JAKAVI® TABLETS

Ruxolitinib (5mg, 10mg, 15mg, 20mg)

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What Jakavi 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 6 years of age and older and adults with graft-versus-host disease (GvHD). 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, usually weeks to months after the transplantation. Almost any organ can be affected by chronic GvHD.

How Jakavi works

Enlargement of the spleen is one of the characteristics of myelofibrosis. Myelofibrosis 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 as a result the spleen becomes significantly enlarged. By blocking the action of certain enzymes (called Janus Associated Kinases), Jakavi can reduce the size of the spleen in patients with myelofibrosis and relieve symptoms such as fever, night sweats, bone pain and weight loss. Jakavi can help reduce the risk of serious blood or vascular complications.

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. Jakavi can relieve the symptoms, reduce spleen size and the volume of red blood cells produced in patients with polycythaemia vera by selectively blocking enzymes called Janus Associated Kinases (JAK1 and JAK2), thus potentially reducing 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) do not recognise the host cells/organs and attack them. By selectively blocking enzymes called Janus Associated Kinases (JAK1 and JAK2), Jakavi reduces 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 this medicine has been prescribed for you, ask your doctor.

Before you use Jakavi

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

When you must not use it

- if you are allergic to ruxolitinib or any of the other ingredients of this medicine.
- if you are pregnant or breast-feeding.

Pregnancy and breast-feeding

Do not take Jakavi during pregnancy. Talk to your doctor about how to use appropriate contraception to avoid becoming pregnant during your treatment with Jakavi.
Do not breastfeed while taking Jakavi. Ask your doctor for advice.
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Before you start to use it

Talk to your doctor or pharmacist before taking Jakavi if:

- you have any infections. It may be necessary to treat your infection before starting Jakavi.
- you have ever had tuberculosis or if you have been in close contact with someone who has or has had tuberculosis. Your doctor may perform tests to see if you have tuberculosis or any other infections.
- you have ever had hepatitis B.
- you have kidney problems oryou have or have ever had liver problems because your doctor may need to prescribe a different dose of Jakavi.
- you have ever had cancer, in particular skin cancer.
- you have or have had heart problems.
- you are 65 years of age or older. Patients aged 65 years and older may be at increased risk of heart problems, including heart attack, and some types of cancer.
- you are a smoker or have smoked in the past.
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Blood tests

Before you start treatment with Jakavi and during treatment, your doctor will do blood tests to find the best sdose, to see how you are responding to the treatment and whether Jakavi is having an unwanted effect. Your doctor may need to adjust the dose or stop treatment. Your doctor will carefully check if you have any signs or symptoms of infection before starting and during your treatment with Jakavi.

Children and adolescents

This medicine is not intended for use by children or adolescents

aged below 18 years, who have the disease myelofibrosis or polycythaemia vera because it has not been studied in this age group.

For the treatment of graft-versus-host disease, Jakavi can be used in patients 6 years and older.

Taking other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is particularly important that you mention medicines containing any of the following active substances, as your doctor may need to adjust the Jakavi dose:

- Some medicines used to treat infections:
  - medicines used to treat fungal diseases (such as ketoconazole, itraconazole, posaconazole, fluconazole and voriconazole)
  - antibiotics used to treat bacterial infections (such as clarithromycin, telithromycin, ciprofloxacin, or erythromycin)
  - medicines to treat viral infections, including HIV infection/AIDS (such as amprenevir, atazanavir, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir, saquinavir)
  - medicines to treat hepatitis C (boceprevir, telaprevir)
  - A medicine to treat depression (nefazodone)
  - Medicines to treat high blood pressure (hypertension) and chest tightness, heaviness or pain (chronic angina pectoris)(mibefradil or diltiazem)
  - A medicine to treat heartburn (cimetidine)
  - A medicine to treat heart disease (avasimibe)
  - Medicines used to stop seizures or fits (phenytoin, carbamazepine or phenobarbital and other anti-epileptics)
  - Medicines used to treat tuberculosis (TB)(rifabutin or rifampicin)
  - A herbal product used to treat depression (St. John's wort (*Hypericum perforatum*))

Talk to your doctor if you are not sure if the above applies to you.

How to use Jakavi
Always take this medicine exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.

How much to use
Myelofibrosis
Adults: The recommended starting dose is 5 mg to 20 mg twice daily. The maximum dose is 25mg twice daily.

Polycythaemia vera
Adults: The recommended starting dose is 10 mg twice daily. The maximum dose is 25 mg twice daily.

Acute and chronic graft versus host disease
- Children 6 years to less than 12 years old: The recommended starting dose is 5mg twice daily.
- Children 12 years and older and adults: The recommended starting dose is 10mg twice daily.

When to use Jakavi
You should take Jakavi every day at the same time, either with or without food.

How long to use Jakavi
You should continue taking Jakavi for as long as your doctor tells you to.

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

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

If you use too much (overdose)
If you accidentally take more Jakavi than your doctor prescribed, contact your doctor or pharmacist immediately.

While you are using Jakavi
Things you must do
Talk to your doctor or pharmacist during your treatment with Jakavi if:
- you experience fever, chills or other symptoms of infections.
- you experience chronic coughing with blood-tinged sputum, fever, night sweats and weight loss (these can be signs of tuberculosis).
- 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 may be signs of a serious brain infection and your doctor may suggest further testing and follow-up.
- you develop painful skin rash with blisters (these are signs of shingles).
- you have any skin changes. This may require further observation, as certain types of skin cancer (non-melanoma) have been reported.
- you experience sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm as these can be signs of blood clots in the veins.

Things you must not do
While you are taking Jakavi
You should 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.

If you stop taking Jakavi
If you interrupt your treatment with Jakavi your symptoms related to myelofibrosis or polycythaemia vera may come back. In graft-versus-host disease, a reduction in your dose or stopping your treatment with Jakavi is possible if you respond to treatment and your doctor will supervise this procedure. Therefore, you should not stop taking Jakavi or change the dose without discussing it with your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Things to be careful of
Driving and using machines
If you experience dizziness after taking Jakavi, do not drive or use 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 this medicine.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Most of the side effects of Jakavi are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Myelofibrosis and polycythaemia vera
Some side effects could be serious.
Seek medical help immediately prior to taking the next scheduled dose if you experience the following serious side effects:
Very common (may affect more than 1 in 10 people):
- any sign of bleeding in the stomach or intestine, such as passing black or bloodstained stools, or vomiting blood
- unexpected bruising 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*)

Common (may affect up to 1 in 10 people):
- any sign of bleeding in the brain, such as sudden altered level of consciousness, persistent headache, numbness, tingling, weakness or paralysis

Other side effects
Other possible side effects include the following listed below. If you experience these side effects, talk to your doctor or pharmacist.
Very common (may affect more than 1 in 10 people):
- high level of cholesterol or fat in the blood *(hypertriglyceridaemia)*
- abnormal liver function test results
- dizziness
- headache
- urinary tract infections
- weight gain
- fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia)
- high blood pressure (*hypertension*), which may also be the cause of dizziness and headaches
- constipation
- high level of lipase in the blood

Common (may affect up to 1 in 10 people):
- reduced number of all three types of blood cells - red blood cells, white blood cells, and platelets (*pancytopenia*)
- frequently passing wind (*flatulence*)

Uncommon (may affect up to 1 in 100 people):
- tuberculosis
- recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-colored urine, right-sided stomach pain, fever and feeling nauseous or being sick).

Graft-versus-host disease (GvHD)
Some side effects could be serious.
Seek medical help immediately prior to taking the next scheduled dose if you experience the following serious side effects:
Very common (may affect more than 1 in 10 people):
- signs of infections with fever associated with:
  - muscle pain, skin redness, and/or difficulty breathing *(cytomegalovirus infection)*
  - pain when urinating (urinary tract infection)
  - fast heart rate, confusion and rapid breathing (sepsis, which is a condition associated with an infection and widespread inflammation)
- frequent infections, fever, chills, sore throat or mouth ulcers
- spontaneous bleeding or bruising - possible symptoms of thrombocytopenia which is caused by low levels of platelets

Other side effects
Very common (may affect more than 1 in 10 people):
- headache
- high blood pressure *(hypertension)*

- abnormal blood test, including:
  - high level of lipase and/or amylase
  - high level of cholesterol
  - abnormal liver function
  - increased level of a muscle enzyme (increased blood creatine phosphokinase)
  - increased level of creatinine, an enzyme which may indicate that your kidneys are not functioning properly
  - low counts of all three types of blood cells: red blood cells, white blood cells, and platelets (*pancytopenia*)
- feeling sick (nausea)
- tiredness, fatigue, pale skin – possible symptoms of anaemia which is caused by low level of red blood cells

Common (may affect up to 1 in 10 people):
- fever, muscle pain, pain or difficulty urinating, blurred vision, cough, cold or difficulty breathing - possible symptoms of infection with BK virus
- weight gain
- constipation

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Jakavi
- *Storage*

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 label.
Do not store above 30°C.

- *Disposal*

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 to protect the environment.

Product Description
What it looks like
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.

Available in blister packs [PVC/PCTFE (Aclar) or PVC/PE/PVdC (Triplex) with aluminium backing] of 14 and 56 tablets.

Not all packs may be marketed in your country.

Ingredients
- *Active ingredients*
  - 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.

- *Inactive ingredients*

The other ingredients are: microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, sodium starch glycolate, povidone, hydroxypropylcellulose, lactose monohydrate.
MAL Number
Jakavi 5MG Tablet:
MAL13025059ARZ

Jakavi 10MG Tablet:
MAL16075030ARZ

Jakavi 15MG Tablet:
MAL13025060ARZ

Jakavi 20MG Tablet:
MAL13025061ARZ

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Novartis Pharmaceutical Manufacturing LLC
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Product Registration Holder
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