

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205580Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

---

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

**\*\*\* This document contains proprietary information that cannot be released to the public\*\*\***

---

**Date of This Review:** March 22, 2018  
**Application Type and Number:** NDA 205580  
**Product Name and Strength:** Belrapzo (bendamustine HCL) Injection  
**Total Product Strength:** 100 mg/4 mL (25 mg/mL)  
**Product Type:** Single Ingredient  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** Eagle Pharmaceuticals, Inc.  
**Panorama #:** 2018- 20949012  
**DMEPA Safety Evaluator:** Idalia E. Rychlik, PharmD.  
**DMEPA Team Leader:** Hina Mehta, PharmD.  
**DMEPA Associate Director:** Mishale Mistry, PharmD, MPH  
**DMEPA Division Director:** Todd Bridges, RPh

---

## Contents

1	INTRODUCTION.....	1
1.1	Product Information .....	1
2	RESULTS.....	1
2.1	Misbranding Assessment.....	1
2.2	Safety Assessment.....	1
3	CONCLUSION .....	5
3.1	Comments to the Applicant.....	5
4	REFERENCES .....	6
	APPENDICES .....	7

## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Belrapzo, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [REDACTED] (b) (4) for this proposed proprietary name.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 2, 2018.

- Intended Pronunciation: bell-RAP-zoh
- Active Ingredient: bendamustine hydrochloride
- Indication of Use: treatment of chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 100 mg/4 mL (25 mg/mL)
- Dose and Frequency: The usual dosage and frequency of administration for this product is:
  - CLL: 100 mg/m<sup>2</sup> infused intravenously over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles
  - NHL: 120 mg/m<sup>2</sup> infused intravenously over 60 minutes on days 1 and 2 of a 21-day cycle, up to 8 cycles

[REDACTED] (b) (4)  
[REDACTED]

- How Supplied: multi-dose vials with an [REDACTED] (b) (4) stopper
- Storage: refrigerated (2°C to 8°C), protected from light

## 2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

### 2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

### **2.2.1 United States Adopted Names (USAN) Search**

There is no USAN stem present in the proprietary name<sup>a</sup>.

### **2.2.2 Components of the Proposed Proprietary Name**

The Applicant did not provide a derivation or intended meaning for the proposed name, Belrapzo in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

### **2.2.3 Comments from Other Review Disciplines at Initial Review**

In response to the OSE, February 22, 2018 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

### **2.2.4 FDA Name Simulation Studies**

Ninety-two (92) practitioners participated in DMEPA's prescription studies. One participant misinterpreted the name Belrapzo as "Darazol" in the voice prescription simulation, which is a close variation to the currently marketed product "Danazol". We note that the name pair have sufficient orthographic and phonetic differences, with a combined POCA score of 40.

Phonetically the first syllables ("Bel-" vs. "Dan") of this name pair provide some phonetic differences. Orthographically, the prefixes (Bel vs. Dan), infixes (rap vs. a), and the presence of an upstroke letter "l" in the suffix of Danazol provide sufficient differences. In addition, Belrapzo and Danazol differ in dosage form (*injection vs. capsule*), routes of administration (*intravenous vs. oral*), and frequency (*once every 21 or 28-day cycle, for a total 6 to 8 cycles vs. 2 to 3 times daily*). We evaluate this name pair in Appendix E.

Appendix B contains the results from the verbal and written prescription studies.

### **2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results**

Our POCA search<sup>b</sup> identified 34 names with a combined phonetic and orthographic score of  $\geq 55\%$  or an individual phonetic or orthographic score  $\geq 70\%$ . These names are included in Table 1 below.

### **2.2.6 Names Retrieved for Review Organized by Name Pair Similarity**

Table 1 lists the number of names retrieved from our POCA search, FDA Name Simulation Studies and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

---

<sup>a</sup> USAN stem search conducted on (2/13/18).

<sup>b</sup> POCA search conducted on (2/13/18) in version 4.2.

# 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.