

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-217

PROPRIETARY NAME REVIEW(S)



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: August 11, 2009

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Subject: Final Proprietary Name Review

Drug Name(s): Valturna (Aliskiren and Valsartan) Tablets 150 mg/160 mg and
300 mg/320 mg

Application Type/Number: NDA 22-217

Applicant: Novartis

OSE RCM #: 2009-335

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1 INTRODUCTION

This review is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Valturna, acceptable in OSE Review #2008-1952, dated February 19, 2009. Since that review, none of Valturna's product characteristics have been altered. Additionally, on December 18, 2008, DDMAC reviewed the proposed name and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Valturna, during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review# 2008-1952 for the proposed proprietary name, Valturna. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded three new names, Ultiva, Ultane, and Ultram, thought to look similar to Valturna and represent a potential source of drug name confusion. These names were evaluated using FMEA. The findings of the FMEA indicate that the proposed name, Valturna, is not likely to result in name confusion with Ultiva, Ultane, or Ultram for the reasons presented in Appendix A.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Valturna, as of July 31, 2009.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Valturna, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Valturna, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Cardiovascular and Renal Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE review # 2008-1952 Proprietary Name Review of Valturna; Griffis, Melina and Taylor, Kellie
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.
3. **Electronic online version of the FDA Orange Book** (<http://www.fda.gov/cder/ob/default.htm>)
The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.
4. **USAN Stems** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)
USAN Stems List contains all the recognized USAN stems.

Appendix A: Product with no numerical overlap in strength or dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Valturna	N/A	150mg/160mg; 300mg/320mg	Take one tablet once daily
Ultiva	Orthographic	EQ 1mg Base/Vial EQ 2mg Base/Vial EQ 5mg Base/Vial	Individualized
Ultane	Orthographic	100%	Individualized
Ultram	Orthographic	50mg	Started at 25 mg per day qAM and titrated in 25 mg increments as separate doses every 3 days to reach 100 mg per day (25 mg q.i.d.). Thereafter the total daily dose may be increased by 50 mg as tolerated every 3 days to reach 200 mg per day (50 mg q.i.d.). After titration, ULTRAM® 50 to 100 mg can be administered as needed for pain relief every 4 to 6 hours not to exceed 400 mg per day.

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