CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216986Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	August 1, 2022
Application Type and Number:	NDA 216986
Product Name and Strength:	Elucirem (gadopiclenol) Injection, 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Guerbet LLC (Guerbet)
PNR ID #:	2022-1044724620
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Elucirem, 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. Guerbet submitted an external name study, conducted by [redacted], for this proposed proprietary name.

1.1 REGULATORY HISTORY

Guerbet previously submitted the proposed proprietary name, [redacted] on March 27, 2020. However, under IND 123673 on August 5, 2020, Guerbet formally withdrew the proprietary name, [redacted]. On May 28, 2021, Guerbet formally submitted the proposed proprietary name, [redacted], for review. Subsequently, [redacted] was found conditionally acceptable under IND 123673 on November 17, 2021.[a] Guerbet submitted [redacted] for review on January 21, 2022 as part of the marketing package for NDA 216986. However, on February 23, 2022, Guerbet formally withdrew the proprietary name, [redacted]. On March 1, 2022, Guerbet submitted the proposed proprietary name, [redacted] under NDA 216986. However, on June 7, 2022, Guerbet formally withdrew the proprietary name, [redacted].

Thus, Guerbet submitted the name, Elucirem, for review on June 7, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 7, 2022.

- Intended Pronunciation: ah – LOOS – er - em
- Active Ingredient: gadopiclenol
- Indication of Use: Indicated in adults and children aged 2 years and older for contrast enhancement in Magnetic Resonance Imaging (MRI) to [redacted]
  - [redacted] the brain, spine and [redacted] tissues
  - [redacted] body [redacted] head and neck, thorax, abdomen, pelvis and musculo-skeletal system.
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 1.5 mmol/3 mL (0.5 mmol/mL), [redacted] mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL)

[a] Kane, D. Proprietary Name Review for Altivity (IND 123673). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 NOV 17. PNR ID No. 2021-1044723996.

- Dose and Frequency: Adults: Gadopiclenol is 0.05 mmol/kg body weight equivalent to 0.1 ml/kg body weight for all indications. Child: No dosage adjustment is considered necessary.
- How Supplied: Elucirem is supplied in the following presentations:
    - Vial (glass)
        - 3 mL vial (filled in 10 mL vial) packed in a carton box of 1 and 10
        - 7.5 mL vial (filled in 10 mL vial) packed in a carton box of 1 and 10
        - 10 mL vial (filled in 10 mL vial) packed in a carton box of 1 and 10
        - 15 mL vial (filled in a 20 mL vial) packed in a carton box of 1 and 10
    - Prefilled Syringe (plastic)
        - 7.5 mL prefilled syringe (filled in 15 mL syringe) packed in a carton box of 1 and 10
        - 10 mL prefilled syringe (filled in 15 mL syringe) packed in a carton box of 1 and 10
        - 15 mL prefilled syringe (filled in 15 mL syringe) packed in a carton box of 1 and 10
    - Pharmacy Bulk Package
        - 30 mL vial (filled in 50 mL vial) packed in a carton box of 1 and 25
        - 50 mL vial (filled in 50 mL vial) packed in a carton box of 1 and 25
        - 100 mL vial (filled in 100 mL vial) packed in a carton box of 1, 6, and 12
- Storage: Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP, Controlled Room Temperature (CRT)].

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Elucirem would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Elucirem. The Division of Medical Imaging and Radiation Medicine (DMIRM) concurred with the findings of OPDP's assessment for Elucirem.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Guerbet did not provide a derivation or intended meaning for the proposed proprietary name, Elucirem, 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 can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On June 28, 2022, the Division of Medical Imaging and Radiation Medicine (DMIRM) did not forward any comments or concerns relating to Elucirem at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred and one (101) practitioners participated in DMEPA's prescription studies for Elucirem. 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. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 113 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	107
Low similarity name pair: combined match percentage score ≤54%	5

[b] USAN stem search conducted on June 24, 2022.

[c] POCA search conducted on June 14, 2022 in version 4.4.

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 113 names contained in Table 1 determined none of the names will pose a risk for confusion with Elucirem as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On August 1, 2022, DMEPA 2 communicated our determination to the Division of Medical Imaging and Radiation Medicine (DMIRM).

3 CONCLUSION

The proposed proprietary name, Elucirem, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO GUERBET LLC

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

If any of the proposed product characteristics as stated in your submission, received on June 7, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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 DNDP. OPDP or DNDP 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 DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [d]

[d] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

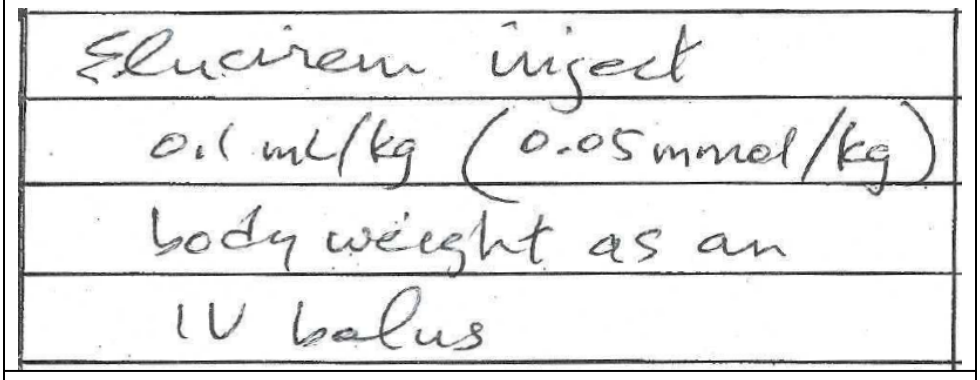
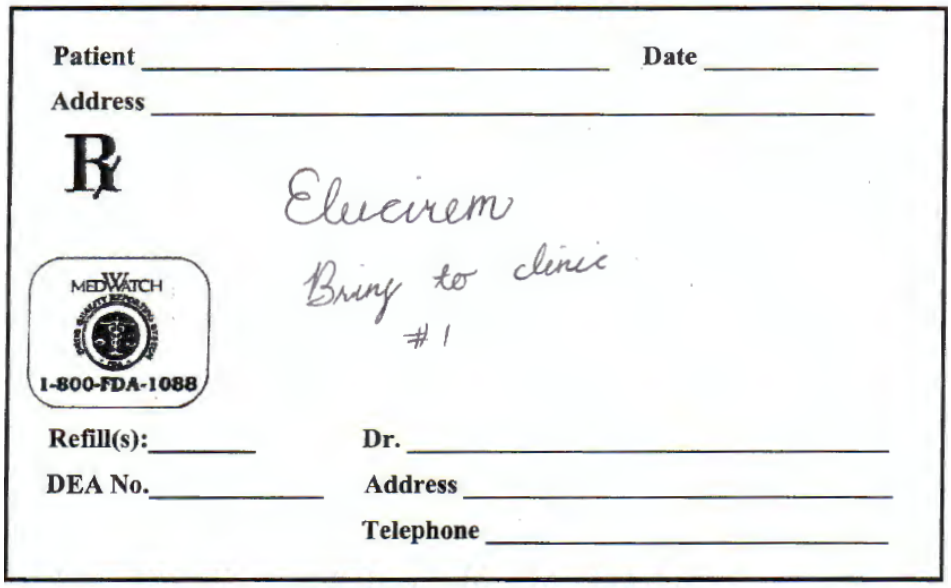
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Elucirem Study (Conducted on June 17, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Elucirem Bring to Clinic #1
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Elucirem	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
101 People Responded

Study Name: Elucirem

Total	24	23	28	26	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
ALLUXYRAM	0	0	1	0	1
ALUCAREM	0	0	1	0	1
ALUCEREM	0	0	1	0	1
ALUCERIM	0	0	2	0	2
ALUCIREM	0	0	1	0	1
ALUCUREM	0	0	1	0	1
ALUSAREM	0	0	1	0	1
ALUSEREM	0	0	6	0	6
ALUSERIM	0	0	2	0	2
ELUCERIM	0	0	1	0	1
ELUCERIN	1	0	0	0	1
ELUCIREM	22	23	1	20	66
ELUCIREM INJECTION	0	0	0	1	1
ELUCIREN	0	0	0	2	2
ELUCIREU	0	0	0	1	1
ELUCIREW	0	0	0	1	1
ELUCIRUM INJECTION	0	0	0	1	1
ELUEIREM	1	0	0	0	1
ELUSEREM	0	0	1	0	1
ELUSERIM	0	0	1	0	1
ELUSERIN	0	0	1	0	1
ILLUSIREM	0	0	1	0	1
OLICEREM	0	0	1	0	1
OLUCERIM	0	0	1	0	1
OLUSEREM	0	0	1	0	1
OLUTHERUM	0	0	1	0	1
PALUSERIN	0	0	1	0	1
POLUSAREM	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Elucirem***	100	Subject of this review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose – N/A

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Epiceram	65	Orthographically, the upstroke from the letter “l” in the second position of Elucirem and the downstroke from the letter “p” in the second position of Epiceram provide some differences.

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Phonetically, the second syllables (LOOS vs. pi) sound different. Although both Elucirem and Epiceram as single strength products (0.5 mmol/mL vs. 5 g), where the strength may be omitted on a prescription order, these products differ in dosage form (injection vs. topical emollient) and route of administration (intravenous vs. topical). Additionally, this name pair differs in recommended dose (0.05 mmol/kg (0.1 mL/kg) vs. a thin layer to affected area) and frequency of administration (once vs. twice daily). We also note Elucirem is a proposed gadolinium based contrast agent, where the medication use process from ordering (separate ordering/CPOE system from drugs in central pharmacy) to administration (order by radiologist and administered under the ordering radiologist's supervision) do not overlap with the medication use process of Epiceram. When considering the above in totality, the risk of name confusion between the name pair is minimized.
2.	Aliskiren	64	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Elestrin	64	Orthographically, the upstroke from the letter "t" in the fifth position of Elestrin provides some difference not seen in Elucirem. Phonetically, the ending syllables (em vs. trin) sound different. Elucirem contains an extra syllable not present in Elestrin. Although both Elucirem and Elestrin are single strength products (0.5 mmol/mL vs. 0.06%), where the strength may be omitted on a prescription order, these products differ in dosage form (injection vs. gel) and route of administration (intravenous vs. topical). Additionally, this name pair differs in recommended dose (0.05 mmol/kg (0.1 mL/kg) vs. one pump) and frequency of administration (once vs. once daily). Thus, the risk of name confusion between the name pair is minimized.
4.	Tellurium	64	This name pair has sufficient orthographic and phonetic differences.
5.	Allerfirm	63	This name pair has sufficient orthographic and phonetic differences.
6.	Rozerem	63	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Elixsure Ib	62	This name pair has sufficient orthographic and phonetic differences.
8.	Elmiron	62	This name pair has sufficient orthographic and phonetic differences.
9.	Fluvirin 2015-2016	62	This name pair has sufficient orthographic and phonetic differences.
10.	Fluvirin 2016-2017	62	This name pair has sufficient orthographic and phonetic differences.
11.	Fluvirin 2017-2018	62	This name pair has sufficient orthographic and phonetic differences.
12.	Glycerin	62	This name pair has sufficient orthographic and phonetic differences.
13.	Lucemyra	62	This name pair has sufficient orthographic and phonetic differences.
14.	Elifemme	61	Orthographically, the upstroke from the letter “f” in the fourth position of Elifemme provides some difference not seen in Elucirem. Phonetically, Elucirem is comprised of four syllables whereas Elifemme is comprised of three syllables. The second syllables (LOOS vs. i) sound different. Although both Elucirem and Elifemme are single strength products (0.05 mmol/mL vs. 0.03 mg/0.04 mg/0.03 mg/0.05 mg/0.075 mg/0.125 mg), where the strength may be omitted on a prescription order, this name pair

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			differs in dosage form (injection vs. tablet) and route of administration (intravenous vs. oral). Additionally, this name pair differs in recommended dose (0.05 mmol/kg (0.1 mL/kg) vs. one tablet) and frequency of administration (once vs. once daily). Thus, the risk of name confusion between the name pair is minimized.
15.	Aloprim	60	This name pair has sufficient orthographic and phonetic differences.
16.	Leucine	60	This name pair has sufficient orthographic and phonetic differences.
17.	Leukeran	60	This name pair has sufficient orthographic and phonetic differences.
18.	Eryderm	58	This name pair has sufficient orthographic and phonetic differences.
19.	Evithrom	58	This name pair has sufficient orthographic and phonetic differences.
20.	Welireg	57	This name pair has sufficient orthographic and phonetic differences.
21.	Eligard	56	This name pair has sufficient orthographic and phonetic differences.
22.	Eligard 22.5	56	This name pair has sufficient orthographic and phonetic differences.
23.	Eligard 30	56	This name pair has sufficient orthographic and phonetic differences.
24.	Eligard 45	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Elucirem **Established name:** gadopiclenol **Dosage form:** Injection **Strength(s):** 1.5 mmol/3 mL (0.5 mmol/mL), (b) (4) mmol/7.5 mL (0.5 mmol/mL), 5 mmol/10 mL (0.5 mmol/mL), 7.5 mmol/15 mL (0.5 mmol/mL), 15 mmol/30 mL (0.5 mmol/mL), 25 mmol/50 mL (0.5 mmol/mL), and 50 mmol/100 mL (0.5 mmol/mL) **Usual Dose:** 0.1 mL/kg (0.05 mmol/kg) as an IV bolus injection once	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
25.	Eligard 7.5	56	This name pair has sufficient orthographic and phonetic differences.
26.	Ilotycin	56	This name pair has sufficient orthographic and phonetic differences.
27.	Ecpirin	55	This name pair has sufficient orthographic and phonetic differences.
28.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.
29.	Eluryng	55	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Alferon N	54
2.	Alosetron	52
3.	Olaparib	50
4.	Losartan	48

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	66	Proposed proprietary name submitted under IND 123673. Sponsor formally withdrew the proposed proprietary name on August 5, 2020. On June 7, 2022, Sponsor submitted the proposed proprietary name, Elucirem***, the subject of this review, for review under NDA 216986.
2.	Alupram	64	International drug product formerly marketed in United Kingdom.
3.	Milprem-200	64	Brand discontinued with no generic equivalents available per Drugs@FDA. NDA 011045 withdrawn FR effective 09/29/1995.
4.	Milprem-400	64	Brand discontinued with no generic equivalents available per Drugs@FDA. NDA 011045 withdrawn FR effective 09/29/1995.
5.	Aleudrin	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Lucidex	59	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
7.	Allethrin	58	This is not a drug. Allethrins are a group of related synthetic compounds used in insecticides.
8.	Curatrem	58	Veterinary drug product.
9.	Elixiral	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
10.	Kelferon	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Wellferon	58	International drug product formerly marketed in several countries including Czech Republic, Italy, New Zealand, Russia, Thailand, Austria, Brazil, and Canada.
12.	Lazer Creme	57	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
13.	Surem	56	International drug product currently marketed in Philippines. International drug product formerly marketed in Spain and United Kingdom.
14.	Ecoderm	55	International drug currently marketed in Singapore and Thailand. International drug product formerly marketed in Malaysia and South Africa.

No.	Name	POCA Score (%)	Failure preventions
15.	Reluri	54	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f].

No.	Name	POCA Score (%)
1.	Iluvien	63
2.	Lutrelin	62
3.	Lisuride	61
4.	Millipred	61
5.	Lidocream	59
6.	Respiram	59
7.	Velosulin	59
8.	(b) (4) ***	58
9.	Calcitrene	58
10.	Celadrin	58
11.	Cloderm	58
12.	Lipram	58
13.	Locorten	58
14.	Lopurin	58
15.	Luesinum	58
16.	Lumasiran	58
17.	Lutetium	58
18.	Luveris	58
19.	Melitracen	58
20.	Mezlocillin	58
21.	Palifermin	58
22.	Velafermin	58
23.	Wellbutrin	58
24.	Alverine	57
25.	Calcidribe	57
26.	Calcium	57
27.	Calcium 600	57
28.	Lapyrium	57
29.	Xelstrym	57

[f] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
30.	Allerfrin	56
31.	Cerium	56
32.	Cicloferon	56
33.	Helicin	56
34.	(b) (4)***	56
35.	Leucovorin	56
36.	Librium	56
37.	Licefree	56
38.	Lidoderm	56
39.	Listerine	56
40.	Loceryl	56
41.	Lufyllin	56
42.	Lufyllin-400	56
43.	Lumizyme	56
44.	Peroderm	56
45.	Soluprep	56
46.	Ultram	56
47.	Zyloprim	56
48.	Almitrine	55
49.	Altren	55
50.	Azlocillin	55
51.	Diglycerin	55
52.	Helicidine	55
53.	Lecithin	55
54.	Lice Md	55
55.	(b) (4)***	55
56.	Lutera	55
57.	Measurin	55
58.	Medi-Derm	55
59.	Perflutren	55
60.	(b) (4)***	55
61.	Silka Cream	55
62.	Tolu-Sed Dm	55
63.	Wellcovorin	55
64.	Welldorm	55

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