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## EPAR summary for the public

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# Xaluprine

## mercaptopurine

This is a summary of the European public assessment report (EPAR) for Xaluprine. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Xaluprine.

### What is Xaluprine?

Xaluprine is a medicine that contains the active substance mercaptopurine. It is available as an oral suspension.

### What is Xaluprine used for?

Xaluprine is used to treat children, adolescents and adults who have acute lymphoblastic leukaemia (ALL), a cancer of the lymphocytes (a type of white blood cell).

Because the number of patients with ALL is low, the disease is considered 'rare', and Xaluprine was designated an 'orphan medicine' (a medicine used in rare diseases) on 30 April 2009.

The medicine can only be obtained with a prescription.

### How is Xaluprine used?

Treatment with this medicine should be supervised by a healthcare professional experienced in treating patients with ALL.

The medicine is taken by mouth, using the syringe provided in the pack, once per day in the evening. The dose is determined for each patient mainly by body surface area and may be adjusted according to its effects in the blood. It can be taken with food (except dairy products) or on an empty stomach but this should be consistent from day to day. For more information, see the summary of product characteristics (also part of the EPAR).



## **How does Xaluprine work?**

The active substance in this medicine, mercaptopurine has a similar chemical structure to purine, which is one of the fundamental chemicals that make up DNA. In the body, 6–mercaptopurine is converted within cells into a substance that interferes with the production of new DNA. This prevents the cells from dividing. In ALL the lymphocytes multiply too quickly and live for too long. 6–mercaptopurine prevents them from dividing and they eventually die, thereby slowing down the progression of the leukaemia. Medicines containing mercaptopurine in tablet form have been already used in the EU for many years to treat patients with ALL.

## **How has Xaluprine been studied?**

Because 6-mercaptopurine has been used for the treatment of ALL in the European Union for a number of years in the tablet form, the company presented results from the scientific literature of studies previously carried out with mercaptopurine tablets.

A study was also carried out to compare the bioavailability of Xaluprine, which is an oral suspension, with that of the tablet. The bioavailability study compared the way the two different forms of the same medicine are absorbed in the human body and the levels of the active substance they produce.

## **What benefit has Xaluprine shown during the studies?**

The effectiveness of 6–mercaptopurine in slowing down the progression of ALL is already well known since it has been used for many years. The added benefit of Xaluprine is that, as an oral suspension, it will provide more accuracy in dosing and it is easier to be taken by children. The bioavailability study showed that Xaluprine is comparable to the tablets, but it works in a more predictable way and has a higher rate of absorption, for which reason the dose will need to be adjusted when a patient switches from one formulation to the other.

## **What is the risk associated with Xaluprine?**

The most common side effects with mercaptopurine (seen in more than 1 patient in 10) are leucopenia (low white blood cell counts) and thrombocytopenia (low blood platelet counts). For the full list of all side effects, see the package leaflet.

Xaluprine must not be used in people who are hypersensitive (allergic) to mercaptopurine or any of the other ingredients. It must also not be used at the same time as patients are having a yellow fever vaccination.

## **Why has Xaluprine been approved?**

The CHMP noted that mercaptopurine is established as an important treatment for ALL and that the only authorised form in the EU is a 50 mg tablet, making it difficult to adjust the dose for smaller children. The Committee considered that an oral suspension allows more accurate dosing and is more convenient for children unable to swallow tablets. The CHMP also noted that the risks of using the medicine are well known.

The Committee concluded that the benefits of Xaluprine are greater than its risks and recommended that it be granted marketing authorisation.

## **Other information about Xaluprine**

The European Commission granted a marketing authorisation valid throughout the European Union for Xaluprine on 9 March 2012.

The full EPAR for Xaluprine can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with Xaluprine, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Xaluprine can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/Rare disease designations](http://ema.europa.eu/Find/medicine/Human%20medicines/Rare%20disease%20designations).

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