

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207844Orig1s000

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: | October 7, 2014 |
| Application Type and Number: | NDA 207844 |
| Product Name and Strength: | Albenza (albendazole) Chewable Tablet, 200 mg |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Rx |
| Applicant/Sponsor Name: | Amedra Pharmaceuticals |
| Submission Date: | September 5, 2014 |
| Panorama #: | 2014-26343 |
| DMEPA Primary Reviewer: | Danielle Neupauer, RPh |
| DMEPA Acting Team Leader: | Tingting Gao, PharmD |
| DMEPA Associate Director: | Lubna Merchant, MS, PharmD |

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Albenza, from a safety and misbranding perspective. NDA 207844 is a new dosage form (chewable tablets) for Albenza and the Applicant is proposing that this dosage form also be marketed under the proprietary name, Albenza. The tablet formulation of Albenza 200 mg was approved on June 11, 1996.

1.1 REGULATORY HISTORY

The product information within is provided in the proprietary name submission and proposed prescribing information submitted by the Applicant on June 19, 2014 and on September 5, 2014.

| Product Information for Albenza | | |
|---------------------------------|--|--|
| Product | Albenza Tablet | Albenza Chewable Tablet |
| Initial Approval Date | June 11, 1996 | Currently under review |
| Active Ingredient | Albendazole | Albendazole |
| Indication | Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, <i>Taenia solium</i> . Treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, <i>Echinococcus granulosus</i> . | Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, <i>Taenia solium</i> . Treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, <i>Echinococcus granulosus</i> . |
| Route of Administration | Oral | Oral |
| Dosage Form | Tablets | Chewable tablets |
| Strength | 200 mg | 200 mg |
| Dose and Frequency | Patients \geq 60 kg, 400 mg twice daily; < 60 kg, 15 mg/kg/day in divided doses twice daily (maximum total daily dose 800 mg). | Patients \geq 60 kg, 400 mg twice daily; < 60 kg, 15 mg/kg/day in divided doses twice daily (maximum total daily dose 800 mg). |
| How Supplied | Bottles of 2 tablets Bottles of 28 tablets | 2 Tablets in 1 Blister Pack (configured as a Wallet Card) |

| | | |
|--------------------------|---|--|
| | | 6 Tablets in 1 Blister Pack; 2 Blister Packs in 1 Carton |
| Storage | Store at (b) (4), 20° to 25°C (68° to 77°F) | Store at (b) (4), 20° to 25°C (68° to 77°F) |
| Container Closure | | Each (b) (4) foil laminate blister has a peel-push or a push-through blister foil lid and contains one tablet. |

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 Anti-Infective Products (DAIP) 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 name¹.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Albenza 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 *Medication Error Data Selection of Cases*

We searched the FDA Adverse Event Reporting System (FAERS) database for name confusion errors involving the tablet formulation of Albenza which would be relevant for this review.

The July 11, 2014 search of FAERS database used the following search terms: Albendazole [active ingredient] and Albenza [product name]

¹USAN stem search conducted on September 30, 2014.

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.

The search yielded 1 relevant case that was received on June 4, 2008. This case reported that a prescription for Albenza was accidentally transcribed as Avinza, and this error was caught prior to dispensing. Although the case did not report any contributing factors, we determined that this error most likely occurred due to phonetic similarity between Albenza and Avinza.

We evaluated this name pair further and determined that the risk of name confusion between Avinza and Albenza is mitigated by the fact that Avinza and Albenza do not share overlapping product characteristics. Avinza is a narcotic available as 30, 60, 90, and 120 mg capsules and is administered once daily. Albenza is available in 200 mg tablets and the dose ranges from 15 mg/kg/day to 400 mg twice daily. Given the length of time that these products have been on the market, and that we have not received additional reports of wrong drug errors associated with Albenza since 2008, we determined there is minimal risk for confusion between this name pair that would lead to medication errors.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 22, 2014 e-mail, the Division of Anti-Infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Multiple Dosage Forms Under a Single Proprietary Name

The new formulation (chewable tablets) will be the same strength (200 mg) as the current marketed formulation (tablets). The Albenza tablet and the proposed chewable tablet share the same active ingredient, same indication, dose and strength. The current and proposed formulations differ in dosage form. We acknowledge that this may lead to possible medication errors where one formulation may be dispensed for the other and may result in an adverse event. However, we evaluated the approved Prescribing Information (PI) for the current marketed formulation (tablets), and noted that it states “in young children, the tablets should be crushed or chewed and swallowed with a drink of water”. Since the current marketed formulation (tablets) may also be chewed, we have no concerns with the proposed new chewable tablet formulation from a medication error perspective.

It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. Although only the dosage form differs between the current Albenza tablets and the proposed Albenza chewable tablets, we determined that the differences can be managed via labeling. Additionally, there are also risks associated with using dual proprietary names. The use of a new proprietary name for the chewable formulation poses a risk of concomitant therapy if practitioners and patients fail to recognize that both products contain albendazole leading to overdose.

Moreover, we have not retrieved any medication errors involving the proprietary name Albenza and other marketed drug products since 2008. 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 Albenza.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anti-Infective Products (DAIP) via e-mail on October 2, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on October 7, 2014, they stated no additional concerns with the proposed proprietary name, Albenza.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 5, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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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10/07/2014

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