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Jakafi

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Generic name: ruxolitinib [RUX-oh-LI-ti-nib]

Drug class: Multikinase inhibitors

Medically reviewed by <u>Judith Stewart</u>, <u>BPharm</u>. Last updated on Sep 29, 2023.

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What is Jakafi?

Jakafi is used to treat certain types of myelofibrosis in adults.

Jakafi is also used to treat polycythemia vera in adults who have already taken a medicine called hydroxyurea and it did not work well enough or they could not tolerate it.

Jakafi is used to treat acute graft versus host disease (aGVHD) in adults and children 12 years of age and older who have taken corticosteroids and they did not work well enough.

Jakafi works by blocking certain enzymes in the body that affect blood cell production.

Warnings

You should not use Jakafi if you are allergic to ruxolitinib, or if you have severe kidney disease.

Before you take this medicine, tell your doctor if you have liver or kidney disease, if you are on dialysis, or if you are pregnant.

You should not breast-feed while you are using this medicine.

To be sure Jakafi is helping your condition and not causing harmful effects, your blood will need to be tested often. This will help your doctor determine the best dose for you to use. When you first start taking this medicine, your blood will need to be tested every 2 to 4 weeks. Do not miss any follow-up visits to your doctor.

Grapefruit and grapefruit juice may interact with Jakafi and can affect the amount of the medication in your blood. Discuss the use of grapefruit products with your doctor.

Follow all directions on your medicine label and package. Tell each of your healthcare providers about all your medical conditions, allergies, and all medicines you use.

Before taking this medicine

You should not use Jakafi if you are allergic to ruxolitinib.

Tell your doctor if you have ever had tuberculosis or if anyone in your household has tuberculosis. Also, tell your doctor if you've had or been exposed to tuberculosis, or if you recently traveled. Some infections are more common in certain parts of the world, and you may have been exposed during travel.

To make sure Jakafi is safe for you, tell your doctor if you have ever had:

- any type of infection;
- shingles (herpes zoster);
- a blood clot, stroke, heart attack, or other heart problems;
- · low white or red blood cell counts;
- any type of cancer;
- · are a current or past smoker;
- kidney disease (or if you are on dialysis);
- liver disease (especially hepatitis B); or
- high cholesterol or triglycerides (types of fat in the blood).

It is not known if ruxolitinib will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

Do not breastfeed while using Jakafi, and for at least 2 weeks after your last dose.

Jakafi is not approved for the treatment of myelofibrosis or polycythemia vera by anyone younger than 18 years old.

1 Jakafi pregnancy and breastfeeding warnings (more detail)

How should I take Jakafi?

Take Jakafi exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Your doctor may occasionally change your dose. You will need frequent medical tests to help your doctor determine the best dose.

You may take Jakafi with or without food. The Jakafi tablet can also be given through a nasogastric (NG) feeding tube.

Read and carefully follow any Instructions for Use provided with the medicine. Ask your doctor or pharmacist if you do not understand these instructions.

If you are on dialysis, Jakafi should be taken after your dialysis.

Using Jakafi may increase your risk of developing other cancers. Ask your doctor about this risk.

Store at room temperature away from moisture and heat.

You should not stop using Jakafi suddenly. Follow your doctor's instructions about tapering your dose.

You may be given other medications to help prevent infection. Keep taking these medicines for as long as your doctor

has prescribed.

Dosing information

Usual Adult Dose of Jakafi for Myeloproliferative Disorder:

Doses should be titrated based on safety and efficacy; CBC (complete blood count) and platelet counts should be performed every 2 to 4 weeks until doses are stabilized and then as clinically indicated

Initial Dose Based on Platelet Count:

- -Platelets greater than 200 x 10⁹/L: 20 mg orally twice a day
- -Platelets 100 x 10(9)/L to 200 x 10⁹/L: 15 mg orally twice a day
- -Platelets 50 x 10⁹/L to less than 100 x 10⁹/L: 5 mg orally twice a day

Comments:

- -Based on limited clinical data, long-term maintenance at 5 mg twice a day has not shown benefit; this dose should be limited to patients for whom the benefits outweigh the potential risks.
- -Discontinue therapy if there is no spleen size reduction or symptom improvement after 6 months of therapy.

Uses:

-For the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocythemia MF.

Usual Adult Dose of Jakafi for Graft Versus Host Disease:

Monitor complete blood counts (CBC), including platelet count and ANC, and bilirubin prior to initiating therapy, every 2 to 4 weeks until doses are stabilized, and then as indicated clinically:

Acute Graft-Versus-Host Disease (GVHD): Initial dose: 5 mg orally 2 times a day

-Dose titration: Consider increasing dose to 10 mg orally 2 times a day after at least 3 days if the ANC (absolute neutrophil count) and platelet counts are not decreased by 50% or more relative to the first day of dosing Duration of therapy: Consider tapering after 6 months for those with response who have stopped therapeutic doses of corticosteroids; taper by 1 dose level every 8 weeks (see comments); if signs or symptoms of GVHD recur during or after taper, consider retreatment

Chronic GVHD: Initial dose: 10 mg orally 2 times a day

-Duration of therapy: Consider tapering after 6 months for those with response who have stopped therapeutic doses of corticosteroids; taper by 1 dose level every 8 weeks (see comments); if signs or symptoms of GVHD recur during or after taper, consider retreatment

Comments:

- -Dose level decreases: 10 mg twice a day to 5 mg twice a day to 5 mg once a day.
- -See Dose Adjustment section for dose modification guidance for adverse reactions.

Uses: For the treatment of steroid-refractory acute GVHD and treatment of chronic GVHD after failure of 1 or 2 lines of systemic therapy.

Usual Adult Dose of Jakafi for Polycythemia Vera:

Doses should be titrated based on safety and efficacy; CBC and platelet counts should be performed every 2 to 4 weeks until doses are stabilized and then as clinically indicated

Initial dose: 10 mg orally twice a day

-Dose may be titrated based on safety and efficacy

Use: For treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.

Usual Pediatric Dose of Jakafi for Graft Versus Host Disease:

12 years or older:

Monitor complete blood counts (CBC), including platelet count and ANC, and bilirubin prior to initiating therapy, every 2 to 4 weeks until doses are stabilized, and then as indicated clinically:

Acute Graft-Versus-Host Disease (GVHD): Initial dose: 5 mg orally 2 times a day

-Dose titration: Consider increasing dose to 10 mg orally 2 times a day after at least 3 days if the ANC (absolute neutrophil count) and platelet counts are not decreased by 50% or more relative to the first day of dosing Duration of therapy: Consider tapering after 6 months for those with response who have stopped therapeutic doses of corticosteroids; taper by 1 dose level every 8 weeks (see comments); if signs or symptoms of GVHD recur during or after taper, consider retreatment

Chronic GVHD: Initial dose: 10 mg orally 2 times a day

-Duration of therapy: Consider tapering after 6 months for those with response who have stopped therapeutic doses of corticosteroids; taper by 1 dose level every 8 weeks (see comments); if signs or symptoms of GVHD recur during or after taper, consider retreatment

Comments:

- -Dose level decreases: 10 mg twice a day to 5 mg twice a day to 5 mg once a day.
- -See Dose Adjustment section for dose modification guidance for adverse reactions.

Uses: For the treatment of steroid-refractory acute GVHD and treatment of chronic GVHD after failure of 1 or 2 lines of systemic therapy in pediatric patients 12 years or older.

Detailed Jakafi dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking Jakafi?

Grapefruit may interact with ruxolitinib and cause side effects. Avoid consuming grapefruit products.

Jakafi side effects

Get emergency medical help if you have **signs of an allergic reaction to Jakafi:**: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Some side effects may be similar to the symptoms of myelofibrosis. Call your doctor at once if you have:

- changes in the size, shape, or color of a mole or skin lesion;
- problems with speech, thought, vision, or muscle movement (these symptoms may start gradually and get worse quickly);
- nausea, vomiting, weakness, general ill feeling;
- cold sores around your mouth, skin sores or blisters, itching, tingling, skin rash, burning pain in your thigh or lower back;
- pain in your arms, back, neck, jaw, or stomach;
- signs of a stroke sudden numbness or weakness, severe headache, slurred speech, problems with vision or balance;
- signs of a blood clot in the lung chest pain, sudden cough or shortness of breath, dizziness, coughing up blood;
- signs of a blood clot deep in the body pain, swelling, or warmth in one leg;
- heart attack symptoms chest pain or pressure, pain spreading to your jaw or shoulder, nausea, sweating;
- signs of infection fever, chills, sore throat, body aches, unusual tiredness, loss of appetite, bruising or bleeding;
- low blood cell counts fever, chills, tiredness, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet, feeling light-headed or short of breath; or
- signs of tuberculosis: fever, cough, night sweats, loss of appetite, weight loss, and feeling very tired.

Common Jakafi side effects may include:

- low blood cell counts;
- · swelling;
- infection;
- · bruising;
- · diarrhea;
- · dizziness; or
- headache.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Jakafi side effects (more detail)

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What other drugs will affect Jakafi?

Sometimes it is not safe to use certain medicines at the same time. Some drugs can affect your blood levels of other drugs you use, which may increase side effects or make the medicines less effective.

Tell your doctor about all your other medicines, especially fluconazole.

This list is not complete and many other drugs may interact with ruxolitinib. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Jakafi drug interactions (more detail)

Does Jakafi interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Jakafi	
+	
Enter a drug name	Add

Popular FAQ

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Professional resources

- Jakafi prescribing information
- Ruxolitinib Phosphate (AHFS Monograph)

Related treatment guides

- Myelofibrosis
- Polycythemia Vera
- Graft Versus Host Disease
- Myeloproliferative Disorders

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Jakafi only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

& Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2011

User Reviews & Ratings

7.5 / 10

33 Reviews

Images

Jakafi 10 mg (INCY 10)



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