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Bendamustine Accord 25 mg/mL concentrate for solution for infusion: Risk of medication errors resulting from incorrect dilution

Dear Healthcare Professional,

The Marketing Authorisation Holder for the bendamustine-containing medicinal product, Accord Healthcare Italia, in agreement with the Italian Medicines Agency (AIFA), would like to inform you of the following:

Summary

- **Bendamustine Accord 25 mg/mL concentrate for solution for infusion has a concentration that is 10 times higher than that of other authorised bendamustine-containing medicinal products.**
- Medication errors may occur due to the higher concentration of this product compared with other bendamustine-containing medicinal products.
- Errors during dilution of the medicinal product may result in overdose, leading to serious adverse reactions, with potentially fatal outcomes.
- Particular care should be taken during the preparation and dilution of the medicinal product.
- The medicinal product should be administered under the supervision of a physician qualified and experienced in the use of chemotherapeutic agents.

Further information on the safety concern

An error during the dilution procedure may result in medication errors. This risk applies exclusively to the 25 mg/mL bendamustine formulation.

The medicinal product must be prepared using aseptic technique and diluted only with 9 mg/mL (0.9%) sodium chloride solution for injection, and subsequently administered by intravenous infusion.

Preparation instructions:

- Aseptically withdraw the volume required for the prescribed dose.
- **No reconstitution is required.**
- Dilute the total dose with 0.9% sodium chloride solution for injection to a final volume of approximately 500 mL.

During dilution, it should be taken into account that the bendamustine concentration (25 mg/mL) of this medicinal product is significantly higher than that of the concentrates obtained after reconstitution of bendamustine powder formulations.

Consequently, an error during the dilution procedure may result in administration of an incorrect dose.

Call for reporting

AIFA reminds all healthcare professionals of the importance of reporting suspected adverse reactions, as this is a fundamental tool for confirming a favorable benefit–risk balance of medicines under real-life conditions of use.

Reports of suspected adverse reactions can be submitted

- *by completing the reporting form and sending it by e-mail to the Pharmacovigilance Officer of one's own institution (https://www.aifa.gov.it/responsabili-farmacovigilanza) or to the company that holds the Marketing Authorisation (MA) for the medicinal product suspected of having caused the adverse reaction,*
- *or directly online on the AIFA website https://servizionline.aifa.gov.it/schedasegnalazioni/#/).*

This DHPC is also published on the AIFA website (https://www.aifa.gov.it/), where regular consultation is recommended to ensure optimal professional knowledge and service to citizens.