKAVI®
ruxolitinib

Edition 2 - March 2021

Welcome

to your JAKAVI booklet

Being diagnosed with a new medical condition and being prescribed a new medication can take some getting used to. You may be feeling a lot of different emotions about your health and concerned about taking a new medication in the right way. Whatever your concerns may be, this booklet provides information to help reassure you.

This booklet contains quite a lot of information about the treatment of myelofibrosis with JAKAVI, so take time to read it, just one section at a time – find out information about how your medication works, how to get the most from it, and how your healthcare team can support you.

Remember the information provided in this booklet does not replace the advice of your healthcare professional team. If you require further information about myelofibrosis or JAKAVI, or have any concerns, please contact your Haematologist as soon as possible.

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Some useful guidance on how to take control and make the most of your treatment with JAKAVI.

Before you start

What is Myelofibrosis?

Myelofibrosis is a chronic disorder in which scar tissue forms in the bone marrow.

Myelofibrosis occurs when abnormal stem cells in the marrow (the soft, fatty tissue inside your bones) produce cells that cause the marrow to become scarred. It can also cause chronic inflammation.

Scarring of the bone marrow means it is unable to produce as many normal blood cells as usual.

The spleen, an organ found just under the lower left ribs, which mainly works to filter the blood, can also produce blood cells. In myelofibrosis, the spleen enlarges as it produces more blood cells than normal to compensate for the reduced blood cell production in the bone marrow.

Myelofibrosis is one of a number of conditions known as myeloproliferative neoplasms (MPNs).

MPNs are a group of disorders of the bone marrow in which excess cells are produced. There are 4 main types of MPNs that add up to around 95 per cent of all cases:

- Myelofibrosis
- Polycythaemia vera (PV)
- Essential thrombocythaemia (ET)
- Chronic myeloid leukaemia (CML).

Myelofibrosis can develop on its own (known as primary myelofibrosis), or as a progression of PV or ET.

What causes myelofibrosis?

Myelofibrosis may be caused by changes in the DNA, known as gene mutations.

Half of the people with myelofibrosis have a mutation in a gene that is partly responsible for the production of blood cells – this gene is called JAK2V617F. This gene mutation causes over-activity of JAK signalling in the body.

Not all patients with myelofibrosis have this mutation, however, the over-activity of JAK signalling can be caused through other mutations or mechanisms. What causes these mutations is not yet known.

Myelofibrosis can affect anyone, but it's most often diagnosed in people aged between 60 and 70 years.

What is JAKAVI?

You've been prescribed JAKAVI to treat the symptoms of myelofibrosis – here are some answers to questions that you may have about your new medication.

What is JAKAVI?

JAKAVI is a prescription medicine used to treat adults with an enlarged spleen or symptoms related to myelofibrosis, a rare blood disorder that affects the bone marrow.

How does it work?

The JAK pathway is involved in regulating blood cell production. As discussed in the previous section, over-activity of JAK signalling may occur in people with myelofibrosis. This leads to abnormal blood cell production and scarring in the bone marrow. JAKAVI contains the active substance ruxolitinib phosphate. This medicine belongs to a group of medicines called JAK inhibitors. This means that it blocks the action of certain enzymes (proteins) in the body called Janus Associated Kinases ('JAK').

As mentioned in the previous section, the spleen can become enlarged in people with myelofibrosis.

Potential outcomes of JAKAVI therapy

What can you expect?

With myelofibrosis, it's important to remember that everyone's symptoms are different and so JAKAVI often affects different people in different ways.

JAKAVI may relieve symptoms of myelofibrosis, such as:

- Abdominal discomfort
- Itching
- Night sweats
- Inactivity
- Fatigue
- Early satiety
- Fever/ high temp
- Concentration problems
- Bone pains
- Weight loss

An improvement in any or all of these symptoms can impact your overall quality of life. You may start to feel better in general and have more energy as a result of better eating and sleeping patterns.

The MPN-10 tracker can be used to help you monitor your symptoms over time, please refer to page 28 for more information.

Reduction in spleen size can help alleviate abdominal pain and feelings of fullness, leading to improved appetite and more regular eating habits.

Starting your treatment with JAKAVI

How to take JAKAVI?

Your Haematologist will explain how much you need to take (your dose) and how to take it.

How should I take JAKAVI?

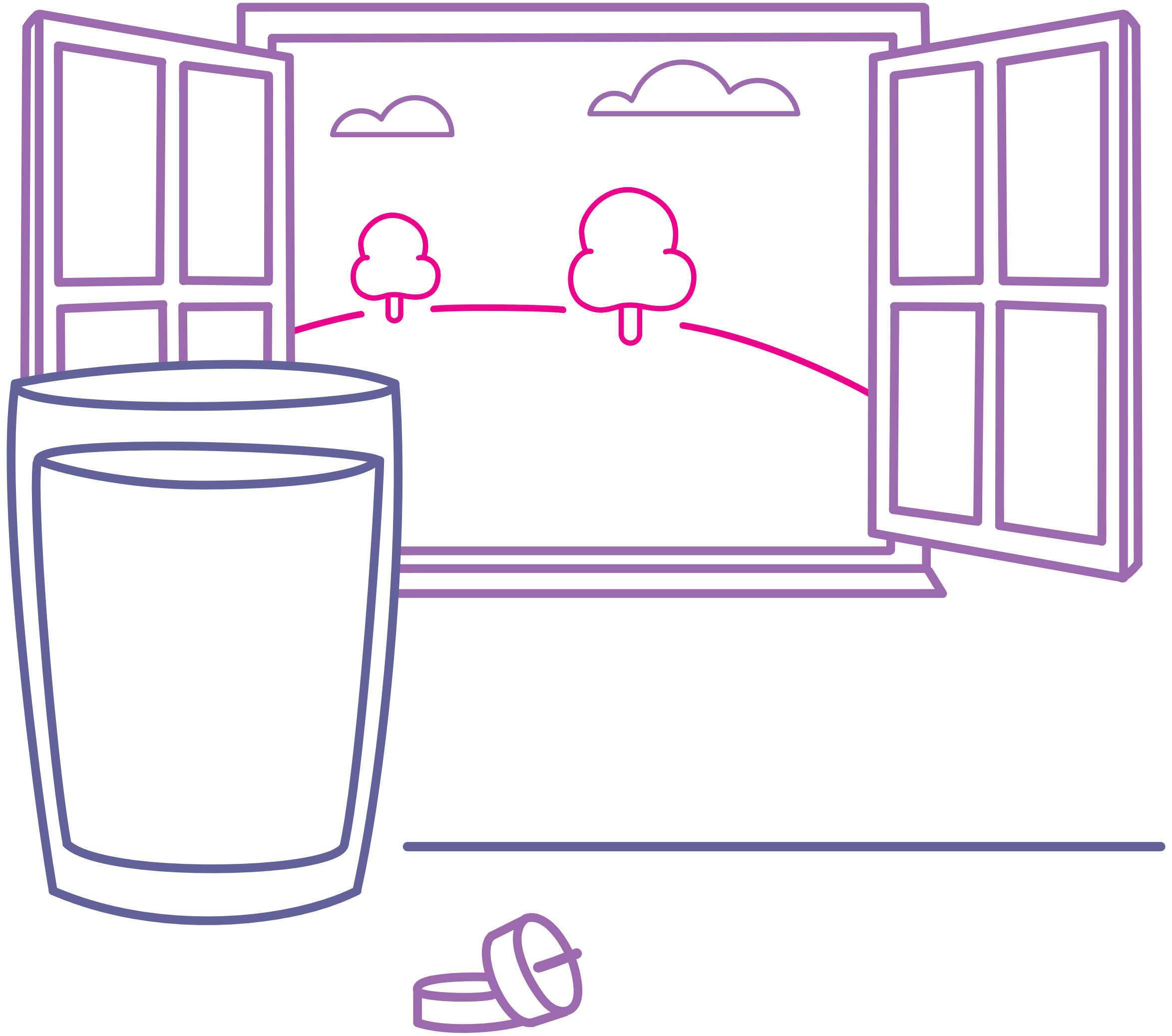
JAKAVI is taken twice a day, every day, and should be taken exactly as your Haematologist has recommended.

JAKAVI comes in tablet form, and is available as 5mg, 15mg and 20mg tablets.
Your Haematologist has recommended a dose that should help reduce your spleen size.

You shouldn't change your dose or stop taking JAKAVI without talking with your Haematologist.

If there are reasons that make you feel that you cannot, or don't want to, take your JAKAVI as recommended, ask your Haematologist for advice.

If you have any questions relating to your JAKAVI treatment and dosage, ask your Haematologist or Pharmacist.



How to take JAKAVI?

Do I need to take JAKAVI at the same time every day?

Yes, JAKAVI should be taken twice a day, every day, at the same time. Take your tablets morning and evening and as near as possible to the same times. Consider fitting it into an existing routine, such as cleaning your teeth, to help get into the habit.

What will my dosage be?

Your starting dose of JAKAVI will be based on your platelet count, which is determined from a blood test your Haematologist will send you for before starting treatment. These results will determine the best dose for you.

The recommended starting dose is usually 15mg or 20mg twice a day, depending on your platelet count. However, some people will start on a dose of 5mg twice a day. The maximum dose that you could be prescribed is 25mg twice daily. Everyone is different, so it is important to take the exact dose that your Haematologist recommends, as your dose is based on your individual situation.

For example, if you have liver or severe kidney problems, your Haematologist may start you on a lower dose.

Your Haematologist may vary your dose during the initial months of treatment until the correct dose of JAKAVI for your specific condition and symptoms is found. This process is called 'dose titration'.

You will need to have a complete blood count every 2–4 weeks until your JAKAVI dose is stabilised, and then on an ongoing basis as required, to help ensure you get the best results from treatment. Your haematologist may also stop your JAKAVI treatment altogether, if you experience certain side effects.

Are you considering stopping JAKAVI?

Do not stop or interrupt your JAKAVI treatment without first discussing it with your Haematologist. JAKAVI is a long-term treatment and is prescribed for people with myelofibrosis to help reduce spleen size and relieve symptoms related to myelofibrosis.

Stopping or interrupting your treatment could result in a quick return of your pre-treatment symptoms.

What JAKAVI looks like

Your JAKAVI tablets will be packaged in boxes that contain four blister packs of 14 tablets; each blister pack represents a week of treatment with a calendar printed on the foil to help you remember to take your tablets twice daily.

JAKAVI comes in the following formulations:


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


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


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

Tablets shown are not actual size.

Top tips for taking JAKAVI

Can I take JAKAVI with other medicines?

Taking JAKAVI with certain other medicines may increase the risk of side effects or reduce the effectiveness of JAKAVI. For example, some medications that treat fungal and bacterial infections and some HIV/AIDS medications may increase the risk of side effects.

Some medications for epilepsy and tuberculosis – an infectious disease that primarily affects the lungs – as well as some herbal products, such as St John's wort, may reduce the effectiveness of JAKAVI.

For a full list of the medications that can affect your JAKAVI treatment, please see the Consumer Medicines Information (CMI) leaflet available from your Pharmacist.

What if I miss a dose?

If you miss a dose of JAKAVI, take your next dose at your regular time. Do not take two doses at the same time to make up for the missed dose. If you have missed more than one dose and feel worried about this, you should call your Haematologist or speak to your Pharmacist for advice.

You may want to combine taking your JAKAVI with other daily routines, use a dosing box, or set an alarm on your mobile phone or watch.

Top tips for taking JAKAVI

What if I take too much JAKAVI?

If you take too much JAKAVI, call your Haematologist or Pharmacist immediately, or go to the nearest hospital emergency department. Take your JAKAVI packaging with you so the healthcare team can determine what they need to do.

Do I take JAKAVI with or without food?

You can take JAKAVI with or without food – it doesn't matter. However, you shouldn't eat grapefruit or drink grapefruit juice while taking JAKAVI.

How to store JAKAVI

Store your JAKAVI medication out of sight and reach of children. Do not store above 30°C. Store in the dosing box in order to protect the contents from moisture.

Use your JAKAVI tablets within 24 months of opening the blister pack. Bottles of JAKAVI® can be stored unopened for 24 months and must be used within 1 month of opening. Do not use them after their expiry date, which is stated on the packaging. Ask your Pharmacist how to dispose of unwanted tablets such as those that might be left in a pack if you forgot to take a dose or two. If your supply of JAKAVI® has expired or is damaged, return it to your pharmacist for disposal.

What is in JAKAVI?

Each tablet contains ruxolitinib phosphate (the active ingredient in JAKAVI) together with other ingredients, such as lactose, designed to keep the active ingredient effective, and allow it to be made into a pill.

What if I can't swallow tablets?

Some people may have problems with swallowing pills. Tell your Haematologist or Pharmacist if you can't take the full JAKAVI tablet by mouth – they will be able to discuss the options available to you to help you take your medication.

Avoid grapefruit

Do not eat grapefruit or drink grapefruit juice while taking JAKAVI, as grapefruit can affect the amount of JAKAVI in your blood.

There are chemicals in grapefruit – especially in grapefruit juice – that may increase the risk of side effects with JAKAVI. These chemicals are specific to grapefruit and are not found in other foods including citrus fruits.

Top tips for taking JAKAVI

I'm on dialysis – does this affect my JAKAVI treatment?

If you are on dialysis, it should be fine to take your JAKAVI as prescribed – your Haematologist will tell you if you need to change how or when to take your dose.

Does it matter how old I am?

JAKAVI is only available for adults. Of the total number of people with myelofibrosis who used JAKAVI during clinical studies, about half were 65 years of age or older. No overall difference in safety or how well JAKAVI worked was observed between these older and younger people.

What if I'm pregnant or breastfeeding?

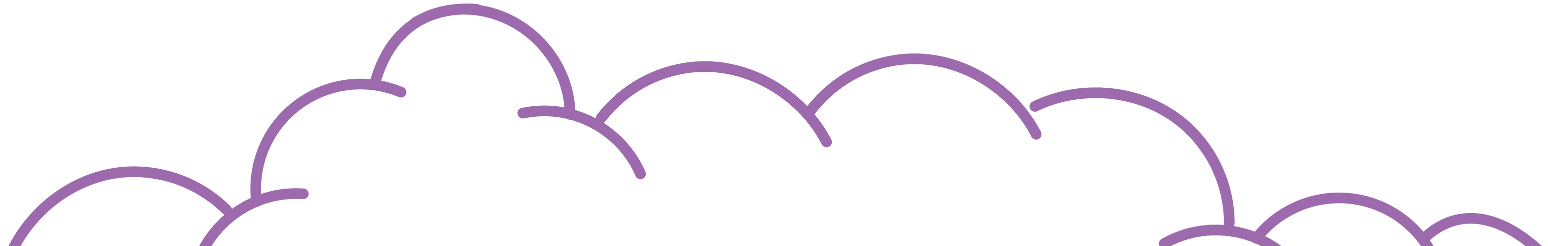
It is not known if JAKAVI affects an unborn child or fertility.

As a precautionary measure, JAKAVI is not prescribed to women who are pregnant. Your Haematologist may ask you to take a pregnancy test before starting JAKAVI if there is any chance that you may be pregnant.

JAKAVI is a long-term treatment – talk to your Haematologist if you are thinking about becoming pregnant in the future.

As it is not yet known if JAKAVI can be transmitted to babies via breast milk, the treatment is not recommended for nursing mothers. Therefore tell your Haematologist if you are breastfeeding.

JAKAVI contains lactose (milk sugar). If you have been told by your doctor that you are intolerant to some sugars, or milk, contact your Haematologist.



What to expect with JAKAVI

All medicines can have side effects – sometimes they are serious, but most of the time they are not.

It's important to work with your Haematologist to weigh up the pros and cons of any treatment, and JAKAVI is no different.

Some people with myelofibrosis who have taken JAKAVI have experienced encouraging improvements in the day-to-day management of their spleen size, symptoms and overall quality of life.

However, they have also reported some side effects, and these – as with all treatments – can affect each person differently. Not everyone experiences side effects, but your Haematologist will discuss the possible side effects with you before you start your JAKAVI treatment.

Side effects

Tell your Haematologist or Pharmacist as soon as possible if you do not feel well while you are taking JAKAVI even if you do not think it is connected with the medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your Haematologist or Pharmacist to answer any questions you may have.

Tell your Haematologist as soon as possible if you notice any of the following:

- Urinary tract infection or other infections
- Shingles (herpes zoster) - painful skin rash with blisters
- Bruising
- Fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia)
- Skin changes – these may require further observation as certain types of skin cancer (non-melanoma) have been reported
- Persistent cough with blood-tinged sputum, fever, night sweats and weight loss (possible symptoms of tuberculosis).

The above list includes serious side effects, which may require medical attention.

Further information can be found in the JAKAVI Consumer Medicines Information at https://www.medsafe.govt.nz/Consumers/CMI/j/jakavi.pdf or by scanning this QR code.

What to expect with JAKAVI

Tell your Haematologist or Pharmacist if you notice any of the following and they worry you:

- Dizziness
- Headache
- Constipation
- Pale skin
- Frequent infections, fever, chills, sore throat or mouth ulcers due to infections
- Weight gain
- Excess amount of gas in the bowels (flatulence)
- Feeling more tired than usual.

The above list includes the more common side effects of your medicine. Most of these side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Tell your Haematologist or Pharmacist if you notice anything that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this booklet. Some of these side effects can only be found when your Haematologist does tests from time to time to check your progress, for example:

- Low level of red blood cells (anaemia), low level of white blood cells (neutropenia), low level of platelet (thrombocytopenia)
- High level of cholesterol (hypercholesterolemia) or fat in the blood (hypertriglyceridemia)
- Abnormal liver function test results.

If you experience side effects such as these, your Haematologist may recommend reducing your JAKAVI dose or temporarily stopping your treatment. In both instances, this should only be done on the recommendation and supervision of your Haematologist.

Note down any side effects on page 36 and make sure you tell your doctor about them.

What to expect with JAKAVI

Managing the risks of infection

Before you start your JAKAVI treatment, your Haematologist will assess your risk of developing serious infections. This is usually done using a complete blood count, which can help identify any active infections you may have and also help determine your body's ability to fight infection. Any serious infections that are still in your system should be resolved before you start your JAKAVI treatment.

Your Haematologist will then monitor your complete blood counts at regular intervals throughout your treatment.

After you've started your treatment with JAKAVI, it's important to report any signs and symptoms of possible infection to your Haematologist as soon as possible.

The following are key indicators of infection:

- Chills
- Aches
- Fever
- Nausea
- Vomiting
- Weakness
- Painful skin rash or blisters

Shingles is one infection in particular that should be treated as early as possible. If you develop a painful skin rash with blisters, this could be a sign of shingles, so make sure you see your local doctor for assessment straight away, or speak with your Haematologist.

Your Haematologist may change your dose

Some side effects that may occur when you are taking JAKAVI are known as 'dose-related' side effects. This means they are more likely with higher doses, and so may be controlled or managed by adjusting your dose. JAKAVI works by blocking the activity of certain enzymes (called Janus Associated Kinases), which are crucial for the formation of blood. So with higher doses of JAKAVI, it becomes more likely one or more of these dose-related side effects – such as anaemia – may occur. The key thing to remember is that these kinds of side effects are considered to be manageable with dose alteration, and are not necessarily a sign that the disease is getting worse.

Long-term treatment

Some people using JAKAVI experience changes in the size of their spleen sooner than others, but if the speed of your improvement is slower, then don't be disheartened.

The end goal is to manage your myelofibrosis – regardless of how long it takes.

Your Haematologist may need to alter your dose once (or more than once) to find exactly the right amount for you before you start showing signs of improvement. Not experiencing rapid results does not mean you won't see any results at all – it might just take a while to get it right.

Getting support

Working with your Haematologist

As with any treatment, working closely with your Haematologist and making the most of your appointments will help maximise the benefit you get from using JAKAVI.

Between appointments, keep track of any changes in your symptoms, or any other signs of how your treatment is working. As you think of them, jot down any questions for your Haematologist – you're less likely to forget them if you note them down as they come to you.

Take your notes and a pen with you when you go to your appointment – this way you can tick off the questions as you ask them, and also write down any answers. And don't be shy – ask as many questions as you need to get the information you want so that you feel comfortable about your condition and the treatment you're getting. Also, consider asking a family member or friend to go with you to appointments for moral support. They can also take notes or even ask questions that may not have occurred to you.

Adapting to a new treatment

Some people feel worried when starting a new treatment – talk to your Haematologist if you are feeling nervous or have any concerns about your JAKAVI treatment.

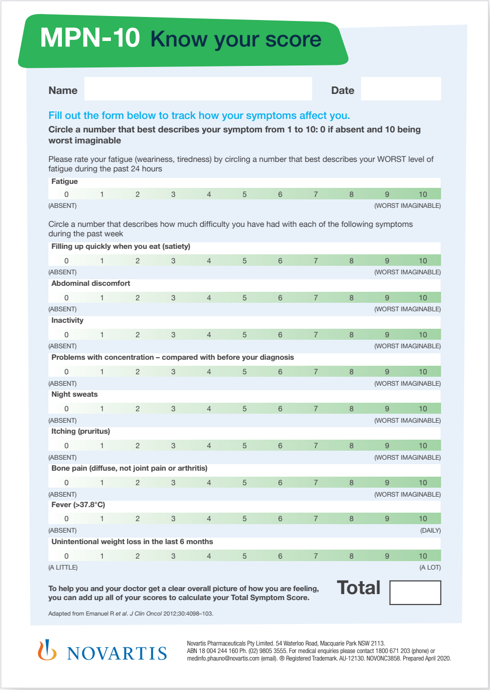
A new treatment can affect different people in different ways. It can be exciting starting a new treatment and you might expect to feel better straight away. But it's important to see the bigger picture and take one step at a time. JAKAVI is often used as a long-term treatment, so you need to be prepared for the prospect of taking this treatment for a long time.

Remember too, that any treatment will come with highs and lows, especially in the early days as you and your Haematologist work to figure out what dose of JAKAVI is right for you and your condition. You might see some improvement in your symptoms, but you may also experience some side effects that are quite new to you. It's important to be prepared for this, and to try and work through any issues as they arise. See page 19 for more information on possible side effects.

Remember, you can talk to your Haematologist or confide in a family member, friend or carer. All these people are there to help and support you.

Working with your Haematologist

It is important to track your symptoms



MPN-10 Know your score

Name **Date**

Fill out the form below to track how your symptoms affect you.

Circle a number that best describes your symptom from 1 to 10: 0 if absent and 10 being worst imaginable

Please rate your fatigue (weariness, tiredness) by circling a number that best describes your WORST level of fatigue during the past 24 hours

Fatigue
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Circle a number that describes how much difficulty you have had with each of the following symptoms during the past week

Filling up quickly when you eat (satiety)
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Abdominal discomfort
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Inactivity
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Problems with concentration – compared with before your diagnosis
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Night sweats
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Itching (pruritus)
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Bone pain (diffuse, not joint pain or arthritis)
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (WORST IMAGINABLE)

Fever (>37.8°C)
0 1 2 3 4 5 6 7 8 9 10
(ABSENT) (DAILY)

Unintentional weight loss in the last 6 months
0 1 2 3 4 5 6 7 8 9 10
(A LITTLE) (A LOT)

To help you and your doctor get a clear overall picture of how you are feeling, you can add up all of your scores to calculate your Total Symptom Score. **Total**

Adapted from Emanuel R *et al. J Clin Oncol* 2012;30:4098–103.

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ABN 18 004 244 160 Ph. (02) 9805 3555. For medical enquiries please contact 1800 671 203 (phone) or medinfo.phauno@novartis.com (email). ® Registered Trademark. AU-12130. NOVONC3858. Prepared April 2020.

The symptoms of MPNs, including myelofibrosis vary, meaning they can affect people differently. In order to ensure you get the most appropriate treatment for your individual circumstances, it's important to be able to explain your symptoms to your Haematologist, and to describe what effect they're having on your day-to-day life.

The MPN-10 is a tracker used to monitor the 10 main symptoms of myelofibrosis. It has been designed to help you record how your symptoms are affecting you over time. You can use the MPN-10 to discuss your symptoms and treatment options with your Haematologist at your next appointment.

Ask your Haematologist for a copy of the MPN-10 tracker to record your symptoms.

Reaching out to others

It's always good to meet and chat to other people with myelofibrosis who might be using JAKAVI or who are experiencing similar symptoms and feelings to you.

Leukaemia & Blood Cancer New Zealand provides services and support throughout New Zealand for patients and families living with a blood cancer. Their Support Services Coordinators provide practical and emotional support, education and advocacy.

Freephone: 0800 15 10 15

Email: info@leukaemia.org.nz

Website: www.leukaemia.org.nz

Taking control

Living well with myelofibrosis

Small changes, big difference

Your Haematologist will suggest ways to manage your condition, and there's a lot you can do to help tackle your symptoms and cut your risk of complications in order to feel as well as you can. Best of all? You may only have to make some simple lifestyle changes to have a real impact.

Your Haematologist will monitor your condition but you also play a vital role – alongside your Haematologist – in managing your condition and your symptoms. As well as following your Haematologist's advice on management, adopting a healthier lifestyle can help lower your risk of complications, as well as help you to cope with symptoms and reduce their impact so you can get on with enjoying the things you want to do – whether that's meeting up with friends, keeping up with your hobbies, going to football matches or playing with your grandchildren. Follow our expert advice for easy lifestyle changes that can leave you feeling better.

Stay active

Doing some exercise is very important for people with myelofibrosis. Here's why:

- It cuts your heart disease risk. People with myelofibrosis are at increased risk of heart disease and staying active is a great way of boosting your heart health.
- Activity boosts your energy levels. While fatigue might mean you don't feel much like exercising, it's worth making an effort as getting active is one of the best ways to feel revitalised.
- Staying active can help you manage stress. If you're feeling anxious about your condition, or its effects on your family or other aspects of your life, fitting in some exercise could help you feel calmer and cope better with worry.
- Exercise helps you keep to a healthy weight and cut your chances of developing a clot, as well as reducing your chances of other conditions such as diabetes and heart disease.

Small changes to try

The amount of exercise you can do depends on how your condition affects you – some people with myelofibrosis are able to exercise as they always have done, while others can do very little. Always speak to your Haematologist before you start any new exercise regime, to check it's safe, and stop if you feel dizzy or breathless, or your heart's racing, and seek medical advice. Your doctor may be able to help you draw up an activity plan that works for you.

Living well with myelofibrosis

Eating right

A balanced diet's important for everyone, but it's particularly crucial if you have myelofibrosis as eating well can help lower your risk of some complications:

You'll cut your chances of cardiovascular disease. People with myelofibrosis have an increased risk, but eating a healthy diet can help to reduce it. Too much salt is connected to high blood pressure, while too much saturated fat is linked to high cholesterol, both of which can further raise your chance of having a heart attack or stroke.

You'll keep to a healthy weight. This is important with myelofibrosis, as being overweight can raise your risk of having a heart attack or stroke. Conversely, some people with myelofibrosis find it hard to eat enough due to loss of appetite and symptoms such as nausea. Eating the right way can help you maintain your weight.

Small changes to try

- You may find it easier to go for small, frequent, high-calorie meals and snacks instead of three main meals, such as yoghurts, fruit smoothies and rice puddings.
- Avoid processed foods. Try to cook meals from scratch to steer clear of the added salt found in processed foods, and flavour dishes with garlic and herbs instead.
- Plan ahead. Getting organised can help you ensure you eat healthily even when you're tired. Cook dishes like chicken casserole, vegetable curry or Bolognese sauce in bulk on days you feel well and freeze individual portions for the days you don't. Try shopping online, for foods which can be stored for a while and cooked quickly when you need them, like nutritious soups, and foods which are easy to prepare, such as cereal, pasta and frozen vegetables.

To discuss with my Haematologist

To discuss with my pharmacist

Consumer mandatory statement:

JAKAVI® (ruxolitinib) 5 mg, 15 mg and 20 mg is a prescription medicine available as tablets for the treatment of disease-related splenomegaly or symptoms in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, as well as the treatment of patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. JAKAVI® is a funded medicine for myelofibrosis, criteria apply. Normal doctor visit fees apply. JAKAVI® is not a funded medicine for polycythemia vera.

Ask your doctor if JAKAVI® is right for you. Use strictly as directed. Always take Jakavi exactly as your doctor has told you and tell your doctor or pharmacist if you are taking any other medicines, or if you start new ones. Take Jakavi twice a day, every day, at about the same time each day. Jakavi has risks and benefits. You should avoid becoming pregnant while taking JAKAVI®. Cautions are urinary tract or other infections, dizziness, headache, bruising, fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing, skin changes. Talk to your doctor right away if you experience any of these. Side effects can include infections, shingles, weight gain, flatulence, constipation, feeling more tired than usual, anaemia and pneumonia, hypertension, pancytopenia, tuberculosis. Refer to the consumer medicine information at the website www.medsafe.govt.nz for full details. JAKAVI® is the registered trademark of Novartis AG. Novartis New Zealand Ltd, Auckland. Ph 0800 354 335.

Novartis would like to acknowledge the Myelofibrosis Advisory Council for their assistance in compiling this booklet.

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