

Applicant	Novartis South Africa (Pty) Ltd
Product Name	Jakavi 5 mg, 10 mg, 15 mg, 20 mg
Strength and dosage form	Tablet containing 5 mg, 10 mg, 15 mg and 20 mg ruxolitinib, respectively
Date of Approval	31 October 2020

Clean Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

JAKAVI 5 mg, 10 mg, 15 mg, 20 mg tablets

Ruxolitinib

Contains lactose

Read all of this leaflet carefully before you start taking JAKAVI because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What JAKAVI is and what it is used for
2. What you need to know before you take JAKAVI
3. How to take JAKAVI
4. Possible side effects
5. How to store JAKAVI
6. Contents of the pack and other information

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1. What JAKAVI is and what it is used for

JAKAVI contains the active substance ruxolitinib.

JAKAVI is used to treat adult patients with an enlarged spleen or with symptoms related to myelofibrosis, a rare form of blood cancer.

JAKAVI is also used to treat adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.

How JAKAVI works

Myelofibrosis is a disorder of the bone marrow, in which the marrow is replaced by scar tissue. The abnormal bone marrow can no longer produce enough normal blood cells and as a result, the spleen starts to produce blood cells which cause a significant increase in the size of the spleen. By blocking the action of certain enzymes (called Janus Associated Kinases), JAKAVI can reduce the size of the spleen and relieve symptoms such as fever, night sweats, bone pain and weight loss.

Polycythaemia vera is a disorder of the bone marrow, in which the marrow produces too many red blood cells. The blood becomes thicker as a result of the increased red blood cells in the blood vessels which increases the risk of serious blood and vascular complications. JAKAVI, by blocking certain enzymes called Janus Associated Kinases (JAK 1 and JAK 2), suppresses the over production of red blood cells by the bone marrow which relieves the disease symptoms, reduces spleen size, and the overproduction of red blood cells which reduces the risk of serious blood or vascular complications.

If you have any questions about how JAKAVI works or why it has been prescribed for you, ask your doctor.

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2. What you need to know before you take JAKAVI

Follow all the doctor's instructions carefully.

Do not take JAKAVI

- if you are allergic to ruxolitinib or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast-feeding your baby
- if you have an acute infection
- if you have latent/dormant/silent tuberculosis of your lungs or other organs
- if you have HIV
- if you have acute hepatitis B or have had Hepatitis B which are not well controlled with appropriate treatment
- if you are to be immunised with a live attenuated bacterial or viral vaccine
- if you have a blood haemoglobin of 8 g/dl or less
- if you have a blood platelet count of 50,000 mm³ or less
- if you have a total neutrophil count of 500 mm³ or less
- if you have a skin cancer called basal cell carcinoma or squamous cell carcinoma
- if you are 18 years of age or below

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

Warnings and precautions

The infections, skin cancers and blood abnormalities listed in the "Do not take JAKAVI section" will first have to be cured/resolved, improved, well controlled or reversed before you can start treatment with JAKAVI.

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Talk to your doctor or pharmacist before taking JAKAVI

- if you have any infections. It is necessary to treat your infection before starting JAKAVI. (see “Do not take JAKAVI”) 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. (see “Do not take JAKAVI”) 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 or ever had hepatitis B. (see “Do not take JAKAVI”)
- if you have any kidney problems. Your doctor may need to prescribe a different dose of JAKAVI.
- if you have or have ever had any liver problems. Your doctor may need to prescribe a different dose of JAKAVI.
- if you are taking other medicines (see section “Other medicines and JAKAVI)
- if you have ever had skin cancer. (see “Do not take JAKAVI”)

Talk to your doctor or pharmacist during your treatment with JAKAVI

- if you experience unexpected bruising, or a swelling containing clotted or partially clotted blood under your skin (haematoma) 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 symptoms or if anyone close to you notices that you have any of these symptoms: confusion or difficulty thinking, loss of balance or difficulty walking, clumsiness, difficulty speaking, decreased strength or weakness on one side of your body,

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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 painful skin rash with blisters (these are signs of shingles).
- if you notice skin changes. This may require further observation, as certain types of skin cancer (non-melanoma) have been reported.

Blood tests

Before you start treatment with JAKAVI, your doctor will perform blood tests to determine the best starting dose for you. You will need to have further blood tests during treatment so that your doctor can monitor the amount of blood cells (white cells, red cells and platelets) in your body and assess how you are responding to the treatment and whether JAKAVI is having an unwanted effect on these cells. Your doctor may need to adjust the dose or stop treatment. Your doctor will carefully check if you have any signs or symptoms of infection before starting and during your treatment with JAKAVI. Your doctor will also regularly check the level of lipids (fat) in your blood. Blood tests will also be done to check on your hepatitis B status.

Stopping JAKAVI

When you stop taking JAKAVI, the myelofibrosis symptoms may come back. Your doctor may want to gradually reduce the amount of JAKAVI taken each day, before stopping it completely.

Children and adolescents

JAKAVI is not intended for use by children or adolescents aged below 18 years because it has not been studied in this age group.

Other medicines and JAKAVI

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

It is particularly important that you mention any of the following medicines containing any of the following active substances, as your doctor may need to adjust the JAKAVI dose for you.

The following may increase the risk of side effects with JAKAVI:

- Some medicines used to treat infections. 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 viral infections, including HIV infection/AIDS (such as amprenavir, 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.

The following may reduce the effectiveness of JAKAVI:

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

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Pregnancy and breastfeeding

You should not be treated with JAKAVI if you are pregnant or if you are planning to become pregnant.

Talk to your doctor about how to take appropriate contraceptive measures to avoid becoming pregnant during your treatment with JAKAVI. Regular pregnancy tests will be done whilst you are on treatment with JAKAVI to exclude pregnancy.

You should not breastfeed your baby while taking JAKAVI

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

Fertility

It is unknown whether your fertility will be affected by treatment with JAKAVI.

Driving and using machines

JAKAVI may influence your ability to drive and operate machines. Do not engage in driving and operating machines until you have ensured that treatment with JAKAVI does not affect your mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgement and/or sound coordination and vision. Side effects of treatment with JAKAVI which may include dizziness, bleeding, anaemia, headache, infections or high blood pressure may influence your ability to drive and operate machines.

JAKAVI contains lactose

JAKAVI contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking JAKAVI.

3. How to take JAKAVI

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Do not share medicines prescribed for you with any other person.

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

The dose of JAKAVI depends on your 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 15 mg twice daily or 20 mg twice daily, depending on your blood cell count.
- The recommended starting dose in polycythaemia vera is 10 mg twice daily.
- The maximum dose is 25 mg twice daily.

Your doctor will always tell you exactly how many and what strength of JAKAVI tablets to take.

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 JAKAVI 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 JAKAVI every day at the same time, either with or without food.

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

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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 JAKAVI, 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 JAKAVI you have to take or tell you to stop taking JAKAVI for a while.

If you take more JAKAVI than you should

If you accidentally take more JAKAVI than your doctor prescribed, contact your doctor or pharmacist immediately.

If you forget to take JAKAVI

If you forgot to take JAKAVI simply take your next dose at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking JAKAVI

If you interrupt your treatment with JAKAVI your myelofibrosis related symptoms may come back. Therefore, you should not stop taking JAKAVI without discussing it with your doctor.

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

4. Possible side effects

JAKAVI can have side effects.

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Not all side effects reported for JAKAVI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking JAKAVI, please consult your health care provider for advice.

If any of the following happens, stop taking JAKAVI and tell your doctor immediately or go to the casualty department at your nearest hospital:

Frequent:

- any sign of bleeding in the brain, such as sudden altered level of consciousness, persistent headache, numbness, tingling, weakness or paralysis
- any sign of bleeding in the stomach or intestine, such as passing black or bloodstained stools, or vomiting blood
- unexpected bruising or a swelling containing clotted or partially clotted blood under your skin (*haematoma*) 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*) or very low levels of all types of blood cells (*pancytopenia*)
- Low levels of blood cells may present with fatigue/tiredness, paleness, bruising, swellings under your skin and bleeding and make you very susceptible to infections.

Other side effects with JAKAVI

Frequent:

- high level of cholesterol or fat in the blood (hypertriglyceridaemia)
- abnormal liver function test results

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- dizziness
- headache
- urinary tract infections
- weight gain
- high blood pressure (hypertension), which may also be the cause of dizziness and headaches
- fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia)
- frequently passing wind (flatulence)
- constipation

Less frequent:

- tuberculosis
- reactivation of Hepatitis B infection
- “shingles” a painful skin rash (reactivation of herpes zoster infection)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of JAKAVI.

5. How to store JAKAVI

Keep this medicine out of the sight and reach of children.

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

Do not store above 25 °C. Protect from moisture.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What JAKAVI contains

- The active substance of JAKAVI is ruxolitinib
 - Each 5 mg JAKAVI tablet contains 5 mg of ruxolitinib.
 - Each 10 mg JAKAVI tablet contains 10 mg of ruxolitinib.
 - Each 15 mg JAKAVI tablet contains 15 mg of ruxolitinib.
 - Each 20 mg JAKAVI tablet contains 20 mg of ruxolitinib.
- The other ingredients are microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, sodium starch glycolate, povidone, hydroxypropylcellulose, lactose monohydrate.

What JAKAVI looks like and contents of the pack

JAKAVI 5 mg tablets are white to almost white round tablets with “NVR” debossed on one side and “L5” debossed on the other side.

JAKAVI 10 mg tablets are white to almost white round tablets with “NVR” debossed on one side and “L10” debossed on the other side.

JAKAVI 15 mg tablets are white to almost white oval tablets with “NVR” debossed on one side and “L15” debossed on the other side.

JAKAVI 20 mg tablets are white to almost white elongated tablets with “NVR” debossed on one side and “L20” debossed on the other side.

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JAKAVI tablets are supplied in blister packs containing 14 or 56 tablets or multipacks containing 168 (3 packs of 56) tablets.

Not all pack sizes or types may be marketed.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

2090

This leaflet was last revised in

31 October 2020

Registration number

JAKAVI 5 mg tablets: 48/34/0109

JAKAVI 10 mg tablets: 52/34/0781

JAKAVI 15 mg tablets: 48/34/0110

JAKAVI 20 mg tablets: 48/34/0111