LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Azacitidine STADA Nordic (azacitidine)

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Summary Public Assessment Report

Azacitidine STADA Nordic
azacitidine

Powder for suspension for injection, 25 mg/ml

This is a summary of the public assessment report (PAR) for Azacitidine STADA Nordic. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Azacitidine STADA Nordic and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Vidaza.

The reference medicine for the product is Vidaza.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

This medicine is an anti-cancer agent which belongs to a group of medicines called 'anti-metabolites'. It contains the active substance 'azacitidine'.

The product is used in adults who are not able to have a stem cell transplantation to treat:
- higher-risk myelodysplastic syndromes (MDS).
- chronic myelomonocytic leukaemia (CMML).
- acute myeloid leukaemia (AML).

These are diseases which affect the bone marrow and can cause problems with normal blood cell production.

How does Azacitidine STADA Nordic work?
This medicine works by preventing cancer cells from growing. Azacitidine becomes incorporated into the genetic material of cells (ribonucleic acid (RNA) and deoxyribonucleic acid (DNA)). It is thought to work by altering the way the cell turns genes on and off, and also by interfering with the production of new RNA and DNA. These actions are thought to correct problems with the maturation and growth of young blood cells in the bone marrow that cause myelodysplastic disorders, and to kill cancerous cells in leukaemia.

How is Azacitidine STADA Nordic used?
The pharmaceutical form is Powder for suspension for injection.

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 in Sweden.

What benefits of Azacitidine STADA Nordic have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Vidaza.

What are the possible side effects from Azacitidine STADA Nordic?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Azacitidine STADA Nordic approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Vidaza, 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 Azacitidine STADA Nordic?

A risk management plan has been developed to ensure that the product 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, 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 Azacitidine STADA Nordic

The full PAR for Azacitidine STADA Nordic can be found on the following website: MRI - Home. For more information about treatment with Azacitidine STADA Nordic, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09.