LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amsacrine NordMedica (amsacrine)

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(amsacrine)

5 mg/1.5 ml concentrate and solvent for concentrate for solution for infusion

This is a summary of the public assessment report (PAR) for Amsacrine NordMedica. It explains how Amsacrine NordMedica 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 Amsacrine NordMedica.

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

What is Amsacrine NordMedica and what is it used for?

Amsacrine NordMedica is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Amsacrine NordMedica is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Amsacrine NordMedica is used to treat acute myeloid leukaemia also known as AML. AML is a form of cancer of the blood and bone marrow.
Amsacrine NordMedica is used in adults, whose disease has not responded to other therapies or in case of relapse.

How does Amsacrine NordMedica work?

Amsacrine NordMedica belongs to a group of medicines called cytostatics (medicine for the treatment of cancer).

How is Amsacrine NordMedica used?

The pharmaceutical form of Amsacrine NordMedica is concentrate and solvent for concentrate for solution for infusion.

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 Amsacrine NordMedica have been shown in studies?

As amsacrine is a well-known substance, and its use in the treatment of acute myeloid leukaemia (AML) in adults, whose disease has not responded to other therapies or in case of relapse, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of amsacrine in the treatment of acute myeloid leukaemia (AML) in adults, whose disease has not responded to other therapies or in case of relapse.

What are the possible side effects of Amsacrine NordMedica?

For the full list of all side effects reported with Amsacrine NordMedica, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Amsacrine NordMedica approved?

The use of Amsacrine NordMedica in the treatment of acute myeloid leukaemia (AML) in adults, whose disease has not responded to other therapies or in case of relapse, is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Amsacrine NordMedica's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Amsacrine NordMedica 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 Amsacrine NordMedica, 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 Amsacrine NordMedica

The marketing authorisation for Amsacrine NordMedica was granted on 2016-06-22 in Sweden.

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

This summary was last updated in 2016-07.