EMADOC-1829012207-67822
EMEA/H/C/005863

Jaypirca (*pirtobrutinib*)

A plain-language overview of Jaypirca and why it is authorised in the EU

What is Jaypirca and what is it used for?

Jaypirca is a cancer medicine used to treat adults with chronic lymphocytic leukaemia (CLL). It is also used to treat mantle cell lymphoma (MCL) in adults whose cancer has come back (relapsed) or no longer responds to treatment (refractory), and who had previously received a type of cancer medicine called a Bruton's tyrosine kinase (BTK) inhibitor. CLL and MCL are two types of cancer of B cells (a type of white blood cell).

Jaypirca contains the active substance pirtobrutinib.

How is Jaypirca used?

Jaypirca can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

The medicine is available as tablets to be taken by mouth once daily. Treatment should be continued until the disease gets worse or the patient gets unacceptable side effects.

For more information about using Jaypirca, see the package leaflet or contact your doctor or pharmacist.

How does Jaypirca work?

The active substance in Jaypirca, pirtobrutinib, works by blocking an enzyme called BTK, which is important for the growth of B cells, including the abnormal B cells in patients with MCL or CLL. By blocking the action of BTK, the medicine is expected to slow the progression of the disease.

What benefits of Jaypirca have been shown in studies?

Mantle cell lymphoma

In a main study, Jaypirca was found to reduce the amount of cancer in the body or remove all signs of cancer in patients with MCL whose cancer had come back or had not responded to previous treatments, including a BTK inhibitor.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The main study involved 164 patients with MCL, and the main analysis involved 90 patients who had previously been treated with a BTK inhibitor and whose disease could be assessed using a scan. Jaypirca was not compared with another treatment in this study.

Around 57% of patients (51 out of 90) had either a complete or partial response to Jaypirca, meaning that there was either no sign of the cancer left or the amount of cancer in the body had decreased after treatment. Around 19% of patients had a complete response (17 out of 90). The response to treatment lasted an average of 18 months.

Chronic lymphocytic leukaemia

One main study showed that Jaypirca is effective at delaying the worsening of CLL, compared with other cancer medicines. The study involved 238 patients with CLL who had previously been treated with a BTK inhibitor and whose disease had come back or had not responded to previous treatments. Patients received either Jaypirca or a combination of other cancer medicines (rituximab given with either idelalisib or bendamustine). The study showed that patients taking Jaypirca lived for a median time of 14 months without the disease getting worse, compared with 9 months for patients given rituximab plus either idelalisib or bendamustine.

A second study involved 282 patients with CLL who had not been treated before. Patients received either Jaypirca or bendamustine plus rituximab. After 24 months, around 93% of patients treated with Jaypirca were alive without the disease getting worse, compared with around 71% of patients treated with bendamustine and rituximab. At 24 months, about 98% of patients treated with Jaypirca were still alive, compared with about 93% of patients treated with bendamustine plus rituximab.

A third study compared Jaypirca with ibrutinib in 662 patients who had not previously received a BTK inhibitor. Some patients had not been treated for CLL before, while others had received other treatments. The cancer responded to treatment in around 87% of patients receiving Jaypirca and around 79% of those receiving ibrutinib, showing that Jaypirca was at least as effective as ibrutinib at treating CLL.

Studies carried out with Jaypirca are described in more detail in the medicine's assessment reports.

What are the side effects and restrictions with Jaypirca?

For the full list of side effects and restrictions with Jaypirca, see the package leaflet.

The most common side effects with Jaypirca (which may affect more than 2 in 10 people) include neutropenia (low levels of neutrophils, a type of white blood cell) and bleeding.

Some side effects can be serious. The most frequent with Jaypirca (which may affect up to 1 in 10 people) include pneumonia (infection of the lungs), bleeding, neutropenia, anaemia (low levels of red blood cells), atrial fibrillation or atrial flutter (irregular and uncoordinated contractions or rapid contractions of the upper chambers of the heart) and urinary tract infections (infections of the parts of the body that collect and pass out urine).

Why is Jaypirca authorised in the EU?

Patients with MCL whose cancer has come back after previous treatments, including treatment with a BTK inhibitor, have few treatment options and a poor prognosis. Although data on Jaypirca at the time of authorisation were limited due to the small number of patients involved in the main study and the absence of a comparator, the European Medicines Agency considered that the proportion of patients who responded to treatment and the average duration of the response represent a meaningful health

benefit for patients with this aggressive form of cancer. Jaypirca was also shown to be effective at delaying the progression of CLL in patients who had not been treated before and in patients whose disease came back or had not responded to previous treatments.

The side effects of Jaypirca were considered manageable and similar to those of other authorised BTK inhibitors.

Jaypirca has been given 'conditional authorisation'. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Jaypirca. It must submit the results of an ongoing study comparing Jaypirca with another BTK inhibitor in patients with MCL who had not previously been treated with a BTK inhibitor.

Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Jaypirca?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Jaypirca have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Jaypirca are continuously monitored. Suspected side effects reported with Jaypirca are carefully evaluated and any necessary action taken to protect patients.

Other information about Jaypirca

Jaypirca received a conditional marketing authorisation valid throughout the EU on 30 October 2023.

Further information on Jaypirca, including the package leaflet and assessment reports, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/jaypirca.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 08-2026.