NOVARTIS

JAKAVI® (ruxolitinib)

5, 15 and 20 mg tablets

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

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

Ruxolitinib

Each 5 mg tablet contains 71.45 mg lactose monohydrate

Each 10 mg tablet contains 142.90 mg lactose monohydrate

Each 15 mg tablet contains 214.35 mg lactose monohydrate

Each 20 mg tablet contains 285.80 mg lactose monohydrate

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
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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.

JAKAVI is also used to treat patients of 6 years of age and older and adults with steroid refractory graft-versus-host disease (GvHD). This disease occurs after transplantation of blood or bone marrow from a healthy donor to a patient and comes with a variety of troublesome symptoms concerning many organs.

There are two forms of GvHD: an early form called acute GvHD that usually develops soon after the transplantation and can affect skin, liver and gastrointestinal tract, and a form called chronic GvHD, which develops later, around three months after the transplantation. It frequently causes symptoms in the skin, liver, mouth, lungs,

gastrointestinal tract, neuromuscular system, or genitourinary tract. In the skin it causes a dry, itchy rash, which is raised and is like alligator skin. There also may be hair loss, decrease in sweating, and premature greying of the hair. Mouth dryness is a common symptom. It may progress to food sensitivity, such that spicy and acid foods may sting. The eyes may also be involved with dryness, irritation and redness. Almost any organ can be affected by chronic GvHD.

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.

Graft-versus-host disease is a complication which occurs after transplantation when specific cells (T cells) in the donor's graft (e.g. bone marrow) don't recognize the host cells/organs and attack them. By selectively blocking enzymes called Janus Associated Kinases JAK1 and JAK2, JAKAVI is effective to reduce signs and symptoms of the acute and the chronic forms of graft-versus-host disease leading to disease improvement and survival of the transplanted cells.

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

2. What you need to know before you take JAKAVI

Follow all the doctor's instructions carefully.

Do not take JAKAVI

- if you or your child 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 or your child have an acute infection;
- if you or your child have latent/dormant/silent tuberculosis of your lungs or other organs;
- if you or your child have HIV;
- if you or your child have acute hepatitis B or have had hepatitis B which are not

well controlled with appropriate treatment;

- if you or your child are to be immunised with a live attenuated bacterial or viral vaccine;
- if you or your child have a blood haemoglobin of 8 g/dL or less;
- if you or your child have a blood platelet count of 50,000 mm^3 or less;
- if you or your child have a total neutrophil count of 500 mm^3 or less;
- if you or your child have a skin cancer called basal cell carcinoma or squamous cell carcinoma.

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.

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 or your child’s doctor or pharmacist during treatment with JAKAVI

- if you or your child 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 or your child experience fever, chills or other symptoms of infections.
- if you or your child experience chronic coughing with blood-tinged sputum, fever, night sweats and weight loss (these can be signs of tuberculosis).
- if you or your child 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, 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 or your child develop painful skin rash with blisters (these are signs of shingles).
- if you or your child notice skin changes. This may require further observation, as certain types of skin cancer (non-melanoma) have been reported.

Blood tests

Before you or your child start treatment with JAKAVI, blood tests will be performed to determine the best starting dose for you or your child. You or your child will need to have further blood tests during treatment so that your or your child's doctor can monitor the amount of blood cells (white cells, red cells and platelets) in the body and assess how you or your child are responding to the treatment and whether JAKAVI is having an unwanted effect on these cells. The doctor may need to adjust the dose or stop treatment. The doctor will carefully check if you have any signs or symptoms of infection before starting and during your treatment with JAKAVI. The 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, who have the disease myelofibrosis or polycythaemia vera. For the treatment of graft-versus-host disease, JAKAVI can be used in patients of 6 years of age and older and adults with steroid refractory graft-versus-host disease (GvHD).

Other medicines and JAKAVI

Tell your or your child's 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 or your child are taking JAKAVI 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.

Pregnancy and breastfeeding

You or your child should not be treated with JAKAVI if you or your child are pregnant or if you or your child are planning to become pregnant. Talk to your or your child’s doctor about how to take appropriate contraceptive measures to avoid becoming pregnant

during your or your child's treatment with JAKAVI. Regular pregnancy tests will be done whilst you or your child are on treatment with JAKAVI to exclude pregnancy.

You or your child should not breastfeed your or your child's baby while taking JAKAVI.

If you or your child are pregnant or breastfeeding, think you or your child may be pregnant or are planning to have a baby, please consult your or your child's 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

Do not share medicines prescribed for you or your child with any other person.
Always take JAKAVI exactly as your or your child ‘s doctor or pharmacist has told you. Check with your or your child’s doctor or pharmacist if you are not sure.

The dose of JAKAVI depends on the blood cell count. The doctor will measure the amount of blood cells in the body and find the best dose for you or your child, particularly if you or your child 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 or your child’s doctor will always tell you or your child exactly how many and what strength of JAKAVI tablets to take.

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

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

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

How much JAKAVI to take if you are below 18 years of age

- You are not allowed to take JAKAVI for myelofibrosis or polycythemia vera as Jakavi is not approved for myelofibrosis and polycythemia vera.
- The recommended starting dose in graft-versus-host disease is 5 mg twice daily if the child is 6 to 12 years old.
- The recommended starting dose in graft-versus-host disease is 10 mg twice daily for patients above 12 years and below 18 years.

How much JAKAVI to take if you are 18 years of age and above

- The recommended starting dose in myelofibrosis is 10 mg twice daily, 15 mg twice daily or 20 mg twice daily, depending on the patient's blood cell count.
- The recommended starting dose in polycythaemia vera is 10 mg twice daily.
- The recommended starting dose in graft-versus-host disease is 10 mg twice daily.

You or your child should continue taking JAKAVI for as long as your or your child's doctor tells you. This is a long-term treatment.

Your or your child's doctor will regularly monitor your or your child's condition to make sure that the treatment is having the desired effect.
If you or your child have questions about how long to take JAKAVI, talk to your or your child's doctor or pharmacist.

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

If you or your child take more JAKAVI than you should

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

If you or your child forget to take JAKAVI

If you or your child forgot to take JAKAVI simply take the 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 or your child interrupt treatment with JAKAVI myelofibrosis and polycythemia vera related symptoms may come back. In GvHD, dose reduction or completely stopping

JAKAVI is possible if you or your child responds to treatment and your or your child's doctor will supervise this process. Therefore, you or your child should not stop taking JAKAVI without discussing it with your or your child' doctor.

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

4. Possible side effects

JAKAVI can have side effects.

Not all side effects reported for JAKAVI are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while taking JAKAVI, please consult your or your child's 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 (hypertriglyceridemia);
- abnormal liver and pancreas function test results (ALT, AST and lipase, amylase) elevated;
- dizziness;
- headache;
- fever, pain when urinating as signs of an infection of the urinary tract (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;
- rash of small fluid-filled blisters, appearing on reddened skin, signs of shingles (herpes zoster);
- bruising.

Less frequent:

- tuberculosis;
- reactivation of hepatitis B infection.

If you or your child notices any side effects not mentioned in this leaflet, please inform your or your child's doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website, or via email to:

patientsafety.sacg@novartis.com. 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.

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

Store at or below 30 °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.

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

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Namibia	
5 mg: 19/32.2/0037	NS2
15 mg: 19/32.2/0038	NS2
20 mg: 19/32.2/0039	NS2