swissmedic

Summary report on authorisation dated 23 December 2025

Jaypirca® (active substance: pirtobrutinib)

Indication extension in Switzerland: 23 September 2025

Film-coated tablets for the treatment of adults with relapsed or refractory chronic lymphocytic leukaemia (CLL)

About the medicinal product

Jaypirca contains the active substance pirtobrutinib.

Jaypirca is used to treat adults with chronic lymphocytic leukaemia (CLL) when the cancer has come back (relapsed) or the previous treatment has not been effective (refractory). Patients must also have received at least two or more previous cancer treatments, including Bruton's tyrosine kinase (BTK) inhibitor therapy.

CLL is a slowly progressing (chronic) form of blood cancer, in which certain white blood cells known as lymphocytes multiply in an uncontrolled way and accumulate in the blood or lymph nodes.

Since CLL is a rare and life-threatening disease, Jaypirca has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Swissmedic first authorised Jaypirca on 30 November 2023 for the treatment of adults with relapsed or refractory mantle cell lymphoma (MCL).

Mode of action

In CLL, a protein called BTK is overactive in the white blood cells. It constantly send signals that help the cancer cells grow and not die off. By inhibiting BTK, Jaypirca can help stop the cancer cells growing and surviving, thereby slowing progression of the disease.

Administration

Jaypirca is a prescription-only medicine.

Jaypirca is available as film-coated tablets for oral administration in dosage strengths of 50 mg and 100 mg. The usual starting dose is 200 mg once daily.

The tablets should be swallowed whole with a glass of water and can be taken with or without food. Jaypirca should be taken at approximately the same time each day.

If certain adverse reactions occur during treatment, the doctor in charge may adjust the dose or suspend treatment.

Efficacy

The efficacy of Jaypirca was investigated, among other studies, in 189 adults with relapsed or refractory CLL who had received at least two prior therapies, one of which was a BTK inhibitor (BRUIN CLL-321, study 20020).

Participants were assigned to one of two groups: 98 patients received 200 mg of Jaypirca once daily, while the patients in the control group received one of two comparator treatments (64 received idelalisib plus rituximab, 27 bendamustine plus rituximab).

The efficacy of Jaypirca was primarily assessed on the length of time for which the disease did not progress – what is known as "progression-free survival" (PFS[1]).

After a median[2] follow-up period of 19.4 months for Jaypirca and 17.7 months for the control arm, progression-free survival was longer for Jaypirca. Median PFS was 13.9 months in the Jaypirca group compared with 8.3 months in the control group.

Interpretation of the overall survival (OS[3]) data was hampered by the relatively short follow-up period, the different treatments in the control arm and the fact that some patients in the control group switched to Jaypirca after their disease progressed (crossover). In all, though, overall survival in both groups was assessed as comparable. However, submission of OS data from an extended follow-up period of five years was required as a condition of authorisation to permit a better assessment of OS at a later point in time.

Precautions, undesirable effects, & risks

Jaypirca must not be used in those who are hypersensitive to the active substance or any of the excipients. Jaypirca must not be used during pregnancy and breastfeeding.

Certain serious or fatal adverse reactions may occur during treatment, requiring monitoring by a doctor. It is particularly important to be aware of the risk of infections, bleeding (haemorrhages), reduced levels of blood cells (cytopenias), and abnormal heart rhythms (atrial fibrillation and atrial flutter). New cancers (second primary malignancies) and liver damage (hepatotoxicity) may also occur. Tumour lysis syndrome (TLS)[4] has been reported in rare cases. Doctors will examine patients regularly and pay attention to possible signs of these adverse reactions.

The most common undesirable effects (affecting more than 15% of patients) are: bleeding, reduced levels of certain white blood cells (neutropenia), fatigue, diarrhoea, reduced levels of red blood cells (anaemia), rash, bruising, oedema, nausea and reduced levels of red blood platelets (thrombocytopenia)

[1] Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

[3] Overall survival: Overall survival (OS) refers to the period between the start of treatment and the death of the patient.

[4] Tumour lysis syndrome (TLS) is a complication that can occur if large numbers of cancer cells are destroyed very quickly. As a result, abnormally large quantities of chemical degradation products are released into the bloodstream and may cause altered kidney function, abnormal heart rhythms or seizures.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

CLL is a form of blood cancer that is difficult to treat, especially in patients whose disease has reoccurred after several therapies – including one course of treatment with a BTK inhibitor – or has failed to respond to treatment. Treatment options are restricted in such a situation and the prognosis is poor.

The pivotal study (BRUIN CLL-321, study 20020) showed that Jaypirca extends the time until disease progression (PFS). Although no benefit in terms of overall survival (OS) was shown, analysis was affected by factors that included patients switching from the control treatment to Jaypirca after their disease had progressed. Moreover, during the study, Jaypirca demonstrated a better safety profile versus idelalisib plus rituximab, one of the two control-group treatments in the pivotal study and an alternative treatment in the authorised indication.

Taking all the risks and precautions into account, and based on the available data, the benefits of Jaypirca outweigh the risks. Swissmedic has therefore authorised the medicinal product Jaypirca containing the active substance pirtobrutinib in Switzerland for the treatment of relapsed or refractory CLL from the third line of treatment.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Jaypirca®

Information for patients (package leaflet): Information for patients Jaypirca®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.