PLEASE READ
IMPORTANT MEDICINE SAFETY INFORMATION
APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

accord

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Direct Healthcare Professional Communication (DHPC)

21st February 2023

Bendamustine Accord 25mg/ml concentrate for solution for infusion
Potential risk of medication errors when diluting higher strength solution

Dear Healthcare Professional,
Accord in agreement with the Health Products Regulatory Authority (HPRA) would like to inform you of the following.

Summary

- There is a risk of medication error given the higher concentration of Bendamustine Accord 25mg/ml concentrate for solution as the concentration (25mg/ml) of bendamustine in this concentrate for solution for infusion is **10 times higher per ml** in comparison with other bendamustine products for intravenous infusion currently available on the market in Ireland**.**
- Medication errors when diluting this higher strength solution could potentially lead to overdose and exacerbation of adverse reactions which may result in a potentially fatal outcome.
- Healthcare Professionals should therefore exercise caution when diluting Bendamustine Accord 25mg/ml concentrate for solution for infusion.

Background on the safety concern

Bendamustine Accord is indicated for:

- First-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.
- Indolent non-Hodgkin's lymphomas as monotherapy in patients, who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen.
- Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib-containing treatment.

Healthcare Professionals should take care of the following steps while diluting Bendamustine hydrochloride 25mg/ml concentrate for solution for infusion. Aseptic technique is to be used.

The concentrate for solution for infusion must be diluted with sodium chloride 9mg/ml (0.9%) solution for injection and then administered by intravenous infusion:

- Aseptically withdraw the volume needed for the required dose from the Bendamustine hydrochloride 25mg/ml concentrate for solution for infusion. No reconstitution is needed.

- Dilute the total recommended dose of Bendamustine hydrochloride 25mg/ml concentrate for solution for infusion with 0.9% sodium chloride solution to produce a final volume of about 500ml.

For further information, the Summary for Product's Characteristics should be consulted.

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system.
All suspected adverse reactions associated with bendamustine should be reported via:
HPRA Pharmacovigilance Website: www.hpra.ie

When reporting please provide as much information as possible, including dose administered, any side effects, medical history, concomitant medication and any other information.

Adverse events can also be reported to the Medical Information at Accord Healthcare Ltd. via E-mail: medinfo@accord-healthcare.com; Tel: +44 (0) 1271 385 257; or by completing the online form at www.accord-healthcare.ie/drug-reaction-report

Company contact point

If you need additional information please contact Accord Healthcare Ltd., Euro House, Euro Business Park, Little Island, Cork, T45 K857, Ireland; E-mail: www.accord-healthcare.ie/medical-information-form; Tel: (0)21 461 9040.

Yours sincerely,

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