CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212660Orig1s000

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:	March 23, 2020
Application Type and Number:	NDA 212690
Product Name and Strength:	Xywav (calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate) oral solution, 0.5 g/mL[a]
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Jazz Pharmaceuticals Ireland Limited (Jazz)
Panorama #:	2020-37463829
DMEPA Safety Evaluator:	Justine Kalonia, PharmD
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

[a] The actual potency is 0.413 g/mL (active moiety; oxybate). The Applicant requested an exception to the salt policy. The decision is pending. (b) (4)

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xywav, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Jazz submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 21, 2020.

- Intended Pronunciation: ZĪE-wāv
- Active Ingredient: calcium oxybate, potassium oxybate, magnesium oxybate, sodium oxybate
- Indication of Use: treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy
- Route of Administration: oral
- Dosage Form: oral solution
- Strength: 0.5 g/mL[b]
- Dose[c] and Frequency:
    - Adults: The recommended starting dose is 4.5 g per night, divided into two doses: 2.25 g at bedtime and 2.25 g taken 2.5 to 4 hours later. Increase the dosage by up to 1.5 g per night at weekly intervals to the effective dose range of 6 g to 9 g.
    - Pediatric (7 years of age and older): Administer orally twice per night. The recommended starting pediatric dosage, titration regimen, and maximum nightly dosage are based on patient weight, as specified in Table 2 of the prescribing information section 2.2.
- How Supplied: Clear slightly opalescent oral solution in one 180 mL amber bottle with child-resistant caps and attached press in bottle adaptor, an oral measuring device (plastic syringe), and a Medication Guide.
- Storage: Store between 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).
- Reference Listed Drug/Reference Product: N/A

2 RESULTS

[b] Actual potency 0.413 g/mL (active moiety). (b) (4) .

[c] Dose is subject to change pending OPQ USP Salt Policy decision.

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Xywav would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Xywav.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Xywav.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[d].

2.2.2 Components of the Proposed Proprietary Name

Jazz did not provide a derivation or intended meaning for the proposed proprietary name, Xywav, 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 24, 2020, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Xywav at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-six practitioners participated in DMEPA's prescription studies for Xywav. 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.

One respondent in the inpatient study provided a supplemental comment. The respondent stated, "close to Xyzal". We evaluated the name pair, Xywav and Xyzal, further and find that there are sufficient orthographic and phonetic differences between the name pair. Orthographically, the suffixes (-wav vs. -zal) of the names look sufficiently different. Xyzal has the upstroke letter 'l' in the suffix whereas, Xywav does not contain any upstroke letters, which gives the names different shapes when scripted. Additionally, the 'z' in Xyzal may scripted with a cross-stroke or downstroke, which may provide additional differentiation. Phonetically, the second syllables (-wāv vs. -zal) sound different when spoken. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is minimal (see Appendix E).

Appendix B contains the results from the prescription simulation studies.

[d] USAN stem search conducted on January 30, 2020.

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