CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206911Orig1s000

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:	October 9, 2015
Application Type and Number:	NDA 206911
Product Name and Strength:	Bromsite (Bromfenac) Ophthalmic Solution, 0.075%
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Insite Vision
Panorama #:	2015-1000439
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Bromsite, 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, Bromsite on December 5, 2013 and found acceptable in OSE Review# 2013-16672, IND 107723, dated May 16, 2014[1]. A description of currently marketed Bromfenac products is also included in this review[1].

1.2 PRODUCT INFORMATION

The following product information is provided in the July 20, 2015 proprietary name submission.

- Intended Pronunciation: BRŏM- sahyt
- Active Ingredient: Bromfenac
- Indication of Use: Treatment of postoperative inflammation and the prevention of ocular pain in patients undergoing cataract surgery
- Route of Administration: Topical ophthalmic
- Dosage Form: Ophthalmic solution
- Strength: 0.075% (Each mL of BromSite contains 0.81 mg, bromfenac sodium (equivalent to 0.76 mg bromfenac free acid)."
- Dose and Frequency: One drop of BromSite ophthalmic solution should be applied to the affected eye twice daily (morning and evening) beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period
- How Supplied: BromSite (0.075% bromfenac ophthalmic solution) will be supplied in white opaque low density polyethylene (LDPE) plastic bottle and LDPE dropper tip, and gray high density polyethylene (HDPE) eyedropper cap. A white tamper evident overcap will be provided and the bottle will be packaged in a foil laminate pouch.
- Storage: Store at 15ºC – 25ºC (59º F – 77ºF). Discard after treatment completion.

2 RESULTS

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[1] Kapoor, Rachna. Proprietary Name Review for Bromsite (IND 107723). 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); 2014 May 16. OSE RCM No.: 2013-16672.

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 would not misbrand the proposed product. DMEPA and the Division of Ophthalmology Products (DTOP) 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[2].

2.2.2 Components of the Proposed Proprietary Name

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. The Applicant indicated in their submission that the proposed name, Bromsite, follows the naming convention described below.

> *Insite Vision would like to use this naming convention for this drug product* (b) (4) *by taking the USAN prefix of the drug and combine it with the suffix "Site", a portion of the company name.*

While generally DMEPA does not agree with this type of approach, because this approach creates similar proprietary names on the marketplace, this information is beyond the scope of this review and the provided information will be evaluated on an individual basis for each proprietary name submitted by the Applicant.

Further, an analysis of components of the proposed name, Bromsite, and medication error data selection of cases is described in our prior review[1].

2.2.3 FDA Name Simulation Studies

Seventy-seven 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. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 12, 2015 e-mail, the Division of Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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[2]USAN stem search conducted on September 10, 2015.

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[3] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	6
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	312
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 318 names contained in Table 1 determined 318 names will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database since last review using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) limiting our analysis to name confusion errors involving cases that describe errors possibly associated with 'Brom'.

Table 2. FAERS Search Strategy	
Search Date	October 5, 2015
Drug Name	**Bromfenac** [active ingredient] **Xibrom** [product name] **Bromday** [product name] **Prolensa** [product name]
Event (MedDRA Terms)	**DMEPA Official Proprietary Name Review Search Terms Event List:** Product name confusion (PT) Medication error (PT) Intercepted medication error (PT)

[3] POCA search conducted on July 28, 2015.

	Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Date Limits	May 2, 2014 – October 5, 2015

No cases were identified.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Ophthalmology Products (DTOP) via e-mail on September 17, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DTOP on September 17, 2015, they stated no additional concerns with the proposed proprietary name, Bromsite.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any 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, Bromsite, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your July 20, 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. [4]

[4] 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 A1: Description of 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Bromsite Study (Conducted on August 5, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: BromSite apply 1 drop to affected eye BID Outpatient Prescription: Bromsite use as directed #1	Bromsite Use as directed #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

244 People Received Study
77 People Responded

Study Name: BromSite

Total	25	25	27
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**
BOB SITE	0	1	0
BRAUMSITE	0	1	0
BROBSITE	0	1	0
BROM SIGHT	0	1	0
BROMCITE	0	3	0
BROMCITGE	0	1	0
BROMCYT	0	1	0
BROMCYTE	0	2	0

BROMFITE	0	0	5
BROMLITE	0	0	1
BROMOSITE	0	0	1
BROMSIT	1	0	0
BROMSITE	17	5	19
BRONSITE	7	3	1
BRUMCITE	0	1	0
BRUMCYT	0	1	0
FROM SITE	0	1	0
FROMSITE	0	2	0
ROMSITE	0	1	0

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

No.	**Proposed name:** Bromsite **Established name:** **Dosage form:** Ophthalmic solution **Strength(s):** 0.075% **Usual Dose:** One drop of BromSite ophthalmic solution should be applied to the affected eye twice daily (morning and evening) beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.	**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.	BROMSITE	100	Subject of this review
2.	BROMINE (Phonetic Score: 70) (Orthographic Score: 76)	73	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases. This is a solution, no strength provided, prescription class, 30 mL size.
3.	BROMATES (Phonetic Score: 70) (Orthographic Score: 75)	72	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases..
4.	BROMFED (Phonetic Score: 78)	72	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalent.

No.	**Proposed name:** Bromsite **Established name:** **Dosage form:** Ophthalmic solution **Strength(s):** 0.075% **Usual Dose:** One drop of BromSite ophthalmic solution should be applied to the affected eye twice daily (morning and evening) beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.	**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.**
5.	BROMALINE (Orthographic Score: 74)	70	The suffixes of this name pair have sufficient orthographic differences. The Bromaline name contains an extra syllable. This product is listed as deactivated in Redbook with no generic available.
6.	BROMANATE (Orthographic Score: 76)	70	The suffixes of this name pair have sufficient orthographic differences. The Bromanate name contains an extra syllable and ending are phonetically different. This product is listed as deactivated in Redbook.

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.	BRODSPEC	66
2.	BROMFED DM	66
3.	BROMFED-DM	66
4.	BAREMSIS***	64
5.	BRONTUSS (Phonetic Score: 75)	64

No.	Name	POCA Score (%)
6.	PROMAZINE	64
7.	BROMHEXINE (Note: Orthographic Score: 70)	63
8.	DOLOMITE	63
9.	FERROCITE	63
10.	THROMBATE	61
11.	BROMPHENEX	60
12.	BENTONITE	59
13.	BROMAX	58
14.	BROMPH DM	58
15.	BRONCHITOL***	58
16.	RUBIVITE	58
17.	BROMDAY	57
18.	HYDROMIDE	57
19.	PROMACOT (Phonetic Score: 70)	57
20.	RENA-VITE	57
21.	IOPROMIDE (Note: This is the established name for Ultravist)	56
22.	NEUROLITE	56
23.	LIDOSITE	54
24.	PROMETA	54
25.	ROBITET	54
26.	ROBITET 500	54
27.	RUVITE	54
28.	PREVALITE	53
29.	PROMETH VC	53
30.	MICROLITE	52

No.	Name	POCA Score (%)
31.	ZINC BROMIDE	52
32.	BROMOCRIPTINE	51
33.	BRONCHO SALINE	51
34.	COBAVITE	51
35.	(b) (4) ***	51
36.	BROVEX ADT	50
37.	HYDROMET	50
38.	ROMYCIN	50

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:** Bromsite **Established name:** Bromfenac **Dosage form:** Ophthalmic solution **Strength(s):** 0.075% **Usual Dose:** One drop of BromSite ophthalmic solution should be applied to the affected eye twice daily (morning and evening) beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.	**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.	BRONTEX (Phonetic Score: 70)	69	The suffixes of this name pair have sufficient orthographic differences (four letter suffix with upstroke near end in –site versus three letter suffix with upstroke at beginning in –tex). The second syllables of this name pair sound different. This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases (2.5 mg/5 mL-75 mg/5 mL, liquid, 473 mL size, CV DEA class.)
2.	BROMFENAC (Note: This is the same as the established name for the proposed product.)	63	The suffixes of this name pair have sufficient orthographic differences. The Bromfenac name contains an extra syllable. This product is available in EQ 0.09% Acid and administered once daily.
3.	PROMACTA	51	The infixes of this name pair have sufficient orthographic differences. The Promacta name contains an extra syllable.

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

No.	Name	POCA Score (%)
1.	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
1.	BROMDEC (Phonetic Score: 70)	69	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalent.
2.	BROMOPRIDE (Orthographic Score: 75)	69	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
3.	BROM-A-COT (Phonetic Score: 75)	68	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
4.	BROMATAPP (Phonetic Score: 72)	68	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
5.	BROMTAPP (Phonetic Score: 77)	68	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
6.	ENROSITE	68	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
7.	BROMATAN	66	This name was identified by the RxNorm database. However, this product is listed as discontinued in Facts and Comparison without generic equivalent.
8.	BROMUPHED (Phonetic Score: 73)	66	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
9.	BROMATOL	65	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
10.	BROMAPHEN	64	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
11.	BRON-TUSS	64	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
12.	BRONITIN	64	This name was identified by the RxNorm database. The Brand is discontinued with no generic equivalent available. NDA 016126 withdrawn FR effective 6/18/2009.
13.	BRONKAID (Phonetic Score: 72)	64	This name was identified by the RxNorm database. The Brand is discontinued with no generic equivalent available. NDA 016803 withdrawn FR effective 6/04/2004.
14.	DUROMINE	64	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
15.	BROMCOMP (Note: Phonetic: 75)	62	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
16.	BROMFED SR	62	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
17.	BROMFENEX	62	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
18.	BROM TANN PE	61	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
19.	BRONKIDS	61	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
20.	PROMACET	61	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
21.	SOMNITE	61	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
22.	BROMPHEN DC	60	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
23.	BRONCHOLATE	60	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
24.	BRONDELATE	60	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
25.	BROMDEC DM	59	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
26.	BROMSPIRO	59	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
27.	PYROLITE	59	This name was identified by the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. NDA 017684 withdrawn FR effective 6/04/2004.
28.	BROMIDE ION	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
29.	BROMPH HD	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
30.	BROMPHEN TIME	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
31.	PROMPT	58	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
32.	BROLENE	57	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
33.	BROMAPP	57	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
34.	BROMPHENYL	57	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
35.	PROMACE	57	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
36.	PROMIT	57	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
37.	BROFED	56	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
38.	BROMPHERIL	56	This name was identified by the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. ANDA 089116 withdrawn FR effective 5/2/2003.
39.	BRONDIL	56	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
40.	BRONKOMETER	56	This name was identified by the Drugs at FDA and RxNorm databases. The Brand is discontinued with no generic equivalent available. NDA 012339 withdrawn FR effective 9/13/2000.
41.	DURAPATITE	56	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
42.	BROMANATE AF	55	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
43.	BROMFENEX PE	55	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
44.	BROMPHEN DX	55	This name was identified by the RxNorm database. The Brand is discontinued with no generic equivalent available. NDA 019279 withdrawn FR effective 6/04/2004.

No.	Name	POCA Score (%)	Failure preventions
45.	BRONCOLIN	55	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
46.	BROMANATE DC	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
47.	BROMAPHEDRINE	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
48.	BROMATAPP SR	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
49.	BROMHIST NR	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
50.	BROMO SELTZER	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
51.	BROMOPHED-DX	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
52.	BROVANEXINE	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
53.	BROVEX D	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
54.	DIBROM SR	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
55.	ORABRITE	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
56.	BROMAZEPAM	53	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
57.	BRONKOSOL	53	This name was identified by the Drugs at FDA and RxNorm databases. The Brand is discontinued with no generic equivalent available. NDA 012339 withdrawn FR effective 9/03/2000.
58.	BROVEX	53	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
59.	BROXIL	53	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
60.	ROMIFIDINE	53	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
61.	BENTIROMIDE	52	This name was identified by the RxNorm database. The Brand is discontinued with no generic equivalent available. NDA 018366 withdrawn FR effective 1/09/1997.

No.	Name	POCA Score (%)	Failure preventions
62.	BROFLEX	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
63.	BROMADINE-DM	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
64.	BROMANATE DM	52	This name was identified by the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. ANDA 088722 withdrawn FR effective 7/03/1990.
65.	BROMELAINS	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
66.	BROMFENEX PD	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
67.	BROMHISTINE-P	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
68.	BRONCHODIL	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
69.	KBROVET	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
70.	SCLROMATE	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
71.	SUCROMATE	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
72.	BROMATANE DX	51	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
73.	BROMETANE DX	51	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
74.	BROMATAN PLUS	50	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
75.	BROMPERIDOL	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
76.	BRONCOTRON	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
77.	BRONOPOL	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
78.	BRONTUSS DX	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
79.	BROVEX CT	50	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
80.	MILBEMITE	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	DRONCIT (Phonetic Score: 77)	70
2.	BANOCIDE	65
3.	TRANDIDE (Phonetic Score: 72)	64
4.	BIOZIDE (Orthographic Score: 71)	62
5.	BRETHINE	62
6.	DARANIDE	62
7.	PRINZIDE (Phonetic Score: 78)	62
8.	TRIMAZIDE	62
9.	BLEOMYCINE	60
10.	(b) (4) ***	60
11.	DRIMINATE	60
12.	GRANOCYTE-13 (Phonetic Score: 72)	60
13.	GRANOCYTE-34 (Phonetic Score: 72)	60

No.	Name	POCA Score (%)
14.	PRE-SATE	60
15.	TRANDATE	60
16.	BANTHINE	58
17.	BENZOATE	58
18.	BREFYTE***	58
19.	BRIAGLIDE***	58
20.	BRIMONIDINE	58
21.	DRAMAMINE	58
22.	PREMPHASE (Phonetic Score: 75)	58
23.	PREMPHASE 14/14 (Phonetic Score: 75)	58
24.	PRIMAZINE	58
25.	PROLIDE***	58
26.	PROSTIN E2	58
27.	TYROSINE	58
28.	BAMATE	57
29.	PRAMINE	57
30.	PRO 12 MOUSSE	57
31.	BAMIPINE	56
32.	BARIUM OXIDE	56
33.	BERKOZIDE	56
34.	BORON CITRATE	56
35.	BORON NITRIDE	56
36.	BREONESIN	56
37.	DELONIDE	56
38.	DORMATE	56
39.	PRAMCORT (Phonetic Score: 74)	56
40.	PRAMOXINE	56

No.	Name	POCA Score (%)
41.	PRECISE	56
42.	PROBUPHINE***	56
43.	PROPINE	56
44.	TOMYCINE	56
45.	TRIBLIDE	56
46.	BRIVUDINE	55
47.	CAROZIDE	55
48.	CERAMIDE 1	55
49.	CERAMIDE 2	55
50.	CERAMIDE 3	55
51.	DERMAFIVE	55
52.	PRIMATENE	55
53.	PROAMATINE	55
54.	B-12 RESIN	54
55.	BARMINE	54
56.	BIO-MYCIN	54
57.	BIOCLATE	54
58.	BLOOD STOP	54
59.	BRETYLATE	54
60.	BRULIDINE	54
61.	BUMINATE	54
62.	BYDRAMINE	54
63.	CREOSOTE	54
64.	DERMOVATE	54
65.	DESONIDE	54
66.	DOCUSATE	54
67.	DRALZINE	54
68.	DRONTAL	54
69.	LOROXIDE	54
70.	NEURAMATE	54

No.	Name	POCA Score (%)
71.	OPRISINE	54
72.	PERISINE	54
73.	PRAMOSONE	54
74.	PROGABIDE	54
75.	TRIONATE	54
76.	BENZONATE	53
77.	BICISATE	53
78.	BONINE	53
79.	FERRONATE	53
80.	MEFRUSIDE	53
81.	NORMOZIDE	53
82.	PRED FORTE	53
83.	APRODINE	52
84.	BARIUM SULFATE	52
85.	BIS-MATE	52
86.	BLISOVI 24 FE***	52
87.	BLISOVI FE***	52
88.	BLISOVI FE 1.5/30***	52
89.	BLISOVI FE 1/20***	52
90.	(b) (4) ***	52
91.	BLU-KOTE	52
92.	DERMA ICE	52
93.	DERMATOP E	52
94.	DEZOCINE	52
95.	(b) (4) ***	52
96.	DUOMINE	52
97.	DURANEST	52
98.	IBRANCE	52
99.	MEDRONATE	52
100.	MICROZIDE	52

No.	Name	POCA Score (%)
101.	OMNICIDE	52
102.	PREDAMIDE	52
103.	PREZATIDE	52
104.	PRIMATUSS 4	52
105.	PRIMSOL	52
106.	PROLINE	52
107.	PROSTEP	52
108.	REMSED	52
109.	TERAMINE	52
110.	THEROXIDE	52
111.	TRIAM-FORTE	52
112.	TRIAMONIDE	52
113.	TRIAMONIDE 40	52
114.	TRIBENOSIDE	52
115.	TRIGLIDE	52
116.	(b) (4)***	52
117.	(b) (4)***	52
118.	TYRAMINE	52
119.	X-TROZINE	52
120.	BARIUM CITRATE	51
121.	BARIUM IODIDE	51
122.	BION TEARS	51
123.	BRINZOLAMIDE	51
124.	BUDESONIDE	51
125.	DESONATE	51
126.	FODOSINE***	51
127.	MYRISTATE	51
128.	PIMOZIDE	51
129.	PRAMLINTIDE	51
130.	PRAMOTIC	51

No.	Name	POCA Score (%)
131.	PROCAINE	51
132.	PROPACET	51
133.	PROPACET 100	51
134.	ROGITINE	51
135.	TRANXENE	51
136.	TRIAMCOT	51
137.	ABRAXANE	50
138.	ATROPINE	50
139.	ATROPINE-1	50
140.	B-FEDRINE	50
141.	BECLAMIDE	50
142.	BELLAMINE	50
143.	BETNOVATE	50
144.	BILTRICIDE	50
145.	BRETHAIRE	50
146.	BREVITAL	50
147.	BUMETANIDE	50
148.	CARNOSINE	50
149.	CETRIMIDE	50
150.	CETROTIDE	50
151.	CRANTEX	50
152.	DERMATOP	50
153.	DERMOLATE	50
154.	DONNAPINE	50
155.	DURATHATE	50
156.	DURATHATE 200	50
157.	DUROPHET	50
158.	EAROXIDE	50
159.	FLUMEZIDE	50
160.	FOAM SAFE	50

No.	Name	POCA Score (%)
161.	FREAMINE 6.9	50
162.	FREAMINE 8.5%	50
163.	KEROSENE	50
164.	MERITATE	50
165.	MONOCETE	50
166.	NORITATE	50
167.	PREDATE-50	50
168.	PRIMAQUINE	50
169.	PRIMIDONE	50
170.	PRINIZE	50
171.	PRO-BANTHINE	50
172.	PRO-MED	50
173.	PROBANTHINE	50
174.	PROCET	50
175.	PRONTO	50
176.	PROP-A-TANE	50
177.	PROPHENE 65	50
178.	PROSTAMATE	50
179.	PROTENATE	50
180.	ROCK SAUCE	50
181.	SOMNOTE	50
182.	STYRAMATE	50
183.	TRAMAKE	50
184.	TRANCOT	50
185.	TRIENTINE	50
186.	TRILISATE	50
187.	TRIMPEX	50
188.	TRIMPEX 200	50
189.	TROCAINE	50
190.	ULTRA MIDE	50

No.	Name	POCA Score (%)
191.	VERCYTE	50

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/s/

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10/09/2015

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10/09/2015