CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208056Orig1s000

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)

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Date of This Review:	July 15, 2015
Application Type and Number:	NDA 208056
Product Name and Strength:	Dexilant SoluTab (Dexlansoprazole) 30 mg Orally Disintegrating Tablets
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Takeda Development Center Americas, Inc.
Panorama #:	2015-370476
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Kendra Worthy, Pharm.D.
Associate Director	Lubna Merchant, Pharm.D., MS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Dexilant SoluTab, from a safety and misbranding perspective. The sources and methods used to evaluate the Dexilant SoluTab are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Dexilant (b) (4) *** on October 2, 2014. On March 26, 2015, we had a teleconference with the Applicant requesting they consider the use of a standard modifier that has already been used in the marketplace to describe the orally disintegrating tablets. On March 31, 2015, the Applicant withdrew the original proprietary name and resubmitted the new proposed name, Dexilant Solutab on May 1, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 1, 2015, proprietary name submission.

Products:	**Dexilant SoluTab Proposed**	**Dexilant Capsules Approved January 30, 2009**
Active Ingredient:	Dexlansoprazole	Dexlansoprazole
Indication:	(b) (4)	Healing of all grades of erosive esophagitis (EE) for up to eight weeks.
	Maintenance of healed EE and relief of heartburn for up to six months.	Maintenance of healed EE and relief of heartburn for up to six months.
	Treatment of heartburn associated with symptomatic non-erasive gastroesophageal reflux disease (GERD) for four	Treatment of heartburn associated with symptomatic non-erasive gastroesophageal reflux disease (GERD) for four weeks.

	weeks.	
Route of Admini-stration:	Oral	Oral
Dosage Form:	Orally disintegrating tablets	Delayed-release capsule
Strength:	30 mg	30 mg and 60 mg
Dose and Frequency	Take 1 (b) (4) tablet (b) (4) once daily	Healing of EE: 60 mg once daily up to 8 weeks. Maintenance of healed EE: 30 mg once daily for upto 6 months. Symptomatic non-erosive GERD: 30 mg once daily for up to 4 weeks.
How Supplied:	Blister packs: Trade unit of 100 (10 packs of 10 tablets) Sample unit of 20 (6 packs of 5 tablets)	Unit dose package of 100, bottle of 30 capsules, bottle of 90 capsules and bottle of 1000.
Storage:	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86° F)	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86° F)

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 Dexilant SoluTab would not misbrand the proposed product. DMEPA and

the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's assessment of the Dexilant SoluTab.

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 proposed proprietary name, Dexilant SoluTab, is comprised of two words: the root name 'Dexilant' and the modifier 'SoluTab'. The Applicant indicated in their submission that the modifier 'SoluTab' accurately describes the pertinent characteristic of the product. Dexilant Solutab is comprised of a delayed-release formulation which is soluble and intended to orally disintegrate when placed on the tongue. Additionally, the Applicant has indicated that "Solutab" is the approved modifier for "Prevacid Solutab", ODT formulation for Lansoprazole, which is also marketed by Takeda.

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 A1 for a description of FAERS database) for name confusion errors involving Dexilant which would be relevant for this review.

Table 2. FAERS Search Strategy	
Date	May 21, 2015
Drug Name(Product Name)	Dexilant
MedDRA Event Search	Medication Errors-HLGT Product Label Issues-HLT

[1]USAN stem search conducted on May 21, 2015

Reference ID: 3792798

	Product Packaging Issues-HLT Product Quality Issues NEC-HLT
Time/Date Limits	May 1, 2013 to May 1, 2015[2]

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, we identified one case that may have been related to name confusion:

This case described an emergency room nurse who entered Dexalone 60 mg daily (Dextromethorphan) instead of Dexilant 60 mg. The root cause of this error was not reported. When the patient was being discharged, the error was discovered and corrected; no patient involvement was reported.

In the original proprietary name review[3], Dexalone was considered to be a potential confusing name with numerical overlap in strength or dose. It is unclear what contributed to the error in this case, however, it is unlikely that Dexalone will cause a name confusion with Dexilant since Dexalone has not been marketed since 2005, and cannot be found in any commonly used drug references.

2.2.4 FDA Name Simulation Studies

87 practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. 53 participants interpreted the proposed name correctly (outpatient n=25 voice=7, inpatient n=21). Appendix B contains the results from the verbal and written prescription studies.

[2]Last FAERS search was conducted for dates: February 25, 2010 to May 1, 2013.

[3]Khoslov, L. Label and Labeling review for Dexilant (NDA 22287). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 06 17. 32 p. OSE RCM No.: 2013-936

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 23, 2015 e-mail, the Division of the Division of Gastroenterology and Inborn Errors Products (DGIEP) 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 Gastroenterology and Inborn Errors Products (DGIEP) via e-mail on July 7, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on July 15, 2015, they stated no additional concerns with the proposed proprietary name, Dexilant SoluTab.

2.2.7 Safety Analysis of the Modifier "Solutab"

The applicant has proposed to use the modifier "Solutab" to represent the orally disintegrating tablet formulation. According to the applicant, the modifier conveys the characteristic of the proposed product (orally disintegrating tablet).

The modifier "SoluTab" has been used in the marketplace for orally disintegrating tablet (e.g. Prevacid Solutab). In addition, we received confirmation from the Office of New Drug Quality Assessment (ONDQA) that the product did meet the criteria for an orally disintegrating tablet. Since the proposed formulation is an orally disintegrating tablet, we find that the proposed modifier is not misleading. Additionally, we are not aware of any cases of name confusion reported with the use of this modifier. We note that modifiers may sometimes be omitted. If the modifier, Solutab, is omitted, the patient may receive the Dexilant capsules, and since both the marketed and the proposed Dexilant products are (b) (4) this error would cause minimal clinical impact. Thus, in this circumstance we believe the addition of a modifier will add a measure of safety. For the reasons discussed above, we agree that the proposed modifier is acceptable for this product.

3.0 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 1, 2015, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

3 REFERENCES

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c) (3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Dexilant SoluTab Study (Conducted on May 29, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Dexilant Solutab 1 po daily	Dexilant SoluTab 1 tab (b) (4) # (b) (4)
Outpatient Prescription: (b) (4) (b) (4)	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

246 People Received Study

87 People Responded

Study Name: Dexilant Solutab

Total	**31**	**25**	**31**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DECOLANT SOLUTAB	0	1	0	1
DESILANT SOLUTAB	0	1	0	1
DEXALAN SOLUTAB	0	1	0	1

DEXALANT SOLUTAB	0	10	1	11
DEXALANT SOLUTABS	0	1	0	1
DEXERIN SOLUTAB	0	1	0	1
DEXICANT SOLUTAB	1	0	0	1
DEXIDANT SOLUTAB	0	0	1	1
DEXILANT SALUTAB	1	0	0	1
DEXILANT SOLU TAB	1	1	0	2
DEXILANT SOLUTAB	25	7	21	53
DEXILANT SOLUTABS	1	0	0	1
DEXILENT SOLUTAB	1	0	0	1
DEXILIANT	1	0	0	1
DEXITANT SOLUTAB	0	0	8	8
DEXSOLANT SOLUTAB	0	1	0	1
DEXULANT SOLUTAB	0	1	0	1

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/s/

SHERLY ABRAHAM
07/15/2015

KENDRA C WORTHY
07/18/2015

LUBNA A MERCHANT
07/19/2015