CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208400Orig1s000
208400Orig2s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	17 January 2017
Application Type and Number:	NDA 208400
Product Name and Strength:	Xatmep (methotrexate) oral solution, 2.5 mg per mL
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Silvergate Pharmaceuticals, Inc.
Panorama #:	PNR 1: 2016- 11734449 PNR 2: 2016- 11734640
DMEPA Pediatric Medication Safety Advisor:	Rhiannon Leutner, PharmD, MPH, MBA
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Xatmep, which was previously reviewed[a] and found conditionally acceptable under NDA 208400 on 29 February 2016. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) and the Division of Pulmonary, Allergy, and Rheumatology (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern, considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The 13 December 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Xatmep, is acceptable from a safety perspective.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at 240-402-2684.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your 6 December 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[a] Leutner, RM. Proprietary Name Review for Xatmep (NDA 208400). 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); 2016 Feb 29. Panorama No. 2015-2328017, 2015-2328022.

4 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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RHIANNON LEUTNER
01/17/2017

HINA S MEHTA
01/17/2017

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:	24 February 2016
Application Type and Number:	NDA 208400
Product Name and Strength:	Xatmep (methotrexate) oral solution, 300 mg per 120 mL bottle; 2.5 mg per mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Silvergate Pharmaceuticals, Inc.
Panorama #:	PNR 1: 2015-2328017 PNR 2: 2015-2328022
DMEPA Pediatric Medication Safety Advisor:	Rhiannon Leutner, PharmD, MPH, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, [redacted], [redacted]. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, [redacted], unacceptable due to orthographic or phonetic similarities and shared product characteristics with the proprietary name, [redacted]

The Applicant previously submitted the proposed proprietary name, [redacted] on 2 October 2015. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, [redacted], unacceptable due to orthographic or phonetic similarities and shared product characteristics with the root name, [redacted] of the currently marketed product, [redacted]

Thus, the Applicant submitted the name, Xatmep, for review on 23 December 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the 23 December 2015 proprietary name submission.

- Intended Pronunciation: \ 'zat-mep\
- Active Ingredient: methotrexate
- Indication of Use:
  - Treatement of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination maintenance therapy regimen.
  - Management of [redacted] with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an insufficient therapeutic response to first-line therapy, including full dose nonsteroidal anti-inflammatory agents (NSAIDs).
- Route of Administration: oral
- Dosage Form: solution
- Strength: 300 mg per 120 mL bottle; 2.5 mg per mL
- Dose and Frequency:
  - ALL: [redacted] mg/m^2 given [redacted] weekly, in multi-agent combination chemotherapy maintenance regimens.

- pJIA: recommended starting dose is 10 mg/m^2 once weekly, adjustment dose to optimal response.

- How Supplied: 120 mL per bottle
- Storage: Keep Refrigerated (2-8 °C/36-46 °F). Avoid freezing and excessive heat.
- Container and Closure Systems: High-density polyethylene (HPDE) bottle with a child-resistant cap.

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, Xatmep, would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) and the Division of Pulmonary, Allergy, and Rheumatology (DPARP) 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 name.[1]

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Xatmep, 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 FDA Name Simulation Studies

Sixty-nine 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. Thirty-two participants interpreted the name correctly (outpatient n=21, voice n=0, inpatient, n=11). In the voice study, the letter 'X' in the first syllable was misinterpreted as the letter 'Z' and the 't' was misinterpreted as the letter 'p' and the letter 'e' in the second syllable was misinterpreted as the letter 'a'. In the written prescription study, the letter 'm' was misinterpreted as 'n' and the letter 'e' was misinterpreted as 'i' and a letter 'm' was mistakenly added. Appendix B contains the results from the verbal and written prescription studies.

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[1]USAN stem search conducted on 30 December 2015.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, 7 January 2016 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

In response to the OSE, 7 January 2016 e-mail, the Division of Pulmonary, Allergy, and Rheumatology (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	44
Low similarity name pair: combined match percentage score ≤49%	n/a

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

Our analysis of the 44 names contained in Table 1 determined 44 names will not pose a risk for confusion as described in Appendix C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on 15 February 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on 22 February 2016, they stated no additional concerns with the proposed proprietary name, Xatmep.

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology (DPARP) via e-mail on 15 February 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail

[2] POCA search conducted on 7 January 2016.

correspondence from the DPARP on 23 February 2016, they stated no additional concerns with the proposed proprietary name, Xatmep.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Kevin Wright, OSE project manager, at 301-796-3621.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your 23 December 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 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. ***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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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. [3]

[3] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

***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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% 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 ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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 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.

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed 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 ≥50% 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Xatmep Study (Conducted on 15 January 2016)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Xatmep 1.26mL po daily Outpatient Prescription: Xatmep Take 4 mL (10mg) po qweek # 16 mL	Xatmep Take 4mL (10mg) po once per week Disp #16 mL

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

239 People Received Study
69 People Responded

Study Name: Xatmep

Total	22	20	27	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
XATEMP	0	0	2	2
XATINEP	0	0	1	1
XATMEP	21	0	11	32
XATMEP 1.26ML	0	0	1	1
XATMIP	0	0	2	2
XATMYS	0	0	1	1
XATNEP	0	0	1	1
XATNIP	0	0	2	2

XATOMEP	0	0	1	1
XATONEP	0	0	1	1
XATREP	0	0	1	1
XODMEP	1	0	0	1
XOTMEP	0	0	2	2
XOTONIP	0	0	1	1
ZAPMAP	0	1	0	1
ZAPMEP	0	2	0	2
ZAT MAP	0	1	0	1
ZATMAP	0	4	0	4
ZATMAP OR AZATMAP	0	1	0	1
ZATMAPP	0	1	0	1
ZATMEP	0	7	0	7
ZATMEP 4 ML/10 MG	0	1	0	1
ZATMEPP	0	1	0	1
ZATNIB	0	1	0	1

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

No.	**Proposed name: Xatmep** **Established name: methotrexate** **Dosage form: oral solution** **Strength(s): 2.5 mg/mL** **Usual Dose(s):** ***Juvenile idiopathic arthritis*: 10 mg/m² once weekly, adjustment dose to optimal response;** ***Acute lymphocytic leukemia*: (b) (4) mg/m² given (b) (4) weekly, in multi-agent combination chemotherapy maintenance regimens.**	**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.**
0.	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score
1.	Matmate	58
2.	Zenpep	58 (74P)
3.	Xoten-C	56
4.	Xoten	53

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Xatmep** **Established name: methotrexate** **Dosage form: oral solution** **Strength(s): 2.5 mg/mL** **Usual Dose(s):** ***Juvenile idiopathic arthritis*: 10 mg/m² once weekly, adjustment dose to optimal response;**	**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**

	***Acute lymphocytic leukemia*: (b) (4) mg/m² given (b) (4) weekly, in multi-agent combination chemotherapy maintenance regimens.**		
5.	Xactdose	67	The suffixes of this name have sufficient orthographic differences due to the absence of a downstroke and the presence of an upstroke in Xactdose. The second syllables of this name pair sound sufficiently different.
6.	Xartemis	58	The suffixes of this name have sufficient orthographic differences due to the absence of a downstroke in Xartemis. The final syllable of this name pair sounds sufficiently different and Xartemis has an extra syllable.
7.	Tranmep	56	The prefixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound sufficiently different.
8.	X-Prep	54	The prefixes of this name have sufficient orthographic differences due to variation in prefix length. The first and second syllables of this name pair sound sufficiently different.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
	N/A	

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
9.	Zaptec	68 (72P)	Product no longer marketed

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	**Name**	**POCA Score**
10.	Atamet	57
11.	Zaltrap	57
12.	Zmapp	57
13.	Cesamet	56
14.	Zanidip	56
15.	Zentrip	56
16.	Zetacet	54
17.	D-Tann At	52
18.	Edtmp	52
19.	Janumet	52
20.	Nasop	52
21.	4 Face Up	51
22.	5 Face Up	51
23.	Face Up	51
24.	Face Up #2	51
25.	Face Up #3	51
26.	Riastap	51

27.	Vascepa	51
28.	Vitapap	51
29.	Zinnat	51
30.	Beta Med	50
31.	Cis-Mdp	50
32.	Deponit	50
33.	Despec	50
34.	Dytan-At	50
35.	Nystop	50
36.	Tatum-T	50
37.	Valmid	50
38.	Vetameg	50
39.	Yasmin	50
40.	Zantac	50
41.	Zantac 150	50
42.	Zantac 25	50
43.	Zantac 300	50
44.	Zantac 75	50

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/s/

RHIANNON LEUTNER
02/24/2016

YELENA L MASLOV
02/29/2016

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:	24 November 2015
Application Type and Number:	NDA 208400
Product Name and Strength:	(b) (4) (methotrexate) oral solution, 300 mg per 120 mL bottle; 2.5 mg per mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Silvergate Pharmaceuticals, Inc.
Panorama #:	PNR 1: 2015-1637743 PNR 2: 2015-1637746
DMEPA Pediatric Medication Safety Advisor:	Rhiannon Leutner, PharmD, MPH, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD
DMEPA Deputy Director:	Lubna Merchant, MS, PharmD
DMEPA Director	Todd Bridges, RPh

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/s/

RHIANNON LEUTNER
11/24/2015

YELENA L MASLOV
11/24/2015

LUBNA A MERCHANT
11/24/2015

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11/24/2015