

Ribomustine[®]

bendamustine

Product Monograph

updated 01/2002



Table of contents

1. Historical review	7
2. Product description	8
2.1 Description of the finished medicinal product	8
2.2 Chemical name and structural formula of the active ingredient	8
2.3 Presentation	8
2.4 Indications	9
2.5 Contraindications	9
2.6 Type of use	9
2.7 Dosage by individual and daily doses	10
3. Toxicology	11
3.1 Acute toxicity	11
3.2 Subchronic toxicity	11
3.3 Mutagenic and carcinogenic effects	12
3.4 Reproductive toxicity and teratogenic activity	12
4. Pharmacology	13
4.1 Efficacy in animal models and cell culture	13
4.2 Mechanism of action	16
5. Pharmacokinetics	17
5.1 Site of absorption and absorption kinetics	17
5.2 Protein binding	17
5.3 Concentration in tissue	17
5.4 CSF penetration	17
5.5 Placental transfer	17
5.6 Excretion in breast milk	17
5.7 Biological half-life	18
5.8 Elimination	18

5.9	Elimination in impaired renal function	18
5.10	Elimination in impaired hepatic function	18
5.11	Dialysability	18
5.12	Metabolism	19
<hr/>		
6.	Clinical efficacy	20
6.1	Hodgkin's disease (stage II-IV)	20
6.2	Non-Hodgkin lymphoma (NHL)	22
6.3	Chronic lymphocytic leukemia (CLL)	29
6.4	Plasmocytoma (multiple myeloma / MM)	32
6.5	Breast cancer	35
6.6	In clinical evaluation – lung cancer	39
6.7	In clinical evaluation – gastrointestinal tumours	39
6.8	In clinical evaluation – head and neck cancer	40
6.9	Effects on lymphocyte subsets	40
<hr/>		
7.	Tolerability	43
7.1	General	43
7.2	Hematopoietic system	43
7.3	Gastrointestinal tract	44
7.4	Nervous system	44
7.5	Allergic reactions / hypersensitivity	44
7.6	Cardiovascular system	44
7.7	Skin, mucosa	45
7.8	Local irritations	45
7.9	Other side effects	45
7.10	Note for drivers	45
<hr/>		
8.	Overdosage	46
8.1	Main symptoms and general signs of overdosage	46
8.2	Treatment of overdosage and intoxication	47
<hr/>		
9.	Summary	48
<hr/>		
10.	References	49
<hr/>		
11.	Abbreviations	55
<hr/>		
	Directions for Use for Physicians	56

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.