Jakavi®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Jakavi?

Jakavi contains the active ingredient ruxolitinib (as phosphate). Jakavi is used to treat adults with myelofibrosis, adults with polycythemia vera, patients aged 28 days and older with acute graft-versus-host disease, and patients aged 6 months and older with chronic graft-versus-host disease (GvHD). For more information, see Section 1. Why am I using Jakavi? in the full CMI.

2. What should I know before I use Jakavi?

Do not take if you have ever had an allergic reaction to ruxolitinib or any of the ingredients listed at the end of the CMI.

Before you start taking Jakavi, your doctor will do some blood tests.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use Jakavi? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Jakavi and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Jakavi?

- Take Jakavi twice a day. Your doctor will tell you how many tablets or how much oral solution to take.
- Jakavi tablets are to be taken by mouth, either with or without food. Swallow the tablets whole with a glass of water.
- Jakavi oral solution can be taken by mouth then followed with some water. If you cannot swallow the solution, it will be given to you through a nasogastric or gastric feeding tube.

More instructions can be found in Section 4. How do I use Jakavi? in the full CMI.

5. What should I know while using Jakavi?

Things you should do	• Keep all of your doctor's appointments so that your progress can be checked • Remind any doctor, dentist, anaesthetist or pharmacist you visit that you are using Jakavi. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine
Things you should not do	• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Do not drive or use machinery if you feel dizzy. • Do not let your child ride a bike or climb if Jakavi makes them dizzy.
Looking after your medicine	• Keep your medicine in the original packaging until it is time to take it. • Tablets: store in a cool, dry place at room temperature, away from moisture and out of reach of children. • Oral solution: Store in the refrigerator but do not place in or too near the freezer section. Once opened, store at room temperature and discard any unused solution after 60 days.

For more information, see Section 5. What should I know while using Jakavi? in the full CMI.

6. Are there any side effects?

The most common side effects include bruising, dizziness, headaches, constipation, feeling tired, infections, fever, chills, sore throat, mouth ulcers, nausea, high blood pressure and pale skin. The more serious side effects include urinary tract and other serious infections, shingles, bruising more easily, blood disorders and trouble breathing. These may require urgent medical attention. **Tell your doctor or pharmacist if you notice anything else that worries you or that may be making you feel unwell.**
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Jakavi (JAK-uh-vee)

Active ingredient: *Ruxolitinib* (RUX-soh-LI-ti-nib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Jakavi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Jakavi.**

Where to find information in this leaflet:

1. Why am I using Jakavi?
2. What should I know before I use Jakavi?
3. What if I am taking other medicines?
4. How do I use Jakavi?
5. What should I know while using Jakavi?
6. Are there any side effects?
7. Product details

1. Why am I using Jakavi?

Jakavi contains the active ingredient ruxolitinib. Jakavi belongs to a group of medicines called "JAK inhibitors".

Jakavi is used to treat:

- **Myelofibrosis in adult patients:**

Myelofibrosis (MF) is a disorder of the bone marrow, in which the marrow is replaced by scar tissue. The abnormal marrow can no longer produce enough normal blood cells and results in variety of symptoms such as fever, night sweats, bone pain, weight loss and a significantly enlarged spleen. Jakavi can reduce spleen size in patients with different forms of MF and relieve the symptoms.

- **Polycythemia vera in adult patients who are intolerant of or not controlled with hydroxyurea:**

Polycythemia vera (PV) 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 leading to a variety of symptoms such as itching (pruritus), headache, vision problems, severe burning pain in the hands or feet, and blood vessels clots. Enlarged spleen is also sometimes present. Jakavi can relieve the symptoms, reduce spleen size and the volume of red blood cells produced in patients with PV.

- **Acute graft-versus-host disease in patients aged 28 days and older who have inadequate response to corticosteroids:**

Graft-versus-host disease (GvHD) is a complication that occurs after transplantation of blood or bone marrow from a healthy donor to a patient, for example when specific cells (T cells) in the donor's graft (e.g. bone marrow) don't recognize the host cells/organs and attack them.

Acute GvHD usually develops soon after the transplantation and can affect skin, liver and gastrointestinal tract.

- **Chronic graft-versus-host disease in patients aged 6 months and older who have inadequate response to corticosteroids:**

Graft-versus-host disease (GvHD) is a complication that occurs after transplantation of blood or bone marrow from a healthy donor to a patient, for example when specific cells (T cells) in the donor's graft (e.g. bone marrow) don't recognize the host cells/organs and attack them.

Chronic GvHD, usually develops later than acute GvHD, around three months after the transplantation. Chronic GvHD frequently causes symptoms in the skin, liver, mouth, lungs, gastrointestinal tract, neuromuscular system, or genitourinary tract. Almost any organ can be affected by chronic GvHD.

Jakavi can reduce the symptoms of acute and chronic GvHD, leading to disease improvement and survival of the transplanted cells.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use Jakavi?

Warnings

Do not take Jakavi if:

- you are allergic to ruxolitinib, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Check with your doctor if you have:

- allergies to any other medicines, foods, preservatives or dyes
- an intolerance to lactose
- an infection
- problems with your kidney
- problems with your liver
- skin cancer or any secondary type of cancer
- tuberculosis
- viral hepatitis B
- cardiovascular risk factors such as high blood pressure, high cholesterol, being overweight, are physically inactive
- smoked in the past or currently smoke

- diverticulitis, an inflammation of parts of the large intestine.

Check with your doctor for a blood test before starting Jakavi

It is important that you have a full blood count before starting Jakavi and regularly during treatment with this medicine. The results will help your doctor decide what dose is best for you.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in Jakavi passes into breast milk. There is a possibility that your baby may be affected.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Children

Acute GvHD: this medicine can be used in patients aged 28 days and older.

Chronic GvHD: this medicine can be used in patients aged 6 months and older.

MF and PV: this medicine can be used in adult patients. There is not enough information to recommend the use of this medicine for children under the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you can buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Jakavi may interfere with each other and affect how it works. These include:

- some medicines used to treat fungal infections, such as ketoconazole, itraconazole, posaconazole and voriconazole
- some medicines used to treat types of bacterial infections, such as antibiotics like ciprofloxacin, clarithromycin, erythromycin or telithromycin
- some medicines used to treat viral infections medicines used to treat HIV/AIDS such as atazanavir, indinavir, nelfinavir, ritonavir, saquinavir
- some medicines used to treat high blood pressure such as verapamil, nifedipine or carvedilol.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information. **Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Jakavi.**

4. How do I use Jakavi?

Jakavi is available as tablets and an oral solution.

How to take Jakavi

Tablets: swallow Jakavi tablets whole with a glass of water.

Oral solution: measure the correct amount of Jakavi solution, then swallow your dose and have some water to ensure the medicine has been completely swallowed.

For more information on how to take the oral solution, please see the instructions for use, available via the hyperlink, your pharmacist or doctor.

If you cannot swallow the oral solution, it will be given to you through a nasogastric or gastric feeding tube.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

- Your doctor will tell you how many tablets or oral solution to take each day.
- Your doctor may adjust your dose depending on how you respond to treatment and results from your blood, liver and kidney tests. Your doctor may also need to know if you are taking any other medicines.
- If you notice you are feeling unwell while taking Jakavi, your doctor might change the amount of Jakavi you take or tell you to stop taking Jakavi for a while.

When to take Jakavi

- Take Jakavi twice a day, every day, either with or without food.
- If you receive dialysis, take one single dose of Jakavi after each dialysis session. Your doctor will tell you how many tablets you need to take.
- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to use Jakavi

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

How long to take it

Continue taking Jakavi for as long as your doctor tells you to.

This is 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.

If you use too much Jakavi

If you think that you or anyone else may have taken too much Jakavi, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Jakavi?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked. Before and during your treatment with Jakavi, your doctor may do some blood tests and check the condition of your liver and kidneys to make sure the medicine is working and to prevent unwanted side effects. Your doctor may also regularly check the level of lipids (fat) in your blood, and periodically check for changes to your skin.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Remind any doctor, dentist or pharmacist you visit that you are using Jakavi.

Call your doctor straight away if you:

- do not feel well while you are taking Jakavi even if you do not think it is connected with the medicine.
- become pregnant while you are taking this medicine.
- develop signs of unusual bleeding, bruising more easily than normal, fatigue/tiredness, shortness of breath, fever.

Things you should not do

- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your doctor tells you to.
- Avoid eating grapefruit or grapefruit juice while taking Jakavi as it may interfere with how the medicine works.
- Do not stop taking your medicine or change the dose without checking with your doctor.
- Do not use the oral solution if it has been opened for more than 60 days.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Driving or using machines

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Jakavi affects you. Children should avoid riding bikes, climbing or any activities where they need to be alert.

Jakavi may cause dizziness in some people. Watch your child until you know how Jakavi affects them.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it.
- Do not store this medicine or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on window sills.

Tablets: Store in a cool, dry place at room temperature (below 30°C) away from direct sunlight.

Oral Solution: Store the bottle in the refrigerator but do not place in or near the freezer section. After opening, store at room temperature (below 30°C) and discard any unused solution after 60 days.

Follow the instructions on the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Disposal

If it has expired or is damaged, return it to your pharmacist for disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Less serious side effects

Less serious side effects	What to do
• Dizziness • Headache • Excess amount of gas in the bowels (flatulence) • Constipation • Nausea • Weight gain • Tiredness, fatigue, pale skin (possible symptoms of anaemia which is caused by low level of red blood cells).	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

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.

Serious side effects

Serious side effects	What to do
Bleeding problems: • Unusual bleeding, cuts that won't stop bleeding • Bruising more easily than normal • Extreme tiredness. **Infections:** • Pain when urinating • fever, chills, sore throat or mouth ulcers • Shingles (herpes zoster) - painful skin rash with blisters • Fast heart rate, fever, confusion and rapid breathing. **Skin disorders:** • Moles which may change size, shape or colour over time, or new moles which may be symptoms - of skin cancer (non-melanoma. **Respiratory disorders:** • Fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia, infection with the cytomegalovirus or infection with the BK virus) • Persistent cough with blood-tinged sputum, fever, night sweats and weight loss (possible symptoms of tuberculosis.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Other side effects not listed here may occur in some people and may only be found when your doctor does tests from time to time to check your progress. These include:

- 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 or kidney function test results
- high blood pressure (hypertension)
- Increased blood level of enzymes from muscle.

Tell your doctor as soon as possible if you notice any of the following side effects. These have been seen with other JAK inhibitors used to treat rheumatoid arthritis, a condition that Jakavi is not used for:

- Chest pain or pressure that may spread to your jaw, neck or left arm
- Shortness of breath, a cold sweat
- Painful swollen legs, redness or tenderness in the leg or arm
- Stomach ache that won't go away, change in bowel habits.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

Jakavi is not addictive.

What Jakavi tablets contain

Active ingredient (main ingredient)	ruxolitinib (as phosphate)
Other ingredients (inactive ingredients)	microcrystalline cellulose magnesium stearate colloidal anhydrous silica sodium starch glycollate type A hyprolose povidone lactose monohydrate.

	microcrystalline cellulose
Potential allergens	Contains sugars as lactose. It does not contain sucrose, gluten, tartrazine or any other azo dyes.

What Jakavi oral solution contains

Active ingredient (main ingredient)	ruxolitinib (as phosphate)
Other ingredients (inactive ingredients)	Propylene glycol citric acid methyl hydroxybenzoate propyl hydroxybenzoate sucralose EVOSPRAY® Strawberry flavour (209386) purified water
Potential allergens	Contains hydroxybenzoates, sucralose. It does not contain sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Jakavi looks like

Jakavi tablets are available in four different strengths and is supplied in packs of 56 tablets.

- 5 mg: round curved and white to almost white tablets with "L5" on one side and "NVR" on the other (AUST R 198934)
- 10mg: Round curved white to almost white tablets with "L10" on one side and "NVR" on the other (AUST R 232702)
- 15 mg: ovaloid curved and white to almost white tablets with "L15" on one side and "NVR" on the other (AUST R 198936)
- 20 mg: elongated curved white to almost white tablets with "L20" on one side and "NVR" on the other (AUST R 198933).

Jakavi 5 mg/mL oral solution (not available) is packed in amber glass bottles of 60 mL. It is a clear, colourless to light yellow solution, it may have small colourless particles or slight sediment. Each bottle is packed in a carton together with one press-in bottle adaptor and two 1 mL oral syringes, (AUST R 522726).

Who distributes Jakavi

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone 1 800 671 203

Web site: www.novartis.com.au

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This leaflet was prepared in July 2026.

(jak310726c.doc) based on PI (jak310726i.doc)