

MCL

CLL

# Spark what's possible with Jaypirca<sup>®</sup> (pirtobrutinib)



KEEP READING TO LEARN  
MORE ABOUT JAYPIRCA

## Indications

Jaypirca is a prescription medicine used to treat adults with **mantle cell lymphoma (MCL)** that has come back or did not respond to previous treatment and who have already received at least 2 treatments for their cancer, including a Bruton tyrosine kinase (BTK) inhibitor medicine.

Jaypirca is a prescription medicine used to treat adults with **chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)** who have already received at least 2 treatments for their cancer, including a BTK inhibitor medicine and a B-cell lymphoma 2 (BCL-2) inhibitor medicine.

Jaypirca was approved based on how many people responded to treatment. Studies are ongoing to confirm the benefit of Jaypirca for this use.

It is not known if Jaypirca is safe and effective in children.

## Select Important Safety Information

**Warnings - Jaypirca may cause serious side effects, including:**

**Infections.** Infections can happen during treatment with Jaypirca. These infections can be serious and may lead to death. Your doctor may prescribe vaccines and certain medicines if you have an increased risk of getting infections. Tell your doctor right away if you have fever, chills, weakness, flu-like symptoms, or any other signs of infection during treatment with Jaypirca.

 **Jaypirca<sup>®</sup>**  
pirtobrutinib 50, 100 mg  
tablets

Please see **Safety Summary** for Jaypirca on pages 8-10.

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# What is Jaypirca?

Jaypirca is a prescription medicine used to treat adults with mantle cell lymphoma (MCL) that has come back or did not respond to previous treatment and who have already received at least 2 treatments for their cancer, including a Bruton's tyrosine kinase (BTK) inhibitor medicine.

Jaypirca is also used to treat adults with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have already received at least 2 treatments for their cancer, including a BTK inhibitor medicine and a B-cell lymphoma 2 (BCL-2) inhibitor medicine.

You may have taken BTK inhibitors before. BTK inhibitors stop, or inhibit, cancer cells from surviving and multiplying, which can slow the spread of your cancer.

Jaypirca, a noncovalent BTK inhibitor, **works differently than other BTK inhibitors you may have taken before.** For MCL, it was developed to work after you have taken a covalent BTK inhibitor. For CLL, it works after you have taken a covalent BTK inhibitor and a BCL-2 inhibitor. There are no completed studies comparing Jaypirca and other BTK inhibitors.

## Select Important Safety Information

**Warnings - Jaypirca may cause serious side effects, including:**

**Bleeding problems (hemorrhage).** Bleeding problems can happen during treatment with Jaypirca. They can be serious and may lead to death. Your risk of severe bleeding may increase if you are also taking a blood thinner medicine. Tell your doctor if you have any signs or symptoms of bleeding, including:

- blood in your stools or black stools (looks like tar)
- pink or brown urine
- unexpected bleeding, or bleeding that is severe or you cannot control
- vomit blood or vomit blood that looks like coffee grinds
- cough up blood or blood clots
- increased bruising
- dizziness
- weakness
- confusion
- changes in your speech
- headache that lasts a long time



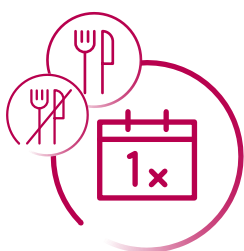
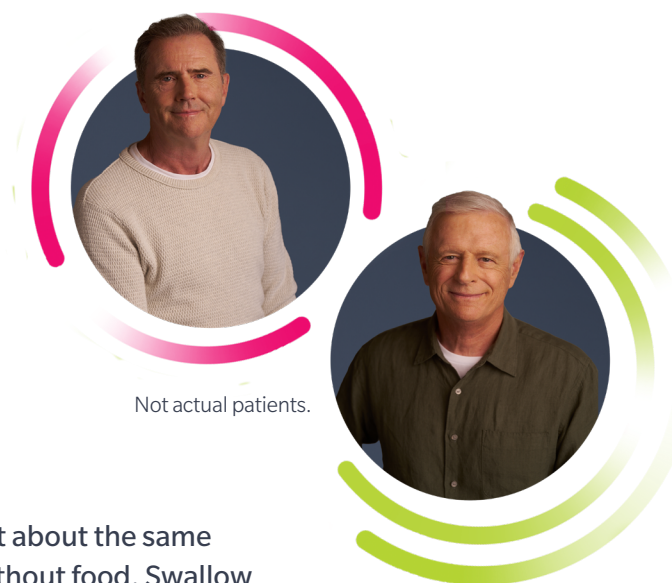
Not actual patients.

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# How to take Jaypirca

Take Jaypirca exactly as your healthcare provider tells you



## How do I take Jaypirca?

Take Jaypirca tablets 1 time each day at about the same time each day. Take Jaypirca with or without food. Swallow Jaypirca tablets whole with water. Do not cut, crush, or chew the tablets.



## What if I miss a dose?

If you miss a dose of Jaypirca, take it as soon as you remember on the same day. If it has been more than 12 hours, skip the missed dose and take your next dose on the next day at your usual time.



## What if I experience side effects?

Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking Jaypirca if you develop side effects. Do not change your dose or stop taking Jaypirca without talking to your healthcare provider first.

## Select Important Safety Information

### Warnings - Jaypirca may cause serious side effects, including:

**Decrease in blood cell counts.** Decrease in white blood cells, platelets, and red blood cells are common with Jaypirca, but can also be severe. This may increase your risk of infection, bleeding, and anemia. Your doctor should do blood tests regularly during treatment to monitor your counts.

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# Understanding the **possible side effects of Jaypirca for MCL and CLL**

## Jaypirca can cause serious side effects, including:

- Infections
- Bleeding problems (hemorrhage)
- Decrease in blood counts (white blood cells, platelets, and red blood cells)
- Heart rhythm problems (atrial fibrillation and atrial flutter)
- Second primary cancers (new cancers including of the skin or other organs)
- Liver problems

## The most common side effects of Jaypirca include<sup>1</sup>:

- Tiredness
- Muscle, joint, and bone pain
- Diarrhea
- COVID-19
- Bruising
- Cough

These are not all the possible side effects of Jaypirca. See accompanying Safety Summary for more information. If you experience side effects while on treatment, it's important to talk to your doctor.

## 9 out of 10 people kept taking Jaypirca without needing to stop treatment due to side effects

In a clinical trial:

- **9% of people with CLL (10 out of 110)** stopped taking Jaypirca permanently due to side effects
- Side effects that caused more than 1% of patients to permanently stop taking Jaypirca included other cancers, COVID-19, and sepsis
- **9% of people with MCL (12 out of 128)** stopped taking Jaypirca permanently due to side effects
- Side effects that caused more than 1% of patients to permanently stop taking Jaypirca included pneumonia

Jaypirca was studied in a clinical trial that included people with relapsed or refractory mantle cell lymphoma (MCL) and previously treated chronic lymphocytic leukemia/ small lymphocytic lymphoma (CLL/SLL). People with MCL had already received at least two treatments for their cancer, including a Bruton tyrosine kinase (BTK) inhibitor medicine, and people with CLL had already received at least two treatments, including a Bruton tyrosine kinase (BTK) inhibitor medicine and a BCL-2 inhibitor medicine. The trial evaluated 120 people with MCL and 108 people with CLL for their response to treatment (a response means their cancer shrank and stopped spreading) and how long the response lasted. People in the trial took Jaypirca once daily until their disease got worse or they were no longer able to tolerate treatment.



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# Half of adults with **MCL** who took Jaypirca **saw their cancer shrink and stop spreading**

IN A CLINICAL TRIAL THAT MEASURED THE NUMBER OF PEOPLE WHO RESPONDED TO TREATMENT AND HOW LONG THE RESPONSE LASTED:



**OF ADULTS WITH MCL** (60 out of 120) saw their **cancer shrink and stop spreading** while taking Jaypirca

OF THE 50%

**13%**

**OF ADULTS** (15 out of 120) had a complete response, which means scans and other tests showed no detectable signs of MCL

**38%**

**OF ADULTS** (45 out of 120) had a partial response, which means scans and other tests showed their MCL shrank in response to treatment

- **65% were still responding** to treatment at 6 months
- For those who saw their MCL shrink and stop spreading, their response lasted a **median\* of 8.3 months**

\*Median is the middle number in a range of numbers.

**In a clinical trial, Jaypirca started working quickly, with some people seeing their cancer reduce in size and stop spreading as soon as 3.5 weeks after starting treatment.**

In a clinical trial of Jaypirca, the median time for the cancer to shrink and stop spreading with treatment was 1.8 months, ranging from 3.5 weeks at the lowest to 4.2 months at the highest. Median is the middle number in a range of numbers ordered from lowest to highest.

## Select Important Safety Information

**Warnings - Jaypirca may cause serious side effects, including:**

**Heart rhythm problems.** Heart rhythm problems including atrial fibrillation and atrial flutter have happened in people treated with Jaypirca. Your risk for heart rhythm problems may be increased if you have high blood pressure or have had heart rhythm problems in the past. Tell your doctor if you have any of the following symptoms:

- fast or irregular heartbeat (palpitations)
- dizziness
- fainting
- chest discomfort
- shortness of breath

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# Most adults with **CLL** who took Jaypirca saw their cancer shrink and stop spreading

IN A CLINICAL TRIAL THAT MEASURED THE NUMBER OF PEOPLE WITH CLL WHO RESPONDED TO TREATMENT AND HOW LONG THE RESPONSE LASTED:



**of adults with CLL** (78 out of 108) saw their **cancer shrink and stop spreading** while taking Jaypirca

- For those who saw their CLL shrink and stop spreading, their response lasted a **median\* of 12.2 months**

**In a clinical trial for people with CLL/SLL** who had received at least two prior treatments, Jaypirca started working quickly. **Some saw their cancer reduce in size and stop spreading approximately 7 weeks after starting treatment.**

In a clinical trial of Jaypirca, the median\* time for the cancer to shrink and stop spreading with treatment was 3.7 months, ranging from 1.7 months at the lowest to 27.9 months at the highest.

\*Median is the middle number in a range of numbers ordered from lowest to highest.

## Select Important Safety Information

### Warnings - Jaypirca may cause serious side effects, including:

**Second primary cancers.** New cancers have happened during treatment with Jaypirca, including cancers of the skin or other organs. Your doctor will check you for other cancers during treatment. Use sun protection when you are outside in sunlight.

**Liver Problems.** Liver problems, which may be severe or life-threatening, or lead to death, can happen in people treated with Jaypirca. Your doctor will do blood tests to check your liver before and during treatment with Jaypirca. Tell your doctor 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.

Your doctor may decrease your dose, temporarily stop, or permanently stop treatment with Jaypirca if you develop severe side effects.

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# See how you may be able to **save on Jaypirca and get support** along the way



## Jaypirca Savings Card

**Eligible, commercially insured covered patients pay as little as \$0 a month\***

**\* Month is defined as 30 days.**

Paying for treatment shouldn't be an additional concern for you and your loved ones, so we've created the Jaypirca Savings Card, which may help you manage treatment costs.

Need a Jaypirca Savings Card? Visit [jaypirca.lilly.com/savings-support#savings](https://jaypirca.lilly.com/savings-support#savings) for more information or call Lilly Support Services™ for Jaypirca® at 1-800-LillyRx (1-800-545-5979).

Subject to Lilly USA, LLC's (Lilly's) right to terminate, rescind, revoke or amend the Jaypirca Savings Card Program ("Card" or "Program") eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2025. **Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.**

**MONTHLY AND ANNUAL MAXIMUM SAVINGS:** For patients with commercial drug insurance coverage for Jaypirca:

You must have commercial drug insurance that covers Jaypirca and a prescription for an approved use consistent with FDA-approved product labeling to pay as little as \$0 for a 1-month prescription fill of Jaypirca. Month is defined as 30-days. Card savings are subject to a maximum monthly savings of wholesale acquisition cost plus usual and customary pharmacy charges and separate maximum annual savings of up to \$9,200 per calendar year. Except where prohibited by applicable state law, Card monthly and annual savings are reduced if Lilly identifies that you are enrolled in a plan or program, sometimes called a maximizer plan, that adjusts your cost sharing amount to be equal to or include some portion of the savings provided by the Card and attempts to prevent the savings from this Card from being applied to your out-of-pocket costs, including but not limited to copayments, coinsurances, and deductibles ("Maximizer"). If the Program identifies you are enrolled in a Maximizer, Card savings are reduced to a maximum monthly savings of up to \$25 and a separate maximum annual savings of up to \$350 per calendar year. If you have reason to believe that the Program erroneously identified enrollment in a Maximizer, please call the Jaypirca Savings Card Program at 1-833-727-4589. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason. Card expires and savings end on 12/31/2025.

## ADDITIONAL TERMS AND CONDITIONS:

You are responsible for any applicable taxes, fees and any amount that exceeds the monthly or annual maximum benefits. Savings card activation is required. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Jaypirca Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at <https://jaypirca.lilly.com/savings-support#savings>. Card benefits void where prohibited by law. **THIS CARD IS NOT INSURANCE.**

TRICARE® is a registered trademark of the Department of Defense (DoD), DHA.

## Questions about savings?

Call the Jaypirca Savings Card Support Line at **1-833-727-4589**.

For all other questions regarding support, call Lilly Support Services™ at **1-800-LillyRx (1-800-545-5979)**. For more information, visit [jaypirca.lilly.com/savings-support](https://jaypirca.lilly.com/savings-support).



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# Safety Summary

## Safety Summary

### Warnings - Jaypirca may cause serious side effects, including:

**Infections.** Infections can happen during treatment with Jaypirca. These infections can be serious and may lead to death. Your doctor may prescribe vaccines and certain medicines if you have an increased risk of getting infections. Tell your doctor right away if you have fever, chills, weakness, flu-like symptoms, or any other signs of infection during treatment with Jaypirca.

**Bleeding problems (hemorrhage).** Bleeding problems can happen during treatment with Jaypirca. They can be serious and may lead to death. Your risk of severe bleeding may increase if you are also taking a blood thinner medicine. Tell your doctor if you have any signs or symptoms of bleeding, including:

- blood in your stools or black stools (looks like tar)
- pink or brown urine
- unexpected bleeding, or bleeding that is severe or you cannot control
- vomit blood or vomit blood that looks like coffee grinds
- cough up blood or blood clots
- increased bruising
- dizziness
- weakness
- confusion
- changes in your speech
- headache that lasts a long time

**Decrease in blood cell counts.** Decrease in white blood cells, platelets, and red blood cells are common with Jaypirca, but can also be severe. This may increase your risk of infection, bleeding, and anemia. Your doctor should do blood tests regularly during treatment to monitor your counts.

**Heart rhythm problems.** Heart rhythm problems including atrial fibrillation and atrial flutter have happened in people treated with Jaypirca. Your risk for heart rhythm problems may be increased if you have high blood pressure or have had heart rhythm problems in the past. Tell your doctor if you have any of the following symptoms:

- fast or irregular heartbeat (palpitations)
- chest discomfort
- dizziness
- shortness of breath
- fainting

**Second primary cancers.** New cancers have happened during treatment with Jaypirca, including cancers of the skin or other organs. Your doctor will check you for other cancers during treatment. Use sun protection when you are outside in sunlight.

**Liver Problems.** Liver problems, which may be severe or life-threatening, or lead to death, can happen in people treated with Jaypirca. Your doctor will do blood tests to check your liver before and during treatment with Jaypirca. Tell your doctor 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.



Not actual patients.

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# Safety Summary (cont'd)

## Warnings - Jaypirca may cause serious side effects, including: (cont'd)

Your doctor may decrease your dose, temporarily stop, or permanently stop treatment with Jaypirca if you develop severe side effects.

### Common side effects

- tiredness
- muscle, joint, and bone pain
- diarrhea
- COVID-19
- bruising
- cough

**These are not all the possible side effects with Jaypirca. Call your doctor for medical advice about side effects. You may report side effects at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

### Before using

Before taking Jaypirca, tell your doctor about all your medical conditions, including if you:

- have an infection or have been advised that you are at increased risk of infection
- have had recent surgery or plan to have surgery. Your doctor may stop Jaypirca for a planned medical, surgical, or dental procedure
- have bleeding problems and/or are taking blood thinner medicine
- have or have had heart rhythm problems
- have high blood pressure
- have a history of other cancers, including skin cancer
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. Jaypirca can harm your unborn baby. If you are able to become pregnant, your doctor will do a pregnancy test before starting treatment  

Females who are able to become pregnant should use effective birth control (contraception) during treatment and for at least 1 week after the last dose of Jaypirca. Tell your doctor right away if you become pregnant or think you are pregnant during treatment
- are breastfeeding or plan to breastfeed. It is not known if Jaypirca passes into breast milk. Do not breastfeed during treatment and for at least 1 week after your final dose

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# Safety Summary (cont'd)

**Also tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking Jaypirca with certain other medicines may affect how Jaypirca or the other medicines work and can cause side effects.

## How to take

- Take Jaypirca exactly as your doctor tells you
- Do not change your dose or stop taking Jaypirca unless your healthcare provider tells you to do so
- Take Jaypirca tablets 1 time each day at about the same time each day
- Take Jaypirca with or without food
- Swallow Jaypirca tablets whole with water. Do not cut, crush, or chew the tablets
- If you miss a dose of Jaypirca, take it as soon as you remember on the same day. If you miss taking a dose by more than 12 hours from the time you usually take Jaypirca, skip the missed dose. Take the next dose on the next day at your usual time

## Learn more

Jaypirca is a prescription medicine. For more information, call 1-800-545-5979 or go to [www.jaypirca.lilly.com](http://www.jaypirca.lilly.com). This summary provides basic information about Jaypirca but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Jaypirca and how to take it. Your doctor is the best person to help you decide if Jaypirca is right for you.

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Please see [Safety Summary for Jaypirca](#) on pages 8-10.



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