

Package leaflet: Information for the patient

Ruxolitinib Torrent 5 mg tablets
Ruxolitinib Torrent 10 mg tablets
Ruxolitinib Torrent 15 mg tablets
Ruxolitinib Torrent 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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”.
- These products are referred to as Ruxolitinib Torrent in this leaflet.

What is in this leaflet

1. What Ruxolitinib is and what it is used for
2. What you need to know before you take Ruxolitinib
3. How to take Ruxolitinib
4. Possible side effects
5. How to store Ruxolitinib
6. Contents of the pack and other information

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 used to treat adults and children aged 2 years and older 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 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").
- If either of the above applies to you, tell your doctor who will then decide whether you should start treatment with Ruxolitinib.

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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 any kidney problems.
- you have or have ever had liver problems. 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, pharmacist or nurse 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.

Blood tests

Before you start treatment with Ruxolitinib, your doctor will perform blood tests to determine the best starting dose for you. You will need to have further blood tests during treatment so that your doctor can monitor the amount of blood cells (white cells, red cells and platelets) in your body and assess how you are responding to the treatment and whether Ruxolitinib is having an unwanted effect on these cells. 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. Your doctor will also regularly check the level of lipids (fat) in your blood.

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 aged 2 years and older.

Other medicines and Ruxolitinib

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

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

The following may increase the risk of side effects with Ruxolitinib:

- Some medicines used to treat infections. These include medicines used to treat fungal diseases (such as ketoconazole, itraconazole, posaconazole, fluconazole and voriconazole), medicines used to treat certain types of bacterial infections (antibiotics 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).
- Nefazodone, a medicine to treat depression.
- Mibefradil or diltiazem, medicines to treat hypertension and chronic angina pectoris.
- Cimetidine, a medicine to treat heartburn.

The following may reduce the effectiveness of Ruxolitinib:

- Avasimibe, a medicine to treat heart disease.
- Phenytoin, carbamazepine or phenobarbital and other anti-epileptics used to stop seizures or fits.
- Rifabutin or rifampicin, medicines used to treat tuberculosis (TB).
- St. John's wort (*Hypericum perforatum*), a herbal product used to treat depression.

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.

Pregnancy and breast-feeding

Do not take Ruxolitinib during pregnancy. Talk to your doctor about how to take appropriate measures to avoid becoming pregnant during your treatment with Ruxolitinib.

Do not breast-feed while taking Ruxolitinib. Tell your doctor if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Driving and using machines

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

Ruxolitinib contains lactose and sodium

Ruxolitinib 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Ruxolitinib

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse 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 dose is 10 mg twice daily.

An other oral solution is available in the market if you have difficulty swallowing the whole tablet and for children less than 6 years old.

Your doctor will always tell you exactly how many Ruxolitinib tablets to take.

You should take Ruxolitinib twice daily at approximately the same time, either with or without food.

You should continue taking Ruxolitinib for as long as your doctor tells you to.

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 you should take Ruxolitinib, talk to your doctor, pharmacist or nurse.

If you take more Ruxolitinib than you should

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

nurse immediately.

If you forget to take Ruxolitinib

If you forgot 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 stop taking Ruxolitinib

If you interrupt your treatment with Ruxolitinib 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 Ruxolitinib is possible if you respond to treatment and your doctor will supervise this procedure.

Therefore, you should not stop taking Ruxolitinib 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, pharmacist or nurse.

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 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 with Ruxolitinib

Other possible side effects include the following listed below. If you experience these side effects talk to your doctor, pharmacist or nurse.

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):

- fever, pain, redness, and/or difficulty breathing (possible symptoms of an infection with the cytomegalovirus (*cytomegalovirus infection*))
- fever, pain when urinating (possible symptoms of a urinary tract infection)
- fast heart rate, fever, confusion and rapid breathing (possible symptoms of sepsis, which is a serious condition that occurs in response to an infection that causes widespread inflammation)
- tiredness, fatigue, pale skin (possible symptoms of anaemia which is caused by low level of red blood cells), frequent infections, fever, chills, sore throat or mouth ulcers due to infections (possible symptoms of neutropenia which is caused by low level of white blood cells), spontaneous bleeding or bruising (possible symptoms of thrombocytopenia which is caused by low levels of platelets)
- low counts of all three types of blood cells - red blood cells, white blood cells, and platelets (*pancytopenia*)

Other side effects

Other possible side effects include the following listed below. If you experience these side effects talk to your doctor, pharmacist or nurse.

Very common (may affect more than 1 in 10 people):

- high level of cholesterol (*hypercholesterolaemia*)
- headache
- high blood pressure (*hypertension*)
- feeling sick (nausea)
- abnormal liver function test results
- increased blood level of enzyme from muscle potentially indicating muscle damage and/or muscle breakdown (increased blood creatine phosphokinase)
- increased blood level of creatinine, a substance normally eliminated by the kidneys into the urine, which may mean that your kidneys are not functioning properly (increased blood creatinine)

Common (may affect up to 1 in 10 people):

- fever, pain, redness, and/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 at: 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 blister and outer carton after "EXP". Do not store above 25°C.

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 (PH 101), Hydroxypropyl cellulose, Povidone (K30), Sodium starch glycolate (Type-A), Silica, colloidal anhydrous, Magnesium stearate

What Ruxolitinib looks like and contents of the pack

- Ruxolitinib Torrent 5 mg tablets are white to off white, round shaped, biconvex, uncoated tablet debossed with "3T" on one side and "5" on the other side. (Approximate tablets dimension: Diameter: 7.5 mm)
- Ruxolitinib Torrent 10 mg tablets are white to off white, round shaped, biconvex, uncoated tablet debossed with "4T" on one side and "10" on the other side. (Approximate tablets dimension: Diameter: 9.4 mm)
- Ruxolitinib Torrent 15 mg tablets are white to off white, oval shaped, biconvex, uncoated tablet debossed with "9T" on one side and "15" on the other side. (Approximate tablets dimension: Length: 15.1 mm, Width: 7.1 mm)
- Ruxolitinib Torrent 20 mg tablets are white to off white, Capsule shaped, biconvex, uncoated tablet debossed with "6T" on one side and "20" on the other side. (Approximate tablets dimension: Length: 16.6 mm, Width: 7.5 mm)

Ruxolitinib tablets are supplied in blister packs containing 14 or 56 tablets.

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (UK) Ltd.
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4 Gatwick Road
Crawley
West Sussex
RH10 9BG
United Kingdom

This leaflet was last revised in 12/2025.

8100872-7803

150 mm
Size: 150 x 700 mm

700 mm



828

Colour Black

LOCATION : Bileshwarapura	COUNTRY : UK	Supersedes A/W No.:
SIZE : 150 x 700 mm -Front/Back Side	V. No.: 01	DATE : 19-12-2025
REMARK : Folding Length 35 mm	CODE : 8100872-7803	
SUBSTRATE :		
Activities	Signature	Date
Prepared By	Name	
Reviewed By	Pkg. Dev	
Approved By	Pkg. Dev	Quality
This colour proof is not colour binding. Follow pantone shade reference for actual colour matching.		