# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 209363Orig1s000

# PROPRIETARY NAME REVIEW(S)

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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| | |
|---|---|
| **Date of This Review:** | April 13, 2017 |
| **Application Type and Number:** | NDA 209363 |
| **Product Name and Strength:** | Solosec (secnidazole) oral granules;<br>2 grams per packet |
| **Product Type:** | Single ingredient |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Symbiomix therapeutics |
| **Panorama #:** | 2017-12886267 |
| **DMEPA Primary Reviewer:** | Sevan Kolejian, Pharm. D. |
| **DMEPA Team Leader:** | Otto L. Townsend, Pharm D |

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Solosec, 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 resubmitted the previously considered external name study, conducted by (b) (4) for this product.

## 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name Solosec to IND 117811. (b) (4) conducted a safety research analysis on the proposed proprietary name dated July 17, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Solosec conditionally acceptable in OSE Review # 2015-1046004[a], dated November 9, 2015.

On January 30, 2017, the Applicant submitted the proposed proprietary name, Solosec, to NDA 209363, for review.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the January 30, 2017 proprietary name submission.

- Intended Pronunciation: soe' loe sek
- Active Ingredient: secnidazole
- Indication of Use: Bacterial vaginosis
- Route of Administration: oral
- Dosage Form: oral granules
- Strength: 2 gram
- Dose and Frequency: single dose 2 gram (1 packet) orally once.
- How Supplied: 2 grams per packet
- Storage: Room Temperature for all points in the medication-use system, both pre- and post-dispensing
- Container and Closure Systems: Foil Packet.

[a] Kolejian, S. Proprietary Name Review for Solosec*** IND117811. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 NOV 9. RCM No.: 2015-1046004

## 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, Solosec, would not misbrand the proposed product. DMEPA and the Division of Anti- Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

### 2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

#### *2.2.1 United States Adopted Names (USAN) Search*

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

#### *2.2.2 Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Solosec, 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*

Eighty-one (81) 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. We note that one of the Rx Study participants commented that proprietary name Solosec "Reminds me of Prilosec (look and sound)". We evaluated the proprietary name Prilosec in our previous proprietary name review for Solosec *(OSE Review # 2015-1046004, Appendix C*) and determined that phonetic and orthographic differences along with differing product characteristics were sufficient to minimize the risk for medication error. We note that none of the proposed product characteristics for Solosec have changed, and we agree with the findings from our previous review.

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, February 22, 2017 e-mail, the Division of Anti-Infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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[b] USAN stem search conducted on February 1, 2017.

### *2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search identified 188 names with the combined score of ≥55%[c].We had identified and evaluated 158 of these names in our previous proprietary name review[d]. We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our review of the names evaluated previously. In this review, we re-evaluated 3 previously identified names of concern with a combined score ≥ 70% based on the revised POCA algorithm. Therefore, Table 1 lists the 30 names not previously analyzed with the combined score of ≥55% retrieved from our POCA search and the 3 names from our previous proprietary name review with a combined score of ≥70% as a result of the update in POCA, which are organized as highly similar, moderately similar or low similarity for further evaluation.

| **Table 1. Similarity Category** | **Number of Names** |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 3 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 30 |
| Low similarity name pair:<br>combined match percentage score ≤54% | None |

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

Our analysis of the 33 names contained in Table 1 determined all 33 names will not pose a risk for confusion as described in Appendices C through H.

### *2.2.7 Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Anti- Infective Products (DAIP) via e-mail on April 4, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on April 11, 2017, they stated no additional concerns with the proposed proprietary name, Solosec.

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[c] POCA search conducted on February 1, 2017 in version 4.0.

[d] . Kolejian, S. Proprietary Name Review for Solosec*** IND117811. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 NOV 9. RCM No.: 2015-1046004.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Janet Higgins, OSE Project Manager, at 240-402-0330.

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 30, 2017 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. [e]

***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)). |

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

| 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[f]. 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 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

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

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?<br>*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?<br>**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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• Alternative expressions of dose: 5 mL may be listed in the prescribing |

<table>
<tr><td></td><td colspan="2">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.<br><br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="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 <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>Orthographic Checklist (Y/N to each question)<br><br>• Do the names begin with different first letters?<br><br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br><br>• Are the lengths of the names dissimilar* when scripted?<br><br>*FDA considers the length of names different if the names differ by two or more letters.<br><br>• 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?<br><br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br><br>• Do the infixes of the name appear dissimilar when scripted?<br><br>• Do the suffixes of the names appear dissimilar when</td><td>Phonetic Checklist (Y/N to each question)<br><br>• Do the names have different number of syllables?<br><br>• Do the names have different syllabic stresses?<br><br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br><br>• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

| | | |
|---|---|---|
| | scripted? | |

**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. Solosec Study (Conducted on February 13, 2017)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>Solosec 2 grams po X1 dose | Solosec<br>take one packet by mouth times one dose.<br>Dispense # 1 |
| Outpatient Prescription:<br>Solosec<br>1 packet po X1 dose<br>#1 | |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Study Name: Solosec**

As of Date 3/13/2017

299 People Received Study
81 People Responded

| **Total** | **28** | **19** | **34** | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| FOLOSEK | 0 | 1 | 0 | 1 |
| GOLOSEE | 0 | 0 | 1 | 1 |
| IDOSIC | 0 | 0 | 1 | 1 |
| SDOSEC | 0 | 0 | 1 | 1 |
| SDOSIC | 0 | 0 | 2 | 2 |
| SOLASE | 1 | 0 | 0 | 1 |
| SOLASEC | 5 | 0 | 0 | 5 |
| SOLOCEK | 0 | 1 | 0 | 1 |
| SOLOFEK | 0 | 1 | 0 | 1 |
| SOLOSEC | 22 | 6 | 19 | 47 |
| SOLOSECK | 0 | 2 | 0 | 2 |
| SOLOSEK | 0 | 1 | 0 | 1 |
| SOLOSIC | 0 | 0 | 7 | 7 |
| SOLSEC | 0 | 0 | 2 | 2 |
| SOLSIC | 0 | 0 | 1 | 1 |
| SOLUSEK | 0 | 1 | 0 | 1 |
| SOMASEC | 0 | 1 | 0 | 1 |
| THOLOSEC | 0 | 1 | 0 | 1 |
| ZOLISEC | 0 | 1 | 0 | 1 |
| ZOLOSAK | 0 | 1 | 0 | 1 |
| ZOLOSEC | 0 | 2 | 0 | 2 |

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

| No. | **Proposed name:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Velosef | 71 | Brand discontinued with no generic equivalent available.<br>ANDA 061763 Withdrawn FR Effective Status Date 05/15/2007<br>ANDA-061764 Withdrawn FR Effective Status Date 12/15/2006<br>ANDA-061976 Withdrawn FR Effective Status Date 12/08/1995<br>ANDA 062683 Withdrawn FR Effective Status Date 11/03/2016<br>ANDA-061859 Withdrawn FR Effective Status Date 02/17/2006<br>ANDA-061866 Withdrawn FR Effective Status Date 12/16/2005<br>NDA-050530 Withdrawn FR Effective Status Date 11/05/1992<br>NDA-050548 Withdrawn FR Effective Status Date 06/25/1993.<br>ANDA-062858 Withdrawn FR Effective Status Date 01/05/2015 |
| 2. | Suleo-C | 70 | International product marketed in Ireland and UK. |
| 3. | Folicet | 70 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Folicet has an upstroke letter “t” in suffix.<br><br>The first and third syllables of this name pair sound different. |

**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.

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Isoleucine | 60 |
| 2. | Soluclenz | 56 |
| 3. | Solurex La | 56 |
| 4. | Xylose | 55 |

**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:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | Glucose | 55 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br><br>The first, second and third syllables of this name pair sound different. |
| 2. | (b) (4) *** | 58 | The suffixes of this name pair have sufficient orthographic differences due to the absence of a upstroke in Solosec and the distinct variation in the suffixes of the name pair.<br><br>The first and second syllables of this name pair sound sufficiently different and Solosec has an extra syllable. |
| 3. | (b) (4) *** | 56 | The suffixes of this name pair have sufficient orthographic differences.<br><br>The third syllables of this name pair sound different. |

**Appendix F:** Low Similarity Names (e.g., combined POCA score is ≤54%)……. (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. | Glo-Sel (Orthographic score 73) | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 2. | Solian | 56 | International amisulpride product marketed in many countries. |
| 3. | Troclosene | 56 | Product is not a drug. It is chemical mainly used as a disinfectant, biocide, industrial deodorant and detergent. It is found in some modern water purification tablets/filters. |
| 4. | Levosert*** | 56 | Proposed proprietary name for NDA 206229 found unacceptable by DMEPA. NDA 206229 approved under new proprietary name Liletta. |
| 5. | Senosol-Ss | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 6. | Ilosone | 56 | Brand discontinued with no generic equivalent available. NDA 050010, Withdrawn FR Effective Status Date 04/04/2005; ANDA 061893, ANDA 061894, ANDA 061895, ANDA 061896, ANDA 061897 was Withdrawn FR Effective Status Date 01/30/2004. |
| 7. | Sevosol | 56 | Veterinary product. |
| 8. | (b) (4) *** | 55 | Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases. |
| 9. | (b) (4) | | |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | (b) (4) *** | 58 |
| 2. | Isclofen | 58 |
| 3. | Cellucon | 56 |
| 4. | Isocet | 56 |
| 5. | Polygesic | 56 |
| 6. | (b) (4) *** | 56 |
| 7. | Sevoflo | 56 |
| 8. | Slofenac Sr | 56 |
| 9. | Osmolex*** | 56 |
| 10. | Tolectin | 55 |
| 11. | Tolectin 600 | 55 |
| 12. | Slow-K | 55 |
| 13. | (b) (4) *** | 55 |
| 14. | (b) (4) *** | 55 |

[g] 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.

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/s/

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SEVAN H KOLEJIAN
04/13/2017

OTTO L TOWNSEND
04/13/2017

**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*****

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| | |
|---|---|
| **Date of This Review:** | November 9, 2015 |
| **Application Type and Number:** | IND 117811 |
| **Product Name and Strength:** | Solosec (secnidazole) oral granules; 2 grams per packet |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Symbiomix therapeutics |
| **Panorama #:** | 2015-1046004 |
| **DMEPA Primary Reviewer:** | Sevan Kolejian, Pharm. D. |
| **DMEPA Team Leader:** | Vicky Borders-Hemphill, PharmD |

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Solosec, 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 submitted an external name study, conducted by [redacted] (b) (4) for this product.

## 1.1 PRODUCT INFORMATION

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

- Intended Pronunciation: soe' loe sek
- Active Ingredient: secnidazole
- Indication of Use: Bacterial vaginosis
- Route of Administration: oral
- Dosage Form: oral granules
- Strength: 2 gram
- Dose and Frequency: single dose 2 gram (1 packet) once (sprinkle over soft food e.g., applesauce, yogurt, or pudding).
- How Supplied: 2 grams per packet
- Storage: Room Temperature for all points in the medication-use system, both pre- and post-dispensing
- Container and Closure Systems: One single use packet of oral granules in a single-use box. Packet is approximately 2.25" by 2.75".

# 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 would not misbrand the proposed product. DMEPA and the Division of Anti- Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

## 2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

### *2.2.1 United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary 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, Solosec, 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*

Seventy eight 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 28, 2015 e-mail, the Division of Division of Anti-Infective Products (DAIP) expressed concerns regarding the orthographic similarity of Solosec to Prilosec if there is a poorly written prescription. Additionally, the Division commented that "solo" may imply single (like single use) or "only".

We evaluate the proprietary name Prilosec in Appendix C. We determined that the interpretation of "solo" implying single use or "only" is not likely to cause a medication error because this product is packaged as a single use packet that is taken as a single dose of the entire packet for the treatment of bacterial vaginosis.

### *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 also includes names identified in the external name study, conducted by (b) (4)

[1]USAN stem search conducted on August 12, 2015.

[2] POCA search conducted on August 12, 2015.

| Table 1. POCA Search Results | Number of Names |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 12 |
| Moderately similar name pair<br>combined match percentage score ≥50% to ≤ 69% | 301 |
| Low similarity name pair:<br>combined match percentage score ≤49% | 10 |

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

Our analysis of the 323 names contained in Table 1 determined all 323 names will not pose a risk for confusion as described in Appendices C through H.

#### *2.2.7 Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of (DAIP) via e-mail on November 2, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on November 9, 2015, there are no additional concerns with the proposed proprietary name, Solosec. However, division noted that one person stated that there might be other drugs with similar names.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

### 3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Solosec should be submitted once the NDA is submitted.

## 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.

## 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]

***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. |

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

| 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 do not share a common strength or dose. | | | |
|---|---|---|---|
| Orthographic Checklist | | Phonetic Checklist | |
| **Y/N** | Do the names begin with different first letters?<br>*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?<br><br>**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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>o 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.<br><br>o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>o 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. |

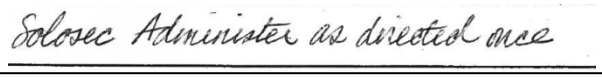
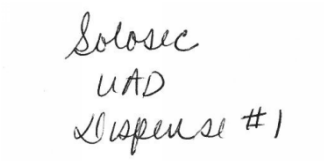
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br><br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br><br>• Are the lengths of the names dissimilar* when scripted?<br><br>*FDA considers the length of names different if the names differ by two or more letters.<br><br>• 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?<br><br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br><br>• Do the infixes of the name appear dissimilar when scripted?<br><br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br><br>• Do the names have different syllabic stresses?<br><br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br><br>• 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. Solosec Study (Conducted on August 14, 2015)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Solosec use as directed<br>Dispense # 1 |
| Outpatient Prescription:<br>  <br> | |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Study Name: Solosec**
244 People Received
Study
78 People Responded
Study Name: Solosec

| **Total** | **30** | **22** | **26** | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| SOLASEC | 1 | 3 | 0 | 4 |
| SOLASEK | 0 | 1 | 0 | 1 |
| SOLESEC | 0 | 1 | 0 | 1 |
| SOLISEC | 0 | 2 | 0 | 2 |
| SOLISEPT | 0 | 1 | 0 | 1 |
| SOLOCEC | 0 | 1 | 0 | 1 |
| SOLOSEC | 27 | 4 | 25 | 56 |
| SOLOSECK | 0 | 1 | 0 | 1 |
| SOLOSECT | 0 | 3 | 0 | 3 |
| SOLOSEK | 0 | 2 | 0 | 2 |
| SOLOSIC | 1 | 0 | 0 | 1 |
| SOLSEC | 1 | 0 | 1 | 2 |
| SOLUSEC | 0 | 1 | 0 | 1 |
| ZOLOSEC | 0 | 2 | 0 | 2 |

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

| No. | **Proposed name:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | SOLOSEC*** | 100 | *Subject of this review* |
| 2. | DOLOTIC | 77 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Dolotic name has cross stroke letter "t" in its suffix.<br>The first and third syllables of this name pair sound different.<br>There is no overlap with strength, dose, or frequency of administration. Dolotic is an Antipyrine/benzocaine product that is an unapproved drug used for ear wax removal. |
| 3. | PRILOSEC | 72 | The prefixes of this name pair have sufficient orthographic differences. The letter string “Pril” is not similar to “Sol”.<br>The first syllables of this name pair sound different.<br>There is no overlap with the dose or frequency of administration. |
| 4. | SULFAC | 72 | The infixes (fa vs. ose) of this name pair have sufficient orthographic differences. The letter “o” in the infix elongates the Solosec name when scripted.<br>The second syllables of this name pair sound different; Solosec name contains an extra syllable.<br>There is no overlap with the frequency of administration. Sulfac is ophthalmic solution applied topically to affected area of eye twice daily. |
| 5. | SULFAC 10% | 72 | *Same as “Sulfac” See above.*<br>Sulfac 10% has the modifier 10% that does not overlap with Solosec strength or dose. If included, the modifier adds orthographic and phonetic differentiation. |

| No. | **Proposed name:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 6. | DOLORAC | 70 | The prefixes of this name pair have sufficient orthographic differences (D vs. S).<br>The first and third syllables of this name pair sound different.<br>There is no overlap with the strength or dose. Dolorac is capsaicin topical cream available 0.025% and 0.075%. |
| 7. | LOSEC | 70 | International product marketed in UK, India, Europe, Venezuela, Mexico, Thailand, South Africa and Singapore. |
| 8. | SILDEC | 70 | The infixes of this name pair have sufficient orthographic differences. Sildec has an upstoke letter "d" in the infix. The letter "o" in the infix elongates the Solosec name when scripted.<br>The second syllables of this name pair sound different; Solosec name contains an extra syllable.<br>There is no overlap with the strength or dose. Sildec is over the counter allergy, nasal congestion preparation that contains Brompheniramine maleate, and pseudoephedrine hydrochloride. |
| 9. | SILDEC 0.8/12 | 70 | *Same as "Sildec", See above.*<br>Sildec 0.8/12 has the modifier that does not overlap with Solosec strength or dose. If included, the modifier adds orthographic and phonetic differentiation. |
| 10. | SILDEC 1/15 | 70 | *Same as "Sildec", See above.*<br>Sildec 1/15 has the modifier that does not overlap with Solosec strength or dose. If included, the modifier adds orthographic and phonetic differentiation. |
| 11. | SILDEC 2/15 | 70 | *Same as "Sildec", See above.*<br>Sildec 2/15 has the modifier that does not overlap with Solosec strength or dose. If included, the modifier adds orthographic and phonetic differentiation. |

| No. | **Proposed name:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 12. | SOLOTUSS | 70 | Brand discontinued with no generic equivalent available. Solutuss (Carbetapentane) products withdrawn FR effective May 6, 1985 for reasons of safety or effectiveness per 21CFR216.24. |

**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. | CHOLETEC (Phonetic > 70% score 74) | 68 |
| 2. | COLDEC (Orthographic > 70% score 70) | 68 |
| 3. | FOLICET (Phonetic > 70% score 85) | 68 |
| 4. | SOLAGE | 66 |
| 5. | SULFOSE | 66 |
| 6. | CYCLOSET | 64 |
| 7. | FOLACIN (Phonetic > 70% score 75) | 64 |
| 8. | SALACYN | 64 |
| 9. | SELSEB | 64 |
| 10. | DOLOGESIC | 63 |
| 11. | SOLESTA | 63 |
| 12. | SOLOSTAR | 63 |
| 13. | CELL-U-JEC (Phonetic > 70% score 72) | 62 |
| 14. | SALAC | 62 |
| 15. | SALIC-2 | 62 |
| 16. | SILAFED | 62 |
| 17. | SOLODYN | 62 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 18. | SOLUREX | 62 |
| 19. | SURELAC | 62 |
| 20. | (b) (4)*** (Phonetic > 70% score 70) | 62 |
| 21. | FOLOTYN | 61 |
| 22. | SELE-PAK | 61 |
| 23. | SLOZEM | 61 |
| 24. | (b) (4)*** | 61 |
| 25. | FLUOCET (Phonetic > 70% score 74) | 60 |
| 26. | SOLIRIS | 60 |
| 27. | SALJET | 59 |
| 28. | SOLOXINE | 59 |
| 29. | SYNOTIC | 59 |
| 30. | CERETEC (Phonetic > 70% score 72) | 58 |
| 31. | DOLOGEN | 58 |
| 32. | SALAGEN | 58 |
| 33. | SALONPAS | 58 |
| 34. | SULTEN-10 | 58 |
| 35. | STAR-OTIC | 57 |
| 36. | SULZEE | 57 |
| 37. | ZOLOFT | 57 |
| 38. | ZOLYSE | 57 |
| 39. | SELENOS | 56 |
| 40. | (b) (4)*** | 56 |
| 41. | DOLOBID | 55 |
| 42. | ISOLYTE S | 55 |
| 43. | SALFLEX | 55 |
| 44. | SOLV X | 55 |
| 45. | CALAGESIC | 54 |
| 46. | DOLOPHINE | 54 |
| 47. | FLUTEX ( Phonetic > 70% score 72) | 54 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 48. | ISOLYTE P | 54 |
| 49. | PILOSTAT | 54 |
| 50. | SATOGESIC | 54 |
| 51. | SILDEC PE | 54 |
| 52. | SILPHEN | 54 |
| 53. | SILTUSSIN | 54 |
| 54. | SOLFOTON | 54 |
| 55. | SULSTER | 54 |
| 56. | STAGESIC | 54 |
| 57. | STAGESIC-10 | 54 |
| 58. | SULFACET-R | 54 |
| 59. | SULFORCIN | 54 |
| 60. | SILACE | 53 |
| 61. | SILAPAP | 53 |
| 62. | SILODOSIN | 53 |
| 63. | DOLORACIN | 52 |
| 64. | FULYZAQ (Phonetic > 70% score 79) | 52 |
| 65. | ISOLYTE E | 52 |
| 66. | NULECIT (Phonetic > 70% score 70) | 52 |
| 67. | PROSED | 52 |
| 68. | LAGESIC | 52 |
| 69. | SALEX | 52 |
| 70. | SALVAX | 52 |
| 71. | SELSUN | 52 |
| 72. | SOLU-CORTEF | 52 |
| 73. | SULFACEL-15 | 52 |
| 74. | SYNALGOS-DC | 52 |
| 75. | SYLLACT | 52 |
| 76. | ZOLADEX | 52 |
| 77. | E-SOLVE 2 | 51 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 78. | ISOLYTE H | 51 |
| 79. | LEROSETT | 51 |
| 80. | VOSOL HC | 51 |
| 81. | XOLOX | 51 |
| 82. | AZO-GESIC | 50 |
| 83. | ISOLYTE M | 50 |
| 84. | SALETO | 50 |
| 85. | SALETO-400 | 50 |
| 86. | SALETO-600 | 50 |
| 87. | SALETO-800 | 50 |
| 88. | SALSALTE | 50 |
| 89. | SALSITAB | 50 |
| 90. | SHELLCAP | 50 |
| 91. | SILTANE | 50 |
| 92. | SUPER C-500 | 50 |
| 93. | SUPROFEN | 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:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | CELLCEPT (Phonetic > 70% score 70) | 54 | The prefixes and infixes of this name pair have sufficient orthographic differences<br>The first syllables of this name pair sound different.<br>Solosec name contains an extra syllable. |
| 2. | COLOCORT | 54 | The prefixes and suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different. |
| 3. | C-SOLVE-2 | 53 | The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences<br>The first, second and third syllables of this name pair sound different. |
| 4. | PRILOSEC OTC | 52 | The prefixes of this name pair have sufficient orthographic differences.<br>The first syllables of this name pair sound different. Prilosec OTC has a modifier "OTC". If included, the modifier adds orthographic and phonetic differentiation. |
| 5. | SALETO-200 | 50 | The suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different. |
| 6. | SALINEX | 54 | The suffixes of this name pair have sufficient orthographic differences.<br>The first and third syllables of this name pair sound different. |

| No. | **Proposed name:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 7. | SANSAC | 58 | The infixes of this name pair have sufficient orthographic differences. Solosec has an upstroke letter "l" in the infix.<br>Solosec name contains an extra syllable. |
| 8. | SENATEC | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The first, second and third syllables of this name pair sound different. |
| 9. | SLO-BID | 50 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and third syllables of this name pair sound different. |
| 10. | SLOW-FE | 54 | The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>The first and third syllables of this name pair sound different. |
| 11. | SOLAICE | 60 | The suffixes of this name pair have sufficient orthographic differences.<br>Solosec name contains an extra syllable.<br>There is no overlap in frequency. |
| 12. | SOLARAZE | 54 | The suffixes of this name pair have sufficient orthographic differences.<br>The third syllables of this name pair sound different. |
| 13. | SOLITHERA*** | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences<br>The third syllables of this name pair sound different.<br>Solithera name contains an extra syllable. |

| No. | **Proposed name:** Solosec<br>**Established name:** secnidazole<br>**Dosage form:** oral granules<br>**Strength(s):** 2 gram per packet<br>**Usual Dose:** single dose 2 gram (1 packet) once | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 14. | SOTRET | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second syllables of this name pair sound different.<br>Solosec name contains an extra syllable. |
| 15. | SOULUS | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Solosec name contains an extra syllable. |
| 16. | SULFOAM | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second syllables of this name pair sound different.<br>Solosec name contains an extra syllable. |
| 17. | SULINDAC | 60 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and third syllables of this name pair sound different. |
| 18. | SULMASQUE | 51 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and third syllables of this name pair sound different. |
| 19. | SULPHO-LAC | 62 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and third syllables of this name pair sound different. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | SKELAXIN | 40 |
| 2. | SEROQUEL | 38 |
| 3. | STARLIX | 35 |
| 4. | SAPHRIS | 32 |
| 5. | SENSIPAR | 32 |
| 6. | SERTRALINE | 30 |
| 7. | SINGULAIR | 30 |
| 8. | SIMVASTATIN | 26 |
| 9. | SENNA | 25 |
| 10. | SEPTRA | 25 |

**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 found unacceptable by DMEPA (OSE# (b) (4)) and reconsideration (OSE # (b) (4)). Product approved under new proprietary name Macrilen. |
| | DOLGESIC | 64 | International product marketed in Spain and Argentina. |
| 2. | VELOSEF | 64 | Brand discontinued with no generic equivalent available. NDA 050530 was withdrawn FR effective 11/5/1992. |
| 3. | VELOSEF '125' | 64 | Brand discontinued with no generic equivalent available. NDA 050530 was withdrawn FR effective 11/5/1992. |
| 4. | VELOSEF '250' | 64 | Brand discontinued with no generic equivalent available. NDA 050530 was withdrawn FR effective 11/5/1992. |
| 5. | VELOSEF '500' | 64 | Brand discontinued with no generic equivalent available. NDA 050530 was withdrawn FR effective 11/5/1992. |
| 6. | CELEVAC (Phonetic > 70% score 79) | 63 | International product marketed in UK and Ireland. |
| 7. | SULEO-C | 63 | International product marketed in Ireland and UK. |
| 8. | PALDESIC | 62 | International product marketed in United Kingdom. |
| 9. | SALICIN | 62 | Product is not a drug - inactive ingredient. |
| 10. | PLUSET (Phonetic > 70% score 71) | 62 | Veterinary product. |
| 11. | SINODEC | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 12. | SUSTAC | 62 | International product marketed in UK, Hungary, Russia, Ukraine, and Argentina. |
| 13. | CLOSE UP | 60 | Product is not a drug. It over the counter Tooth paste. |
| 14. | (b) (4)*** | 60 | Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). Application ANDA (b) (4) is pending approval; new proprietary name, (b) (4)*** conditionally acceptable. |
| 15. | SIL TEX | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 16. | SOLIS | 60 | International product marketed in UK |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 17. | SOLUTAB*** | 60 | Name identified in Names Entered by Safety Evaluator database. Product is not a product it is modifier used to describe product. |
| | DOLAGESIC | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 18. | SALITOP | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 19. | CO-GESIC | 58 | Product withdrawn from the market due to safety concerns ANDA 087757 (tablet), FR Effective 03/27/2014; ANDA 089360 (capsule) was previously withdrawn, FR Effective 08/06/2011. |
| 20. | SELEPEN | 57 | International product marketed in Canada. |
| 21. | SOLATENE | 57 | Brand discontinued with no generic equivalent available. NDA 017589 withdrawn FR effective 10/02/1996 |
| 22. | SULPAK | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 23. | SHELLAC | 56 | Product is not a drug. It is a substance used as stabilizer in various products. |
| 24. | SULMET | 56 | Veterinary product |
| 25. | (b) (4) *** | 56 | Proposed proprietary name found unacceptable by DMEPA (OSE# 2012-460). Product approved under new proprietary name Suclear. |
| 26. | SOY ACID | 55 | Product is not a drug - inactive ingredient |
| 27. | CELLEGESIC*** | 54 | Proposed proprietary name found unacceptable by DMEPA (OSE# 2009-1999). Product approved under new proprietary name RECTIV |
| 28. | CELLULOSE | 54 | Product is not a drug. It is pharmaceutical excipient. |
| 29. | CHOLOVUE | 54 | Brand discontinued with no generic equivalent available. NDA 18077 and NDA 018076 was withdrawn FR effective 3/13/2009. |
| 30. | COLOGEL | 54 | International product marketed in UK. |
| 31. | COLOVAGE | 54 | Brand discontinued with no generic equivalent available. ANDA 071320 was withdrawn FR effective 2/2/2001. |
| 32. | SALZONE | 54 | International product marketed in UK. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 33. | | | (b) (4) |
| 34. | TYLOSIN | 54 | Product is not a drug. It is additive used in pharmaceuticals. |
| 35. | ANSOLYSEN | 52 | Brand discontinued with no generic equivalent available. NDA 009372 was withdrawn FR effective 11/05/1992 |
| 36. | BALACET (Phonetic > 70% score70) | 52 | Product withdrawn from the market due to safety concerns. |
| 37. | DOLOMITE | 52 | Product is not a drug. It is a mineral containing calcium, magnesium carbonite, and trace heavy metals |
| 38. | DOLOXENE | 52 | Product withdrawn from the market due to safety concerns. |
| 39. | DUOGESIC | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 40. | PROGESIC | 52 | International product marketed in United Kingdom and Ireland. |
| 41. | OMESEC | 52 | International product marketed in Hong Kong, Malaysia and Singapore. |
| 42. | | | (b) (4) |
| 43. | SALPIX | 52 | Plasma aldosterone level: Intravenous doses used have included: 2-3 L of normal saline IV infused over 4 to 6 hr, [5][6] 1.25 L of normal saline IV over 2 hr, or 2 L normal saline IV over 4 hr [7] |
| 44. | SILICON | 52 | Product is not a drug. It is a chemical element. |
| 45. | SILODRATE | 52 | International product marketed in Switzerland and Germany. |
| 46. | SORBET | 52 | Product is not a drug. It is a frozen dessert. |
| 47. | SPIRETIC | 52 | International product marketed in UK. |
| 48. | SANO LOG | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 49. | CHOLOXIN | 50 | Brand discontinued with no generic equivalent available. NDA 012302 was withdrawn FR effective 7/8/2011. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 50. | COLOMYCIN | 50 | International product marketed in Ireland, UK and China. |
| 51. | KESSO-GESIC | 50 | Product withdrawn from the market due to safety concerns ANDA 083544, withdrawn FR effective 09/12/2014. |
| 52. | ETOGESIC | 50 | Veterinary product. |
| 53. | SARALASIN | 50 | Brand discontinued with no generic equivalent available. NDA 018009 was withdrawn FR effective 9/29/1995. |
| 54. | SERICIN 1 | 50 | Product is not a drug. It is a protein created by silkworms in the production of silk. |
| 55. | SULFAMAG | 50 | Name identified in RxNorm database.<br>Unable to find product characteristics in internal databases. |
| 56. | SULFO-LO | 50 | Product is not a drug. Sulfo-Lo is soap contain Sulfer for acne treatment. |
| 57. | SULFAMED | 50 | Veterinary product |
| 58. | SOLPRIN | 50 | International product marketed in Australia. |
| 59. | SURECLICK*** | 50 | Name (modifier) entered by SE for BLA (b) (4) IND 105188 (BLA 125522). Product is not a drug. Product is an auto injector used in combination with Enbrel and other pending applications. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | COLTEC EC | 67 |
| 2. | DOLACET (Phonetic > 70% score 78) | 66 |
| 3. | FOLBIC | 64 |
| 4. | CHOLINE C-11 | 62 |
| 5. | DOLGIC | 62 |
| 6. | VASOTEC | 62 |
| 7. | CYTOTEC | 61 |
| 8. | DOLSED | 61 |
| 9. | PILOPTIC | 61 |
| 10. | PILOPTIC-1 | 61 |
| 11. | PILOPTIC-1/2 | 61 |
| 12. | PILOPTIC-2 | 61 |
| 13. | PILOPTIC-3 | 61 |
| 14. | PILOPTIC-4 | 61 |
| 15. | PILOPTIC-6 | 61 |
| 16. | MALOTIC | 60 |
| 17. | MOLASSES | 60 |
| 18. | PHOSPHOTEC | 60 |
| 19. | CHOLAC | 59 |
| 20. | COLDEC D | 59 |
| 21. | CLEEVEC | 57 |
| 22. | TOLU-SED DM | 57 |
| 23. | COSURIC | 56 |
| 24. | CYOTIC | 56 |
| 25. | FLO-PRED | 56 |
| 26. | FLOVENT | 56 |
| 27. | FOLATE | 56 |
| 28. | PALGIC | 56 |
| 29. | PRO OTIC | 56 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 30. | ULORIC | 56 |
| 31. | CORTIC | 55 |
| 32. | CALCET | 54 |
| 33. | CLORFED | 54 |
| 34. | DALACIN T | 54 |
| 35. | (b) (4) *** | 54 |
| 36. | DROTIC | 54 |
| 37. | FERUS PIC-150 | 54 |
| 38. | FLONASE | 54 |
| 39. | FLUTUSS HC | 54 |
| 40. | FOLBECAL | 54 |
| 41. | FOLTABS | 54 |
| 42. | FOLVITE | 54 |
| 43. | PELODIS | 54 |
| 44. | PROTAC | 54 |
| 45. | PROZAC | 54 |
| 46. | PSORIATEC | 54 |
| 47. | ULTEC | 54 |
| 48. | CHOLATE | 53 |
| 49. | CLOBEX | 53 |
| 50. | COLLAGEN | 53 |
| 51. | COLREX | 53 |
| 52. | DYLOJECT | 53 |
| 53. | FERRO BASIC | 53 |
| 54. | GLADASE-C | 53 |
| 55. | ZOLENE HC | 53 |
| 56. | C10-36 OLEFIN | 52 |
| 57. | C24-28 OLEFIN | 52 |
| 58. | C30-45 OLEFIN | 52 |
| 59. | CELLULASE | 52 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 60. | CEPHULAC | 52 |
| 61. | COLDEC DS | 52 |
| 62. | COLDEC-TR | 52 |
| 63. | COLFED-A | 52 |
| 64. | COLHIST | 52 |
| 65. | COLPREP*** | 52 |
| 66. | COLSTAT*** | 52 |
| 67. | DUROPHET | 52 |
| 68. | FOLCAPS | 52 |
| 69. | (b) (4) *** | 52 |
| 70. | FOLEX | 52 |
| 71. | FOLITAB | 52 |
| 72. | FOLLUTEIN | 52 |
| 73. | FOLNATE | 52 |
| 74. | FOLPLEX | 52 |
| 75. | FOSVESET | 52 |
| 76. | FRUSETIC | 52 |
| 77. | FUROCOT | 52 |
| 78. | HALOTEX | 52 |
| 79. | LASALOCID | 52 |
| 80. | MALASEB | 52 |
| 81. | MOOREDEC | 52 |
| 82. | NOTUSS AC | 52 |
| 83. | POLY PACT | 52 |
| 84. | POLY-DEX | 52 |
| 85. | PRO1TEK | 52 |
| 86. | PROCET | 52 |
| 87. | PROTOPIC | 52 |
| 88. | TYLOPHEN | 52 |
| 89. | VOLUVEN | 52 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 90. | COLESTID | 51 |
| 91. | DELAZINC | 51 |
| 92. | DILTZAC | 51 |
| 93. | NALACET | 51 |
| 94. | PLATET | 51 |
| 95. | ROSAC | 51 |
| 96. | TALACEN | 51 |
| 97. | ALA SEB | 50 |
| 98. | CHLO TUSS | 50 |
| 99. | CHLOROPTIC | 50 |
| 100. | CINOBAC | 50 |
| 101. | COLACE | 50 |
| 102. | DARVOCET | 50 |
| 103. | DILOTAB | 50 |
| 104. | DOLASETRON | 50 |
| 105. | DUOCET | 50 |
| 106. | FASLODEX | 50 |
| 107. | FERRLECIT | 50 |
| 108. | FLAREX | 50 |
| 109. | FODOSINE*** | 50 |
| 110. | FOLLISTIM | 50 |
| 111. | FOLPACE RX | 50 |
| 112. | FOLTRATE | 50 |
| 113. | FOLTX | 50 |
| 114. | FOSTEX | 50 |
| 115. | GLEEVEC | 50 |
| 116. | LOBAC | 50 |
| 117. | LORCET | 50 |
| 118. | MALDEC | 50 |
| 119. | ORETIC | 50 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 120. | POLY HIST HC | 50 |
| 121. | POLY-TUSSIN AC | 50 |
| 122. | POLY-VENT | 50 |
| 123. | PRO RED AC | 50 |
| 124. | PROVISC | 50 |
| 125. | RELCOF C | 50 |
| 126. | RILUTEK | 50 |
| 127. | VALENAC | 50 |

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/s/

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11/09/2015

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