LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amsalyo
(amsacrine)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Amsalyo
(amsacrine)

Powder for concentrate for solution for infusion; 75 mg

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

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

What is Amsalyo and what is it used for?

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

This medicine is an anticancer (cytostatic) agent. It is used in combination with other chemotherapeutic (anticancer) agents to treat a form of cancer of the white cells in your blood, acute myeloid leukaemia. It prevents the growth of certain cells.

Amsalyo is mainly indicated in case of recurrence or failure of conventional treatments.

How does Amsalyo work?

This medicine is an anticancer (cytostatic) agent. It is used in combination with other chemotherapeutic (anticancer) agents to treat a form of cancer of the white cells in your blood, acute myeloid leukaemia. It prevents the growth of certain cells.

Amsalyo is mainly indicated in case of recurrence or failure of conventional treatments.

How is Amsalyo used?

The pharmaceutical form of Amsalyo is powder 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 Amsalyo have been shown in studies?

As *amsacrine* is a well-known substance, and its use in the treatment of *Salvage therapy of refractory/relapsed acute myeloid leukaemia (AML) in adults, in combination with other chemotherapeutic agents,* 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 *Salvage therapy of refractory/relapsed acute myeloid leukaemia (AML) in adults, in combination with other chemotherapeutic agents.*

What are the possible side effects of Amsalyo?

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

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

Why is Amsalyo approved?

The use of Amsalyo in the treatment of *Salvage therapy of refractory/relapsed acute myeloid leukaemia (AML) in adults, in combination with other chemotherapeutic agents,* 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 Amsalyo'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 Amsalyo?

A risk management plan has been developed to ensure that Amsalyo 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 Amsalyo, 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 Amsalyo

The marketing authorisation for Amsalyo was granted on 2018-06-14 in Sweden.

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

This summary was last updated in 2018-08.