**Package leaflet: Information for the patient**

**Jaypirca® 50 mg film-coated tablets**
**Jaypirca® 100 mg film-coated tablets**
pirtobrutinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**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.

**What is in this leaflet**

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


## 1. What Jaypirca is and what it is used for

Jaypirca is a cancer medicine that contains the active substance pirtobrutinib. It belongs to a class of medicines called Bruton's tyrosine kinase (BTK) inhibitors.

It is used on its own (monotherapy) to treat the following blood cancers in adult patients:
- Mantle cell lymphoma (MCL) . MCL is an aggressive (fast growing) cancer of a type of white blood cell called B-cells. B-cells are part of the immune system (the body's natural defences). This medicine is used in patients who have been previously treated with another BTK inhibitor when the cancer has come back (relapsed), or previous treatment has not worked (refractory).
- Chronic lymphocytic leukaemia (CLL): a type of cancer affecting white blood cells called lymphocytes. This medicine is used in patients who have not previously been treated for CLL or in patients who have previously been treated for CLL when the cancer has come back (relapsed), or previous treatment has not worked (refractory).

**How Jaypirca works**
Jaypirca works by blocking BTK, a protein in the body that helps MCL and CLL cells grow and survive. By blocking BTK, Jaypirca helps to kill these cells and can reduce their number, which can slow down the worsening of the cancer.

## 2. What you need to know before you take Jaypirca

**Do not take Jaypirca**
- If you are allergic to pirtobrutinib or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before taking Jaypirca:
- If you have an infection or are at an increased risk of developing an opportunistic infection (infections seen in patients with a weakened immune system). Your doctor may give you medicines to treat or prevent infections.
- If you have or ever had unusual bruising or bleeding or are on any medicines or supplements that could increase your risk of bleeding. See section "Other medicines and Jaypirca" below.
- If you recently had low counts of red blood cells (anaemia), neutrophils (a type of white blood cell that fights infections) or platelets (components that help the blood to clot).
- If you have recently had any surgery or are planning to have surgery. Your doctor may ask you to stop taking Jaypirca for a short time (3 to 5 days) before and after your surgery.
- If you have or ever had an irregular heartbeat or have other heart and/or blood vessel problems, such as high blood pressure, history of a heart attack or have heart valve damage.
- If you have liver problems.

You may get infections during treatment with Jaypirca. Contact your doctor if you have fever, chills, weakness, confusion, body aches, cough, cold or flu symptoms, feel tired, feel short of breath, have pain or burning feeling when passing urine. These could be signs of an infection.

Talk to your doctor if you develop a new lesion or any change in the appearance of an area on the skin, as treatment with Jaypirca may increase your risk of developing skin cancer. Use sun protection and make regular skin examinations.

Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells, known as tumour lysis syndrome (TLS), have been reported rarely during treatment with Jaypirca. This may lead to changes in kidney function, abnormal heartbeat, or seizures. Your doctor or another healthcare professional may do blood tests to check for TLS.

Your doctor will monitor you for the signs and symptoms of bleeding (see section 4) and check your blood cell counts as needed during treatment.

Your doctor may monitor your heart rhythm for any irregularities throughout treatment.

Liver problems can happen in people treated with Jaypirca. Your healthcare provider will do blood tests to check your liver before and during treatment with Jaypirca. Tell your healthcare provider or get medical help right away if you have any signs of liver problems, including stomach pain or discomfort, dark-colored urine, or yellow skin and eyes.

**Children and adolescents**
Do not give Jaypirca to children and adolescents aged less than 18 years. This is because it has not been studied in this age group.

**Other medicines and Jaypirca**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Jaypirca may make you bleed more easily. This means you should tell your doctor if you take other medicines that increase your risk of bleeding. This includes medicines such as:
- acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatories (NSAIDs) such as ibuprofen and naproxen,
- anticoagulants such as warfarin, heparin and other medicines for treating or preventing blood clots,
- supplements that may increase your risk of bleeding such as fish oil, vitamin E or flaxseed.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Jaypirca.

Tell your doctor or pharmacist if you take any of the following medicines as Jaypirca may affect how well these medicines work:

- Repaglinide, rosiglitazone, or pioglitazone (used to treat diabetes)
- Dasabuvir (used for Hepatitis C infection)
- Selexipag (used to treat a type of high blood pressure in the lungs called pulmonary arterial hypertension)
- Rosuvastatin (a statin, a type of medicine to treat high cholesterol)
- Montelukast (used to treat asthma)
- Digoxin (used to treat heart disorders)
- Dabigatran etexilate (an anticoagulant, a type of medicine used to prevent blood clots)
- Phenobarbital (a barbiturate, a type of medicine used to treat seizures)
- Mephenytoin, phenytoin, and carbamazepine (a type of medicine used to treat seizures)
- Midazolam (sedative),
- Alfentanil (medicine used for anesthesia)
- Tacrolimus (used to prevent organ rejection and skin conditions)
- Rifampicin (antibiotic)
- Methotrexate (medicine used to treat other cancers or immune system disorders)
- Mitoxantrone (medicine used to treat other cancers)

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, 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 use Jaypirca during pregnancy. If you are a woman of childbearing age, you must use an effective method of contraception during treatment and for 5 weeks after your last dose of Jaypirca. Tell your doctor immediately if you become pregnant.

If you are a man, you must use an effective method of contraception during treatment and for 3 months after your last dose of Jaypirca.

Do not breast-feed while taking Jaypirca and for one week after your last dose of Jaypirca. It is unknown whether Jaypirca passes into breast milk.

It is unknown whether Jaypirca will have an effect on fertility. Talk to your doctor or pharmacist for advice if you are planning to have a baby.

**Driving and using machines**
Jaypirca has a minor effect on your ability to drive and use machines. You may feel tired, dizzy or weak after taking Jaypirca and this may affect your ability to drive or use machines.

**Jaypirca contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**Jaypirca contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per 200 mg daily dose, that is to say essentially ‘sodium-free’.

## 3. How to take Jaypirca

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

The recommended dose of Jaypirca is 200 mg once a day.

If you get certain side effects while you are taking Jaypirca, your doctor may stop treatment temporarily or lower your dose.

Jaypirca should be taken at about the same time every day. You can take the tablets with or without food. Swallow the tablet whole with a glass of water. Do not chew, crush, or split tablets before swallowing to ensure you receive the correct dose.

**If you take more Jaypirca than you should**
If you have taken more Jaypirca than you should, contact a doctor or go to a hospital immediately for advice. Take the tablets and this leaflet with you. Medical treatment may be necessary.

**If you forget to take Jaypirca**
- If less than 12 hours have passed after your usual time for taking a dose: Take the missed dose right away. Take the next dose at your usual scheduled time the next day.
- If more than 12 hours have passed after your usual time for taking a dose: Skip the missed dose. Take the next dose at your usual scheduled time the next day.
- Do not take a double dose of Jaypirca to make up for a forgotten dose. Take the next dose at your usual scheduled time.
- Do not take a double dose of Jaypirca if you experience vomiting. Take the next dose at your scheduled usual time.

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.

**Stop taking Jaypirca and tell a doctor right away if you notice any of the following side effects:**

- itchy bumpy rash, difficulty breathing, swelling of your face, lips, tongue or throat – you may be having an allergic reaction to the medicine.

**Contact your doctor immediately if you experience any of the following side effects:**
- fever, chills, feeling weak or confused, cough, cold or flu symptoms, shortness of breath, pain or burning feeling when passing urine; these could be signs of an infection. These could include the very common side effects (may affect more than 1 in 10 people) of infection of the lung (pneumonia), nose, sinus or throat (upper respiratory tract infection) or infection of the urinary tract (may affect up to 1 in 10 people).
- bleeding, which may affect more than 1 in 10 people. Signs could include the common side effects (may affect up to 1 in 10 people) of nosebleeds, collection of blood under tissue (haematoma), bleeding in the tissue lining the eye and pink or brown urine. Other signs of bleeding may include black stools or stools with blood, bleeding gums, vomiting or coughing up blood.
- irregular heartbeats, weak or uneven pulse, light headedness, shortness of breath, chest discomfort as these are symptoms of heart rhythm problems (may affect up to 1 in 10 people).

**Tell your doctor, pharmacist, or nurse if you notice any of the following other side effects:**

**Very common** (may affect more than 1 in 10 people)
- low levels of neutrophils (a type of white blood cell that fights infection; neutropenia)
- frequent or loose stools (diarrhoea)
- rash
- low red blood cell counts (anaemia), which can cause tiredness and pale skin

- tiredness (fatigue)
- bruising
- low blood platelet counts (cells that help blood to clot; thrombocytopenia)
- contusion
- feeling sick (nausea)
- joint pain (arthralgia)
- headache

**Common** (may affect up to 1 in 10 people)
- swollen hands, ankles or feet
- belly (abdominal) pain
- tiny blood spots under the skin (petechiae)
- lymphocytosis (a higher-than-normal amount of lymphocytes, a type of white blood cell, in the blood)

**Not known** (frequency cannot be estimated from the available data)
- increased levels of liver enzymes

**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 Jaypirca

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 and blister after EXP. The expiry date refers to the last day of that month.

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 Jaypirca contains**
The active substance is pirtobrutinib. Each film-coated tablet contains 50 or 100 mg pirtobrutinib.
The other ingredients are:
- Tablet core: hypromellose acetate succinate; cellulose, microcrystalline; lactose monohydrate (see section 2 “Jaypirca contains lactose”); croscarmellose sodium (see section 2 “Jaypirca contains sodium”); magnesium stearate; silica, colloidal hydrated.
- Tablet film-coat: hypromellose; titanium dioxide; triacetin; indigo carmine (E132).

**What Jaypirca looks like and contents of the pack**
Jaypirca 50 mg is supplied as a blue, arc-triangle shaped film-coated tablet (tablet) debossed with “Lilly 50” on one side and “6902” on the other side. It is available in blister packs of 28, 30 or 84 film-coated tablets.

Jaypirca 100 mg is supplied as a blue, round tablet debossed with “Lilly 100” on one side and “7026” on the other side. It is available in blister packs of 28, 30, 56, 60, 84 or 168 film-coated tablets.

Not all the pack sizes may be marketed.

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**This leaflet was last revised in April 2026**.

This medicine has been given ‘conditional approval’.
This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.