LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Azacitidine STADA (azacitidine)

SE/H/2844/001

The Summary Public Assessment Report was written in 2026 by the previous RMS (NL) after initial procedure NL/H/4659/001/DC and is attached at the end of this document. RMS transfer from NL to SE was completed 19-01-2026.

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COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Azacitidine CF 25 mg/ml, powder for suspension for injection

(azacitidine)

NL/H/4659/001/DC

Date: 3 December 2025

Summary Public Assessment Report

Generics

Azacitidine CF 25 mg/ml, powder for suspension for injection
Active substance: azacitidine

This is a summary of the public assessment report (PAR) for Azacitidine CF. It explains how this medicine 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 Azacitidine CF.

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

What is Azacitidine CF and what is it used for?

Azacitidine CF is a generic medicine. This means that it is similar to a reference medicine already authorised in the European Union (EU) called Vidaza 25 mg/ml, powder for suspension for injection.

Azacitidine CF 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 this medicine work?

Azaciditine CF contains the active substance azacitidine. Azacitidine is an anti-cancer medicine which belongs to a group of medicines called anti-metabolites. It works by preventing cancer cells from growing. Azacitidine becomes incorporated into the genetic material of cells (RNA and DNA). It is thought to work by changing the way the cell turns genes on and off. It is also thought to work 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 this medicine used?

The pharmaceutical form of Azacitidine CF is a powder for suspension for injection and the route of administration is subcutaneous (under the skin).
The recommended dose is 75 mg per m^2 body surface area. The doctor will decide the right dose for the patient. This depends on the patient's general condition, height and weight. Azacitidine CF is given to the patient as an injection under the skin by a doctor or nurse. It is given every day for 1 week, followed by a rest period of 3 weeks. This treatment cycle will be

repeated every 4 weeks. Patients usually receive at least 6 treatment cycles. At the start of each treatment cycle, the patient will be given another medicine to prevent nausea and vomiting.

The medicine can only be obtained with a prescription.

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

How has this medicine been studied?
No additional studies were needed as Azacitidine CF is a generic medicine that is given by injection and contains the same active substance as the reference medicine, Vidaza.

What are the possible side effects of this medicine?
Because Azacitidine CF is a generic medicine and is therapeutically similar 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 all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Vidaza, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Azacitidine CF, 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 and reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Azacitidine CF was granted on 16 April 2020.

The full PAR for this medicine can be found on the website https://mri.cts-mrp.eu/portal/home. For more information about treatment with Azacitidine CF, read the package leaflet (which can be found here) or contact your doctor or pharmacist.

This summary was last updated in December 2025.