LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oribamide
(hydroxycarbamide)

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Summary Public Assessment Report

Oribamide
hydroxycarbamide

Capsule, hard, 500 mg

This is a summary of the public assessment report (PAR) for Oribamide. It explains how Oribamide was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Oribamide.

For practical information about using Oribamide, patients should read the package leaflet or contact their doctor or pharmacist.

What is Oribamide and what is it used for?

Oribamide is a ‘generic medicine’. This means that Oribamide is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Hydrea.

Oribamide is used for the treatment of blood diseases (tumours of the bone marrow: chronic myeloid leukaemia, essential thrombocythaemia and polycythaemia vera).

How does Oribamide work?

Oribamide contains the active substance hydroxycarbamide, which belongs to a group of medicines used in certain blood diseases, and which interferes with the growth of cancer cells.

The exact mechanism of action of hydroxycarbamide is unknown. The most important effect of hydroxycarbamide appears to be blocking of an enzyme system (the ribonucleotide reductase system) resulting in reduced synthesis of DNA, which is important for growing cancer cells.

How is Oribamide used?

The pharmaceutical form of Oribamide is capsule, hard, for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Oribamide have been shown in studies?

Because Oribamide is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Hydrea. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Oribamide?

Because Oribamide is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Oribamide approved?

It was concluded that, in accordance with EU requirements, Oribamide has been shown to have comparable quality and to be bioequivalent to the reference medicine Hydrea. Therefore, the Medical Products Agency in Sweden decided that, as for Hydrea, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Oribamide is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Oribamide, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Oribamide

The marketing authorisation for Oribamide was granted on 2019-04-08 in Sweden.

The full PAR for Oribamide can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Oribamide, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2019-05.