

JAYPIRCA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking JAYPIRCA?

JAYPIRCA contains the active ingredient pirtobrutinib. JAYPIRCA is used to treat adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor.

For more information, see Section [1. Why am I using JAYPIRCA?](#) in the full CMI.

2. What should I know before I take JAYPIRCA?

Do not use if you have ever had an allergic reaction to JAYPIRCA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use JAYPIRCA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with JAYPIRCA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take JAYPIRCA?

- The recommended dose is 200 mg (two 100 mg tablets, OR four 50 mg tablets) once a day.
- Tablets should be swallowed whole with a glass of water. Do not chew, crush or split the tablets before swallowing. JAYPIRCA may be taken with or without food.

More instructions can be found in Section [4. How do I use JAYPIRCA?](#) in the full CMI.

5. What should I know while using JAYPIRCA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using JAYPIRCA.</p> <ul style="list-style-type: none"> ● Tell your doctor, pharmacist or nurse if you notice any signs or symptoms of an infection, unusual or increased bleeding, if you recently had low blood counts of red and white blood cells or platelets, if you have recently had any surgery or planning to have surgery, have or ever had irregular heartbeat or other heart and/or blood vessel problems. ● Protect your skin from sun exposure. Monitor your skin, and have regular skin checks.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine or lower the dosage without checking with your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools until you know how JAYPIRCA affects you.

Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Store below 30°C.
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For more information, see Section [5. What should I know while using JAYPIRCA?](#) in the full CMI.

6. Are there any side effects?

Side effects include diarrhoea, nausea, abdominal pain, bruising or mass of clotted blood (haematoma), nose bleeds, feeling tired (fatigue), discomfort or aching joints, swelling in the hands, ankles or feet, headache, rash, broken blood vessels which show as small coloured spots on the skin (petechia), low red blood cells (anaemia). These side effects are usually not severe. Serious side effects such as upper respiratory tract infections, urinary tract infections, pneumonia, and allergic reactions require urgent medical attention. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

JAYPIRCA®

Active ingredient: *pirtobrutinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using JAYPIRCA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JAYPIRCA.**

Where to find information in this leaflet:

- [1. Why am I taking JAYPIRCA?](#)
- [2. What should I know before I take JAYPIRCA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take JAYPIRCA?](#)
- [5. What should I know while taking JAYPIRCA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking JAYPIRCA?

JAYPIRCA contains the active ingredient pirtobrutinib. JAYPIRCA is a cancer medicine that belongs to a class of medicines called Bruton's tyrosine kinase (BTK) inhibitors. JAYPIRCA works by blocking BTK, a protein that helps certain types of cancer cells grow.

JAYPIRCA is used on its own (monotherapy) to treat chronic lymphocytic leukemia/small lymphocytic lymphoma, a type of cancer affecting white blood cells called lymphocytes, in adult patients previously treated with a BTK inhibitor. This medicine is used when the cancer has come back (relapsed), or treatment has not worked or stopped working (refractory).

2. What should I know before I take JAYPIRCA?

Warnings

Do not use JAYPIRCA if:

- you are allergic to pirtobrutinib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have an infection or are at an increased risk of developing an infection. Your doctor may give you medicines to treat or prevent infections or may adjust your dose of JAYPIRCA.
- have or ever had unusual bruising or bleeding or are taking medicines/supplements that could increase your risk of bleeding (see Section [3. What if I am taking other medicines?](#)).
- have recently had any surgery or are planning on having surgery. Your doctor may stop your JAYPIRCA for a short time (3 to 5 days) before and after surgery.
- have recently had a blood test which has shown a low count of red blood cells (anaemia); low count of a type of white blood cell called neutrophils which help fight infections (neutropenia); low count of platelets which help the blood clot (thrombocytopenia). Your doctor may need to adjust your dose.
- have or ever have had an irregular heartbeat (atrial fibrillation/atrial flutter) or have any other heart problems. Your doctor may need to adjust your dose.
- take any medicines for any other condition.

Talk to your doctor if you notice any changes to the appearance of an area on the skin or develop a new lesion. Treatment with JAYPIRCA may increase your risk of developing skin cancers. Use sun protection and have regular skin checks.

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 will assess your risk of developing tumour lysis syndrome and perform regular blood tests to monitor you.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

JAYPIRCA may make you bleed more easily. Be sure to tell your doctor if you take any other medicines that increase your risk of bleeding. These types of medicines include:

- anticoagulants/blood thinners such as warfarin, heparin and other medicines used to treat/prevent blood clots.
- aspirin and non-steroidal anti-inflammatories (NSAIDs) such as ibuprofen or naproxen.
- supplements that may increase your risk of bleeding such as fish oil, vitamin E or flaxseed.

JAYPIRCA may interact with other medicines. These medicines may affect how well these medicines work, such as:

- loperamide, a medicine used to treat diarrhoea
- montelukast, a medicine used to treat asthma
- itraconazole, a medicine used to treat fungal infections
- rifampin, an antibiotic used to treat bacterial infections

- repaglinide and pioglitazone, medicines used to treat diabetes
- rosuvastatin, a type of medicine (statin) used to treat high cholesterol
- dabigatran etexilate, a type of medicine used to prevent blood clots
- digoxin, a type of medicine to treat heart disorders.
- midazolam, a type of medicine used for sedation
- alfentanil, a medicine used for anaesthesia
- tacrolimus, a medicine used to prevent organ rejection
- phenobarbital and mephenytoin, medicines to treat seizures
- methotrexate, a medicine used to treat other cancers or immune system disorders
- mitoxantrone, paclitaxel, and enzalutamide, medicines used to treat other cancers.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JAYPIRCA.

4. How do I take JAYPIRCA?

How much to take

- The recommended dose of JAYPIRCA is 200 mg (two 100 mg tablets, OR four 50 mg tablets) once a day.
- Follow the instructions provided and use JAYPIRCA until your doctor tells you to stop.
- Your doctor may modify your dose of JAYPIRCA based on your side effects and blood test results.

- Your doctor may increase your dose of JAYPIRCA if you are taking certain medicines. Do not take more JAYPIRCA unless your doctor tells you to.

When to take JAYPIRCA

- Take JAYPIRCA about the same time each day.

How to take JAYPIRCA

- Take the tablets orally (by mouth) with a glass of water.
- Swallow the tablets whole. Do not chew, crush or split the tablets.

If you forget to take JAYPIRCA

JAYPIRCA should be used regularly at the same time each day.

If you miss your dose at the usual time:

- and less than 12 hours have passed, take the missed dose right away. Then take your next dose at the usual time the next day.
- more than 12 hours have passed, skip the dose you missed. Take your next dose the next day when you are meant to. **Do not take a double dose to make up for the dose you missed.**

If vomiting occurs, do not take a double dose. Continue with the next schedule dose the next day.

If you use too much JAYPIRCA

If you think that you have used too much JAYPIRCA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking JAYPIRCA?

Things you should do

Call your doctor straight away if you:

- Notice any signs of an infection. You may get infections during treatment with JAYPIRCA (see Section [6. Are there any side effects?](#)).
- Notice any signs or symptoms of increased bleeding (see Section [6. Are there any side effects?](#))

Remind any doctor, dentist or pharmacist you visit that you are using JAYPIRCA.

Things you should not do

- Do not stop using this medicine suddenly or reduce your dose without speaking with your doctor.

Regular skin-checks

- It is important to have regular skin checks with your doctor while taking JAYPIRCA. JAYPIRCA may increase your risk of developing skin cancers.
- Monitor your skin for any changes and inform your doctor if you notice any changes.
- It is important to protect your skin from sun exposure, especially when outdoors, to reduce the risk of developing skin cancers.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how JAYPIRCA affects you.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or

- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Stomach-related:</p> <ul style="list-style-type: none"> • diarrhoea • nausea • abdominal pain <p>Blood-related:</p> <ul style="list-style-type: none"> • low levels of red blood cells (anaemia) which can cause weakness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>and feeling tired (fatigue)</p> <ul style="list-style-type: none"> ● increased bleeding. Symptoms may include bruising, or mass of clotted blood (haematoma), nose bleeds <p>General:</p> <ul style="list-style-type: none"> ● feeling tired (fatigue) ● swelling in the hands, ankles or feet ● discomfort or aching joints ● headache ● rash ● broken blood vessels which show as small coloured spots on the skin (petechia) 	

Serious side effects

Serious side effects	What to do
<p>Infections:</p> <ul style="list-style-type: none"> ● pneumonia, a severe infection of the lungs. 	<p>Call your doctor straight away, or go straight to the Emergency</p>

Serious side effects	What to do
<p>Symptoms may include fever, cough, difficulty breathing or shortness of breath, rapid breathing, loss of appetite.</p> <ul style="list-style-type: none"> ● upper respiratory tract infection which are infections involving the nose and throat. Symptoms may be mild to severe; sore throat, sneezing, stuffy nose, fever, cough. ● bladder (urinary tract) infection. Symptoms may include; fever, reddish or brownish discolouration of urine, cloudy and unclear urine, discomfort when passing or increased need to urinate, unpleasant urine odour, blood in urine. <p>Allergic reaction:</p> <p>Symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none"> ● rashes 	<p>Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● itching and rapid swelling of the tissues of the neck, face, mouth and/or throat ● hives (urticaria) ● problems breathing or swallowing. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects may only be found when your doctor does blood tests. These can include:

- low level of red blood cells (anaemia)
- low level of white blood cells (neutropenia)
- low count of platelets which help the blood clot (thrombocytopenia)
- high level of a type of white blood cell that fights infection (lymphocytosis).

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What JAYPIRCA contains

Active ingredient (main ingredient)	Pirtobrutinib
Other ingredients (inactive ingredients)	Croscarmellose sodium Hypromellose Acetate Succinate Lactose Monohydrate Magnesium Stearate Microcrystalline Cellulose Silicon Dioxide <u>Film coating</u> Hypromellose Titanium dioxide

	Triacetin Indigo carmine aluminium lake
Potential allergens	lactose (as monohydrate)

Do not take this medicine if you are allergic to any of these ingredients.

What JAYPIRCA looks like

JAYPIRCA is a blue film-coated tablet.

50mg tablets are an arc-triangle shape debossed with "Lilly 50" on one side and "6902" on the other side (Aust R 481185). JAYPIRCA 50mg is available in packs of 30 film-coated tablets.

100mg tablets are a round shape and debossed with "Lilly 100" on one side and "7026" on the other side (Aust R 483365). JAYPIRCA 100mg are available in packs of 30 or 60 film-coated tablets.

**Not all pack sizes may be marketed.

Who distributes JAYPIRCA

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney, NSW 2000

AUSTRALIA

If you have any questions about JAYPIRCA, contact Eli Lilly at 1800 454 559 (Australia) or your healthcare professional for assistance.

To check for CMI updates and obtain the latest version, visit www.ebs.tga.gov.au

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