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## Ruxolitinib

pronounced as (rux" oh li' ti nib)

### Why is this medication prescribed?

Ruxolitinib is used to treat myelofibrosis (a cancer of the bone marrow in which the bone marrow is replaced by scar tissue and causes decreased blood cell production). It is also used to treat polycythemia vera (PV; a slow growing cancer of the blood in which the bone marrow makes too many red blood cells) in people who were not able to be treated successfully with hydroxyurea. Ruxolitinib is also used to treat acute graft versus host disease (aGVHD; a complication of hematopoietic stem-cell transplant [HSCT; a procedure that replaces diseased bone marrow with healthy bone marrow] that usually develops within the first months after HSCT) in adults and children 12 years of age and older who were treated unsuccessfully with steroid medications. It is also used to treat chronic GVHD (cGVHD; a complication of HSCT that usually develops at least 3 months after HSCT) in adults and children 12 years of age and older who were treated unsuccessfully with 1 or 2 other treatments. Ruxolitinib is in a class of medications called kinase inhibitors. It works to treat myelofibrosis and PV by blocking the signals that cause cancer cells to multiply. This helps to stop the spread of cancer cells. It works to treat GVHD by blocking the signals of the cells that cause GVHD.

### How should this medicine be used?

Ruxolitinib comes as a tablet to take by mouth. It is usually taken with or without food two times a day. Take ruxolitinib at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ruxolitinib exactly as directed. Do not take more or less of it, or take it more often than prescribed by your doctor.

If you are being treated for myelofibrosis or PV your doctor may start you on a low dose of ruxolitinib for the first four weeks of treatment, and gradually increase your dose after that time, not more than once every 2 weeks. If you are being treated for acute GVHD your doctor may start you on a low dose of ruxolitinib and may increase your dose after at least 3 days of therapy. If you are being treated for acute or chronic GVHD your doctor may gradually lower your dose of ruxolitinib after at least 6 months of therapy.

Swallow the tablets whole; do not chew or crush them.

If you can not have food by mouth and have a nasogastric (NG) tube, your doctor may tell you to take ruxolitinib through the nasogastric (NG) tube. Your doctor or pharmacist will explain how to prepare

ruxolitinib to give through an NG tube.

Your doctor will order blood tests before and during your treatment to see how you are affected by this medication. Your doctor may increase or decrease your dose of ruxolitinib during your treatment, or may tell you to stop taking ruxolitinib for awhile. This depends on how well the medication works for you, your lab test results, and if you experience side effects. Talk to your doctor about how you are feeling during your treatment. Continue to take ruxolitinib even if you feel well. Do not stop taking ruxolitinib without talking to your doctor. If your doctor decides to stop your treatment with ruxolitinib, your doctor may decrease your dose gradually.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking ruxolitinib,

- tell your doctor and pharmacist if you are allergic to ruxolitinib, any other medications, or any of the ingredients in ruxolitinib. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antifungal medications including itraconazole (Sporanox), ketoconazole, and voriconazole (Vfend); carbamazepine (Carbatrol, Equetro, Tegretol, others); clarithromycin; efavirenz (Sustiva, in Atripla, Symfi); erythromycin (E.E.S, Eryc, Ery-tab); fluconazole (Diflucan); HIV protease inhibitors including indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra, Viekira Pak), and saquinavir (Invirase); nefazodone; nevirapine (Viramune); phenytoin (Dilantin, Phenytek); pioglitazone (Actos, in Oseni, Duetact); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, in Rifamate, Rifater); and telaprevir (Incivik). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with ruxolitinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have anemia, an infection, if you are on dialysis, or if you were recently around someone who has tuberculosis (TB, a severe lung infection) or visited or lived where TB is common. Also tell your doctor if you are a current or past smoker; if you have or have ever had TB; high cholesterol or triglycerides; a blood clot, heart attack, stroke, or other heart problems; skin cancer; herpes zoster (shingles); hepatitis B or other liver disease; or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking ruxolitinib, call your doctor. You should not breast-feed while taking ruxolitinib and for 2 weeks after your final dose.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Ruxolitinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- dizziness
- headache
- tiredness
- shortness of breath
- weight gain
- gas
- diarrhea
- constipation
- nausea
- rash
- muscle or joint pain
- swelling of the arms, legs or other parts of the body

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- unusual or heavy bleeding or bruising
- fever, sore throat, chills, cough, chest pain, night sweats, frequent, painful, urgent urination, and other signs of infection
- burning, tingling, itching, or skin sensitivity on one side of the body or face with painful rash or blisters appearing several days later.
- new sores, bumps, or discoloration or other changes to the skin
- pale skin, tiredness, or shortness of breath (especially while exercising)
- difficulty moving or keeping your balance, weakness of the legs or arms that keeps getting worse, difficulty understanding or speaking, loss of memory, vision problems, or changes in personality
- swelling, pain, tenderness, warmth or redness in one or both legs
- shortness of breath
- difficulty breathing
- pain in the chest, arms, back, neck, jaw, or stomach
- breaking out in cold sweat

- nausea or vomiting
- lightheadedness
- slow or difficult speech
- numbness or weakness of the face, arm, or leg on one side of your body

Ruxolitinib may increase the risk that you will develop skin cancer or other cancers. Talk to your doctor about the risks of taking this medication.

Ruxolitinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- unusual bleeding or bruising
- dizziness
- headache

- tiredness
- fever, sore throat, chills, cough, and other signs of infection

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to ruxolitinib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Jakafi

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