CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206356Orig1s000

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:	September 23, 2015
Application Type and Number:	NDA 206356
Product Name and Strength:	Orfadin (Nitisinone) Oral Suspension, 4 mg/mL
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Swedish Orphan Biovitrum
Submission Date:	July 31, 2015
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph
DMEPA Team Leader:	Kendra Worthy, Pharm.D.
DMEPA Associate Director:	Lubna Merchant, M.S., Pharm.D.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Orfadin, from a safety and misbranding perspective. NDA 206356 is a new dosage form (Oral Suspension) for Orfadin and the Applicant is proposing that this dosage form also be marketed under the proprietary name, Orfadin. The capsule formulation of Orfadin (nitisinone) was approved on January 18, 2002 under NDA 21232.

1.1 REGULATORY HISTORY

The product information in Table 1 is provided in the proprietary name submission and proposed prescribing information submitted by Applicant on July 31, 2015.

Products:	**Orfadin Oral Suspension** **Proposed**	**Orfadin Capsules** **Approved January 18, 2002**
Active Ingredient:	Nitisinone	Nitisinone
Indication:	Adjunct to dietary restriction of tyrosine and phenylalanine in the treatment of hereditary tyrosinemia type 1 (HT-1)	Adjunct to dietary restriction of tyrosine and phenylalanine in the treatment of hereditary tyrosinemia type 1 (HT-1)
Route of Admini-stration:	Oral	Oral
Dosage Form:	Oral Suspension	Capsule
Strength:	4 mg/mL	2 mg, 5 mg and 10 mg
Dose and Frequency	1 mg/kg/day divided into two daily doses	1 mg/kg/day divided into two daily doses
How	100 ml Brown bottle	Bottle of 60 capsules

Supplied:		
Storage:	Store refrigerated, 2-8°C (36-46°F)	Store refrigerated, 2-8°C (36-46°F)
Container and Closure System:	Child resistant HDPE screw cap	Tamper-resistant low density (LD) polyethylene snap-on cap

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 does not misbrand the proposed product. DMEPA and the Division of Gastroenterology and Inborn Error Products (DGIEP) 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[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Orfadin, 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.

[1]USAN stem search conducted on August 27, 2015

2.2.3 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A for a description of FAERS database) for name confusion errors involving the tablet formulation of Orfadin. This search did not yield any cases of name confusion with Orfadin.

Table 2. FAERS Search Strategy	
Date	**August 28, 2015**
Drug Name(Product Name)	**Orfadin (Nitisinone)**
MedDRA Event Search	**DMEPA Official Proprietary Name Review Search Terms Event List:** Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Time/Date Limits	August 1, 2010 to August 1, 2015

2.2.3 Multiple Dosage Forms Under a Single Proprietary Name

Orfadin is currently marketed as capsules under NDA 21232. We note that the Orfadin oral suspension shares the same active ingredient, same

indication, [redacted] (b) (4) and same route of administration. They differ in some characteristics including strength and dosage form. It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. Differences in strengths and dosage form can be managed via labeling.

Moreover, we have not retrieved any medication errors involving the proprietary name Orfadin. Therefore, given the precedent for using this naming convention, we have no safety concerns with the proposal to market this product with the proprietary name Orfadin.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 12, 2015, the Division of Gastroenterology and Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastrointestinal and Inborn Error Products (DGIEP) via e-mail September 10, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on September 23, 2015, they stated no additional concerns with the proposed proprietary name, Orfadin.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact, Alexander Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Orfadin, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your July 31, 2015, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES AND DATABASE DESCRIPTION.

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**

   USAN Stems List contains all the recognized USAN stems.

2. **FDA Adverse Event Reporting System (FAERS)**

   The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

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