Johnson&Johnson

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22 September 2025

Discontinuation of RIBOMUSTIN® (bendamustine hydrochloride) 25mg & 100mg powder for infusion as of 30 November 2025

Dear Healthcare Professional,

Janssen-Cilag Pty Ltd (**Janssen**), a Johnson and Johnson company, would like to inform you of the discontinuation of RIBOMUSTIN® (bendamustine hydrochloride) 25mg and 100mg powder for infusion in New Zealand as of **30 November 2025** for:

- RIBOMUSTIN® (bendamustine hydrochloride) 25 mg powder for infusion vial: TT50-9353a
- RIBOMUSTIN® (bendamustine hydrochloride) 100 mg powder for infusion vial: TT50-9353

RIBOMUSTIN® is currently **an unfunded medicine in New Zealand,** registered for the treatment of:

First line treatment of Chronic Lymphocytic Leukaemia (Binet stage B or C).
Previously untreated indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma. RIBOMUSTIN® should be used in combination with rituximab in CD20 positive patients.
Relapsed/Refractory indolent Non-Hodgkin's lymphoma.

Please refer to the full RIBOMUSTIN® Data Sheet should you need any information on this product, available at:
https://innovativemedicine.jnj.com/newzealand/download/ribomustin-data-sheet.pdf

RIBOMUSTIN® was licensed from Astellas Deutschland GmbH (Astellas). Pharma& Gmbh has since acquired RIBOMUSTIN®. Janssen has made the decision to discontinue RIBOMUSTIN® in certain markets, including New Zealand. The decision to discontinue this product is not due to safety or efficacy reasons. If you are currently treating or planning to treat a patient with RIBOMUSTIN®, there is a reimbursed generic option available in New Zealand.

Adverse Event and Product Quality Complaints Reporting
Janssen is committed to monitoring the safety of our products. We encourage Healthcare Professionals to report any suspected adverse events and other safety information for RIBOMUSTIN® to Medsafe at https://pophealth.my.site.com/carmreportnz/s/ and/or Janssen's Medical Information Department, and to report product quality complaints to Janssen's Medical Information Department.

If you have further questions, please contact Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com.

Yours sincerely,

Anna Dekkers
Electronically signed by: Anna Dekkers
Reason: I am approving this document
Date: Sep 22, 2025 09:19:02 GMT+10

Anne Dekkers, MD MSc
Medical Advisor, Medical & Scientific Affairs
Johnson & Johnson, Australia & New Zealand

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RIBOMUSTIN® – Minimum Data Sheet

RIBOMUSTIN® is an is an unfunded medicine – a prescription charge will apply;

Indications: First line treatment of Chronic Lymphocytic Leukaemia (Binet stage B or C). Previously untreated indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma. RIBOMUSTIN® should be used in combination with rituximab in CD20 positive patients. Relapsed/Refractory indolent Non-Hodgkin's lymphoma.

Contraindications: RIBOMUSTIN® is contraindicated in patients with: Hypersensitivity to the active substance or to any of the excipients; Severe hepatic impairment (serum bilirubin > 3.0 mg/dL);Jaundice; Severe bone marrow suppression and severe blood count alteration (leukocyte and/or platelet values dropped to < 3x109/L or <75x109/L, respectively); Major surgery less than 30 days before start of treatment; Infections, especially involving leukocytopaenia; Yellow fever vaccination; RIBOMUSTIN® is also contraindicated during breast-feeding.

Precautions: Myelosuppression; infections; skin reactions; hepatitis B reactivation; patients with cardiac disorders; nausea, vomiting; tumour lysis syndrome; anaphylaxis; extravasation; **Non-melanoma skin cancer,* other malignancies; pregnancy (category C); lactation; children; see full Data Sheet.

Dose and method of use: For intravenous infusion over 30 - 60 minutes. Infusion must be administered under the supervision of a physician qualified and experienced in the use of chemotherapeutic agents.
Monotherapy for chronic lymphocytic leukaemia 100 mg/m² body surface area bendamustine hydrochloride on days 1 and 2; every 4 weeks, for up to 6 cycles. *Monotherapy for indolent non-Hodgkin's lymphomas refractory to rituximab* 120 mg/m² body surface area bendamustine hydrochloride on days 1 and 2; every 3 weeks, for at least 6 cycles. *Combination therapy with rituximab for first-line non-Hodgkin's lymphoma and mantle cell lymphoma* 90 mg/m2 on days 1 and 2 of a 4-week cycle for up to 6 cycles. Treatment should be terminated or delayed if leukocyte and/or platelet values dropped to < 3x109/L or < 75x109/L, respectively.
RIBOMUSTIN® must be diluted with 0.9% NaCl solution and not with any other injectable solution.

Interactions with other medicines: Myelosuppressive agents; cyclosporine; tacrolimus; live-virus vaccination; CYP1A2 inhibitors such as fluvoxamine, ciprofloxacin, acyclovir, cimetidine, see full Data Sheet.

Adverse events: neutropaenia, thrombocytopaenia, anaemia, leukopaenia, nausea, vomiting, diarrhoea, constipation, stomatitis, pyrexia, abdominal pain, dyspepsia, fatigue, weight decreased, anorexia, dehydration, decreased appetite, back pain, headache, dizziness, insomnia, dyspnoea, cough, rash, chills, peripheral oedema, asthenia, upper respiratory tract infection, herpes zoster, urinary infection; others, see full Data Sheet

Presentation: RIBOMUSTIN® is supplied in Type I brown glass vials of 26 ml or 60 ml with rubber stopper and an aluminum flip-off cap. 26 mL vials contain 25 mg bendamustine hydrochloride; supplied in cartons containing 1 vial. 60 mL vials contain 100 mg bendamustine hydrochloride; supplied in cartons containing 1 vial. The vials are for single use only.
Date of Preparation: 26 May 2021

Before prescribing please review full Data Sheet (available from https://innovativemedicine.jnj.com/newzealand/download/ribomustin-data-sheet.pdf)
Janssen-Cilag Pty Ltd, PO Box 62185, Sylvia Park, Auckland 1644, New Zealand.
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