

## PART III: CONSUMER INFORMATION

Pr**JAKAVI**<sup>®</sup>

(ruxolitinib tablets)  
(as ruxolitinib phosphate)

This leaflet is part III of a three-part "Product Monograph" published when JAKAVI was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JAKAVI. Contact your healthcare professional (doctor, pharmacist or nurse) if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### What the medication is used for:

JAKAVI is a prescription drug used to treat adult patients with enlarged spleen and/or its associated symptoms caused by myelofibrosis, a rare form of blood cancer.

JAKAVI is also used to control the haematocrit (the amount of red blood cells in the blood) in adult patients with polycythemia vera who are unable to use or who do not have their hematocrit controlled with a cytoreductive agent.

JAKAVI should be prescribed and monitored by a physician experienced in the use of anti-cancer therapies.

#### What it does:

Myelofibrosis is a disorder of the bone marrow, in which the marrow is replaced by scar tissue. JAKAVI is a kinase inhibitor that works at reducing spleen size and/or its associated symptoms caused by myelofibrosis.

Polycythemia vera is a disorder of the bone marrow, in which the marrow produces too many red blood cells. This makes the blood thicker. JAKAVI is a kinase inhibitor that can reduce the amount of red blood cells in the blood in patients with polycythemia vera.

#### When it should not be used:

##### **Do not take JAKAVI if you:**

- are **allergic** (hypersensitive) to ruxolitinib, or any of the other ingredients of JAKAVI listed under "*What the nonmedicinal ingredients are*".
- have or have had a disease called progressive multifocal leukoencephalopathy (PML).

#### What the medicinal ingredient is:

Ruxolitinib phosphate.

#### What the nonmedicinal ingredients are:

microcrystalline cellulose, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, colloidal silicon dioxide, sodium starch glycolate (Type A), povidone.

#### What dosage forms it comes in:

Tablets; 5 mg, 10 mg, 15 mg and 20 mg

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

Serious infections have been reported in patients treated with JAKAVI. Some cases were life-threatening or lead to death.

#### **BEFORE you use JAKAVI talk to your doctor or pharmacist if you:**

- have any type of infections. It may be necessary to treat your infection before starting 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 had or has tuberculosis. Your doctor may test you to see if you have tuberculosis.
- have any kidney problems.
- have or have ever had liver problems.
- have any heart problems, including low heart rate, or if you ever have fainting spells.
- have intolerance to lactose (milk sugar). JAKAVI contains lactose.
- are pregnant or plan to become pregnant. JAKAVI is not recommended during pregnancy. You must use an effective method of birth control to avoid becoming pregnant while taking JAKAVI.
- are breast –feeding. JAKAVI may harm your baby.
- are a male patient. You must take appropriate precautions to avoid fathering a child during JAKAVI treatment.
- have ever had skin cancer.
- have ever had viral hepatitis B (a liver disease).

#### **Children and adolescents (under 18 years old)**

The safety of JAKAVI in patients younger than 18 years old have not been established.

#### **During your treatment with JAKAVI**

Tell your doctor straight away:

- If you experience unexpected bruising and/or bleeding, unusual tiredness, shortness of breath with exercise or at rest, looking pale, or frequent infections (signs of blood disorders).

- If you experience fever, chills or any symptoms of infections or if you develop painful skin rash with blisters (signs of shingles).
- If you experience chronic cough with blood-tinged sputum, fever, night sweats, and weight loss (these are 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, blurred and/or loss of vision (these are signs of progressive multifocal leukoencephalopathy).
- If you notice any skin changes. This may require further observation, as certain types of skin cancer (non-melanoma) have been reported with the use of JAKAVI. You should minimize your exposure to sunlight and other sources of UV light, such as tanning beds, while taking JAKAVI.
- If you have fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia).

## INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

It is particularly important that you mention any of the following medicines:

- some medicines used to treat infections. These include medicines which treat fungal diseases (antifungals like fluconazole, ketoconazole, itraconazole, posaconazole and voriconazole, or medicines to treat types of bacterial infections (antibiotics like clarithromycin, or telithromycin), or medicines to treat viral infections, including HIV/AIDS (atazanavir, indinavir, nelfinavir, ritonavir, saquinavir).
- Any medications that you are taking that affect the heart or blood pressure, such as antiarrhythmics, digitalis glycosides, antihypertensives and cimetidine (a medicine to treat heartburn).

**While you are taking JAKAVI** you should never start a new medicine without checking first with the doctor who has prescribed you JAKAVI. This includes prescribed medicines, over the counter medicines and herbal or alternative medicines.

## PROPER USE OF THIS MEDICATION

Follow your doctor's instructions carefully. Do not take more JAKAVI than what your doctor told you.

### Usual adult dose:

**Patients with Myelofibrosis:** 15 mg or 20 mg by mouth twice daily

**Patients with Polycythemia vera:** 10 mg by mouth twice daily

The maximum dose is 25 mg twice daily.

It is important to take JAKAVI at about the same time every day. If you require hemodialysis, you only need to take a single dose of JAKAVI after each hemodialysis session.

JAKAVI can be taken either with or without food. **Swallow whole** with a glass of water. Do NOT cut, break, dissolve, crush or chew the tablet.

### **How long to take JAKAVI**

You should continue taking JAKAVI for as long as your doctor tells you to. This is a long-term treatment. Your doctor will regularly monitor your condition to make sure that the treatment is having the desired effect.

If you have questions about how long to take JAKAVI, talk to your doctor or pharmacist.

### **Monitoring during your treatment with JAKAVI**

Before you start treatment with JAKAVI, your doctor will perform blood tests to determine the starting dose for you. Your doctor will carefully check if you have any signs or symptoms of infection before starting and during your treatment with JAKAVI.

You will have some blood tests during your treatment with JAKAVI to monitor the amount of blood cells in your body (white and red blood cells, platelets), and your kidney and liver functions. These tests are performed to see how you respond to the treatment, or to see if JAKAVI is having an unwanted effect. Your doctor may need to adjust the dose of JAKAVI or interrupt your treatment with JAKAVI. You will also have other tests during your treatment with JAKAVI to monitor the condition of your heart beat and blood pressure. Your doctor may also regularly check the level of lipids (fat) in your blood.

### Overdose:

If you take more JAKAVI than you should or in case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### Missed Dose:

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

### **If you stop taking JAKAVI**

If you are taking JAKAVI to treat myelofibrosis and you interrupt your treatment, your myelofibrosis related symptoms may come back. Therefore, you should not stop taking JAKAVI while being treated for myelofibrosis without checking first with your doctor.

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

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include:

- High level of cholesterol (hypercholesterolemia) or fat (hypertriglyceridemia) in the blood
- Dizziness
- Headache
- Abnormal liver function test results
- Weight gain
- Frequently passing gas (flatulence), diarrhea, nausea
- Muscle spasms
- Ringing in the ears
- Back pain
- Numbness
- Anxiety
- Cough, pain in the mouth and/or throat
- Nose bleeds
- Constipation
- High blood pressure (hypertension) may also be the cause of dizziness and headache

**If any of these affects you severely, tell your doctor or pharmacist.**

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Very Common</b>			
-Urinary tract infection: Symptoms like frequent urination, painful urination, blood in the urine		√	
-Tiredness, fatigue, shortness of breath, pale skin (symptoms of anemia which is caused by low level of red blood cells)		√	
-Frequent infections, fever, chills, sore throat or mouth ulcers due to infections (symptoms of neutropenia which is caused by low level of white blood cells)		√	
-Spontaneous bleeding or bruising (symptoms of thrombocytopenia which is caused by low levels of platelets)		√	
<b>Common</b>			
- Painful skin rash with blisters (symptoms of shingles)		√	
-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.			√
- Any sign of heart problems such as low heart beat, chest pain, dizziness, vertigo, fainting			√
- Palpitation		√	
<b>Uncommon</b>			
-Chronic cough with blood-tinged sputum, fever, night sweats, and weight loss (symptoms of tuberculosis)			√
<b>Unknown frequency</b>			

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
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 (symptoms of progressive multifocal leukoencephalopathy).			√

<http://www.novartis.ca>

or by contacting the sponsor  
Novartis Pharmaceuticals Canada Inc., at:  
1-800-363-8883

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PrJAKAVI® (ruxolitinib) is a registered trademark.

*This is not a complete list of side effects. For any unexpected effects while taking JAKAVI contact your doctor or pharmacist.*

**HOW TO STORE IT**

- Do not take JAKAVI after the expiry date shown on the box.
- Store between 15-25 °C.
- Store in the original package.
- Keep out of the reach and sight of children.

Disposal of unused medicines should follow local rules and requirements.

**REPORTING SUSPECTED SIDE EFFECTS**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at MedEffect;(www.healthcanada.gc.ca/medeffect)
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: