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Package leaflet: Information for the patient
Ruxolitinib 5 mg tablets
Ruxolitinib 10 mg tablets
Ruxolitinib 15 mg tablets
Ruxolitinib 20 mg tablets
ruxolitinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The information in this leaflet is for you or your child – but in the leaflet it will just say "you".

What is in this leaflet

1. WHAT RUXOLITINIB IS AND WHAT IT IS USED FOR

Ruxolitinib contains the active substance ruxolitinib.
Ruxolitinib is used to treat adult patients with an enlarged spleen or with symptoms related to myelofibrosis, a rare form of blood cancer.
Ruxolitinib is also used to treat adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.
Ruxolitinib is also used to treat:
- children aged 28 days and older and adults with acute graft versus host disease (GvHD).
- children aged 6 months and older and adults with chronic 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 Ruxolitinib 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), Ruxolitinib can reduce the size of the spleen in patients with myelofibrosis and relieve symptoms such as fever, night sweats, bone pain and weight loss in patients with myelofibrosis. Ruxolitinib can help reduce the risk of serious blood or vascular complications.
Polycythaemia vera is a disorder of the bone marrow, in which the marrow produce too many red blood cells. The blood becomes thicker as a result of the increased red blood cells.
Ruxolitinib 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), Ruxolitinib 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 Ruxolitinib works or why this medicine has been prescribed for you, ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RUXOLITINIB

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

Do not take Ruxolitinib
- if you are allergic to ruxolitinib or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast-feeding (see section 2 "Pregnancy, breast-feeding and contraception").

Warnings and precautions
Talk to your doctor or pharmacist before taking Ruxolitinib if:
- you have any infections. It may be necessary to treat your infection before starting Ruxolitinib.
- 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 or you have or have ever had liver problems because your doctor may need to prescribe a different dose of Ruxolitinib.
- 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.

Talk to your doctor or pharmacist during your treatment with Ruxolitinib 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.

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, Ruxolitinib can be used in patients 28 days and older.

Other medicines and Ruxolitinib
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. While you are taking Ruxolitinib you should never start a new medicine without checking first with the doctor who prescribed Ruxolitinib. This includes prescription medicines, non-prescription medicines and herbal or alternative medicines.
It is particularly important that you mention medicines containing any of the following active substances, as your doctor may need to adjust the Ruxolitinib 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 amprenavir, 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.

Pregnancy, breast-feeding and contraception
Pregnancy
- 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.
- Do not take Ruxolitinib during pregnancy (see section 2 "Do not take Ruxolitinib ").

Breast-feeding
- Do not breastfeed while taking Ruxolitinib (see section 2 "Do not take Ruxolitinib"). Ask your doctor for advice.

Contraception
- Taking Ruxolitinib is not recommended for women who could become pregnant and who are not using contraception. Talk to your doctor about how to use appropriate contraception to avoid becoming pregnant during treatment with Ruxolitinib.
- Talk to your doctor if you become pregnant while using Ruxolitinib.

Driving and using machines
If you experience dizziness after taking Ruxolitinib, do not drive or use machines.

Ruxolitinib contains lactose and sodium
Ruxolitinib contains a sugar called lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

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3. HOW TO TAKE RUXOLITINIB

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Before you start treatment with Ruxolitinib and during treatment, your doctor will do blood tests to find the best dose, to see how you are responding to the treatment and whether Ruxolitinib 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 Ruxolitinib.

Myelofibrosis
- Adults: The recommended starting dose is 5 to 20 mg twice daily. The maximum dose is 25 mg 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 5 mg twice daily.
- Children 12 years and older and adults: The recommended starting is 10 mg twice daily.

An oral solution is available if you have difficulty swallowing the whole tablet and for children less than 6 years old.
You should take Ruxolitinib every day at the same time, either with or without food.
Your doctor will always tell you exactly how many Ruxolitinib tablets to take.
You should continue taking Ruxolitinib for as long as your doctor tells you to.

If you take more Ruxolitinib than you should
If you accidentally take more Ruxolitinib than your doctor prescribed, contact your doctor or pharmacist immediately.

If you forget to take Ruxolitinib
If you forget to take Ruxolitinib 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Most of the side effects of Ruxolitinib 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 disorder
- 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 results, 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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RUXOLITINIB

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 or blister after "EXP". The expiry date refers to the last day of that month.
PVC/PCTFE - Alu Blister pack: Do not store above 30°C.
OPA/Alu/PVC-Alu Blister pack: This medicine does not require any special storage conditions.
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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ruxolitinib contains
- The active substance of Ruxolitinib is ruxolitinib.
- Each 5 mg Ruxolitinib tablet contains 5 mg of ruxolitinib.
- Each 10 mg Ruxolitinib tablet contains 10 mg of ruxolitinib.
- Each 15 mg Ruxolitinib tablet contains 15 mg of ruxolitinib.
- Each 20 mg Ruxolitinib tablet contains 20 mg of ruxolitinib.

The other ingredients are: lactose monohydrate, cellulose, microcrystalline, sodium starch glycolate, hydroxypropylcellulose, povidone K30, silica, colloidal anhydrous and magnesium stearate.

What Ruxolitinib looks like and contents of the pack
Ruxolitinib 5 mg tablets are round curved white to almost white tablets debossed with "MR" on one side and "14" on other side.
Ruxolitinib 10 mg tablets are round curved white to almost white tablets debossed with "MR" on one side and "11" on other side.
Ruxolitinib 15 mg tablets are ovaloid curved white to almost white tablets debossed with "MR" on one side and "12" on other side.
Ruxolitinib 20 mg tablets are elongated curved white to almost white tablets debossed with "MR" on one side and "13" on other side.
Ruxolitinib tablets are supplied in blister packs containing 14 tablets or 14 x 1 tablets; 56 tablets or 56 x 1 tablets; multipacks containing 168 (3 packs of 56) tablets.
Not all packs may be marketed in your country.

Marketing Authorisation Holder
MSN Laboratories Europe Ltd,
Invision House, Wilbury Way,
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KW20A Kordin Industrial Park,
Paola, PLA 3000,
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