CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205613Orig1s000

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:	April 9, 2014
Application Type and Number:	NDA 205613
Product Name and Strength:	Uceris (Budesonide) Rectal Foam 2 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Salix
Submission Date:	February 18, 2014
Panorama #:	2014-16934
DMEPA Primary Reviewer:	Matthew Barlow BSN
DMEPA Team Leader:	Lubna Merchant MS PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Uceris, from a safety and promotional perspective. The applicant submitted the proprietary name amendment on March 26, 2014. NDA 205613 is a new dosage form (rectal foam) for Budesonide and the Applicant is proposing that this dosage form also be marketed under the proprietary name, Uceris. The tablet formulation of Uceris (Budesonide tablets) 9 mg was approved January 14, 2013.

1.1 PRODUCT INFORMATION

The product information within, Table 1, is provided in the February 18, 2014 proprietary name submission and the amendment submitted by the Sponsor on March 26, 2014.

Table 1: Product Characteristics Comparison

Products:	**Uceris Rectal Foam**	**Uceris Extended-release Tablets**
Active Ingredient:	Budesonide	Budesonide
Indication:	Induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge.	Induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge.
Route of Administration:	Rectal	Oral
Dosage Form:	Rectal Foam	Extended Release Tablets
Strength:	2 mg	9 mg
Dose and Frequency	1 metered dose (2 mg) administered twice daily for 2 weeks followed by 1 metered dose administered once daily for 4 weeks. Maximum daily dose of 4 mg	One tablet by mouth once daily
How Supplied:	Supplied in an aerosol container and packaged with 14 PVC applicators coated with paraffin lubricant for administration of the foam. The container will deliver 14 doses.	Bottles of 30
Storage:	Store at room temperature.	USP controlled room temperature
Container and Closure System:	The primary container closure system for the drug product is	(b) (4) safety cap

	comprised of a 54-mL, white, aluminum [redacted] canister [redacted], fitted with a 1-inch metering valve consisting of a [redacted] valve body and stem affixed with a 1.35-mL metering head. A plastic safety tab that prevents accidental actuation is attached to a foam shield and must be removed prior to use.	

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Division of Gastrointestinal and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's promotional 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 indicated in their submission that the proposed name, Uceris, is derived from the approved and currently marketed 9 mg tablets with same indication as the proposed rectal foam. 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 March 14, 2014.

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 Uceris. This search did not yield any cases of name confusion with Uceris.

Table 2. FAERS Search Strategy	
Date	March 21, 2014
Drug Name(Product Name)	Uceris
MedDRA Event Search	Medication Errors-HLGT Product Label Issues-HLT Product Packaging Issues-HLT Product Quality Issues NEC-HLT
Time/Date Limits	FDA Rec'd To Date:03/01/2014

2.2.4 Multiple Dosage Forms Under a Single Proprietary Name

The currently marketed Uceris tablets and the proposed Rectal Foam share the same active ingredient and indication, but have other characteristics that differ including dosage form, strength, dosing frequency and route of administration.

It is a common and accepted practice to have a product line with multiple dosage forms given via different routes managed under one proprietary name. We note that the strength, dose and frequency differs between the two dosage forms, however these differences can be managed via labeling. There are currently other marketed products available in different strengths administered at different frequencies which are managed safely under one proprietary name. Additionally, there are also risks associated with using dual proprietary names. The use of a new proprietary name for the rectal foam poses a risk of concomitant therapy of these medications if practitioners and patients fail to recognize that both products contain Budesonide leading to overdose.

Moreover, we have not retrieved any medication errors involving the proprietary name Uceris and other marketed drug products. 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 Uceris.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 26, 2014 e-mail, the Division of Gastrointestinal and Inborn Error Products (DGIEP), and the office of Prescription Drug Promotion (OPDP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 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 on March 26, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on April 7, 2014, they stated no additional concerns with the proposed proprietary name, Uceris.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact, Pete Do, OSE project manager, at 301-796-4795.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your February 18, 2014 submission are altered, 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 post market 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. Adverse events and medication errors are coded 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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04/09/2014

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