# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 207964Orig1s000

# 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:** | January 17, 2018 |
| **Application Type and Number:** | NDA 207964 |
| **Product Name and Strength:** | ReadyPrep CHG (Chlorhexidine Gluconate) Cloth, 2% |
| **Product Type:** | Multi-Ingredient Product |
| **Rx or OTC:** | OTC |
| **Applicant/Sponsor Name:** | Medline Industries, Inc. |
| **Panorama #:** | 2017-18589074 |
| **DMEPA Safety Evaluator:** | Grace P. Jones, PharmD, BCPS |
| **DMEPA Team Leader:** | Chi-Ming (Alice) Tu, PharmD, BCPS |
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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, ReadyPrep CHG, 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, ReadyPrep CHG, for chlorhexidine gluconate cloth, 2%, on October 7, 2014, under IND 107899. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, ReadyPrep CHG, conditionally acceptable on February 6, 2015[a] under IND 107899.

The Applicant filed NDA 207964 on February 9, 2016 and submitted the proposed proprietary name, ReadyPrep CHG, for review on February 23, 2016. However, the Agency found the application incomplete to allow for a substantive review, and on April 8, 2016, the application received a Refuse to File (RTF) letter.

The Applicant again submitted NDA 207964 on October 20, 2017 and submitted the proposed proprietary name, ReadyPrep CHG, for review, on October 26, 2017.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the October 26, 2017 proprietary name submission.

- Intended Pronunciation: the Applicant indicated that the pronunciation of the proposed proprietary name should be self-evident because it is comprised of everyday English words and an abbreviation that is common to the intended marketplace.
- Active Ingredient: chlorhexidine gluconate
- Indication of Use:
    - Helps reduce bacteria that can potentially cause skin infection
    - For preparation of skin prior to surgery
- Route of Administration: topical
- Dosage Form: cloth
- Strength: 2%
- Dose and Frequency: Directions from Drug Facts Label (DFL)

[a] Jones, G. Proprietary Name Review for ReadyPrep CHG IND 107899. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 FEB 06. Panorama No. 2014-39498.

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Product and packaging are not sterile. Do not microwave. Follow your hospital policy for skin preparation with non-sterile products.
- Use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- Discard each cloth after a single use.
- After package has been opened, discard any unused cloths.
- Dry surgical sites (such as abdomen or arm)
    - Use one cloth to cleanse each 161 cm area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to dry for one (1) minute. Do not rinse. After package has been opened, discard any unused cloths.
- Moist surgical sites (such as inguinal fold)
    - Use one cloth to cleanse each 65 cm area (approximately 2x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to dry for one (1) minute. Do not rinse. After package has been opened, discard any unused cloths.

- How Supplied: Two 9x10.5 in disposable cloths in one package
- Storage: store between 20-25°C (68-77°F). Avoid excess heat above 40°C (104°F)

We note this NDA submission includes more detail in dose and frequency (shown above) compared to the dose and frequency submitted under IND 107899[b], but all other product characteristics remains the same.

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT & INITIAL COMMENTS

At the initial phase of the review, in response to our initial OSE, November 15, 2017 email, the Division of Nonprescription Drug Products (DNDP) had no concerns relating to the proposed

[b] Dose and frequency submitted under IND 107899: follow hospital policy for skin preparation with non-sterile products; use one cloth to cleanse area of skin to be prepared and vigorously scrub skin back and forth for 1 to 3 minutes wetting treatment area and then discard cloth.

proprietary name, ReadyPrep CHG. DMEPA concurs with DNDP's assessment at initial review and concludes that the proposed proprietary name does not misbrand the proposed product.

## 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 proposed proprietary name[c].

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

The Applicant indicated in their submission that the proposed name, ReadyPrep CHG, is comprised of 3 parts:

- "Ready" describes the product's ready-to-use nature,
- "Prep" refers to the product's use as a patient preoperative skin preparation, and
- "CHG" that is an abbreviation for the active ingredient, chlorhexidine gluconate.

This proposed proprietary name is comprised of multiple words: the root name ReadyPrep and the modifier CHG, that do not contain any components (i.e. route of administration, dosage form, etc.) that are misleading or can contribute to medication error. We discuss our assessment of ReadyPrep in Sections 2.2.4 through 2.2.6 and CHG in Section 2.2.7.

### *2.2.3 FDA Name Simulation Studies*

Eighty-six 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 Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our November 9, 2017 POCA search[d] identified 73 names with a combined phonetic and orthographic score of **≥**55% or an individual phonetic or orthographic score **≥**70%**.** We had identified and evaluated some of the names in our previous proprietary name review.[a] We re-evaluated the previously identified names of concern considering the additional details in dose and frequency, and any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed name. We agree with the findings from our previous review for the names evaluated previously. Therefore, our November 9, 2017 POCA search identified 36 names that were not previously analyzed. These names are included in Table 1 below.

[c] USAN stem search conducted on November 30, 2017.

[d] POCA search conducted on November 9, 2017 in version 4.2.

### *2.2.5 Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA search. These name pairs 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% | 0 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 27 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 9 |

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

Our analysis of the 36 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

### *2.2.7 Evaluation of the modifier, CHG*

We evaluated the modifier CHG in our previous review[a] and did not object to the use of the proposed modifier. We re-evaluated the proposed modifier CHG and we maintain our previous decision. Moreover under NDA 207964, the proposed product still contains the active ingredient chlorhexidine gluconate, thus, it appears reasonable that the modifier CHG communicates the proposed product's association with chlorhexidine gluconate.

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

DMEPA communicated our findings to the Division of Nonprescription Drug Products (DNDP) via e-mail on January 9, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNDP on January 17, 2018, they stated no additional concerns with the proposed proprietary name, ReadyPrep CHG.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 26, 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)). |
| **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)). |

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

| 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

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary

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 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>• 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>• 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>• 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. |

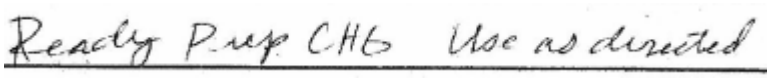
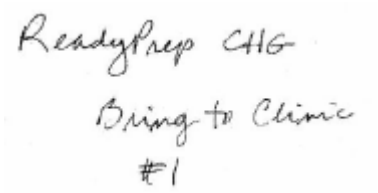
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when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

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

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

**Appendix B:** Prescription Simulation Samples and Results

**Figure 1. ReadyPrep CHG Study (Conducted on November 15, 2017)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | ReadyPrep CHG<br>Bring to clinic<br>Dispense #1 |
| Outpatient Prescription:<br>  <br> | |

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

294 People Received Study
86 People Responded

Study Name: ReadyPrep CHG

| **Total** | **29** | **23** | **34** | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| READPREP DHZ | 0 | 1 | 0 | 1 |
| READY PREG CHG | 0 | 0 | 1 | 1 |
| READY PREP | 0 | 0 | 1 | 1 |
| READY PREP CH6 | 0 | 0 | 8 | 8 |
| READY PREP CHB | 0 | 0 | 1 | 1 |
| READY PREP CHG | 4 | 7 | 21 | 32 |
| READY PUMP CH6 | 0 | 0 | 1 | 1 |
| READYPREP | 1 | 0 | 0 | 1 |
| READYPREP CHG | 23 | 2 | 1 | 26 |
| READY-PREP CHG | 0 | 5 | 0 | 5 |
| READYPRP CHG | 1 | 0 | 0 | 1 |
| REDI PREP CHG | 0 | 1 | 0 | 1 |
| REDIPREP CHG | 0 | 6 | 0 | 6 |
| REDI-PREP CHG | 0 | 1 | 0 | 1 |

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

| No. | **Proposed name:** ReadyPrep CHG<br>**Established name:**<br>Chlorhexidine Gluconate<br>**Dosage form:** Cloth solution<br>**Strength(s):** 2%<br>**Usual Dose:** Use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas. | **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.** |
|---|---|---|---|
| | N/A | | |

**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. | Ak-pred | 57 |
| 2. | A-Methapred | 56 |
| 3. | Depopred | 60 |
| 4. | Rucaparib | 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:** ReadyPrep CHG<br>**Established name:**<br>Chlorhexidine Gluconate<br>**Dosage form**: Cloth solution<br>**Strength(s):** 2%<br>**Usual Dose:** Use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas. | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 5. | Anuprep-Hc | 56 | The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. |
| 6. | Econopred | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 7. | Orapred | 62 | This name pair has sufficient orthographic and phonetic differences. |
| 8. | pred Forte | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 9. | (b) (4) | 62 | The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. |
| 10. | Sterapred | 58 | This name pair has sufficient orthographic and phonetic differences. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 11. | Ear-Dry | 48 |
| 12. | Erypar | 48 |
| 13. | Eryped | 52 |
| 14. | Eryped 200 | 52 |
| 15. | Eryped 400 | 52 |
| 16. | Paradyne | 54 |
| 17. | Paraldehyde | 44 |
| 18. | prelay | 38 |
| 19. | (b) (4) | 52 |

**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 |
|---|---|---|---|
| 20. | Baytet pref | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 21. | Key-pred | 59 | Name identified in RxNorm and Red Book databases. Product is discontinued and no generic alternatives are available. |
| 22. | Key-pred Sp | 58 | Name identified in RxNorm and Red Book databases. Product is discontinued and no generic alternatives are available. |
| 23. | Poly-pred | 55 | Name identified in Drugs at FDA database. Product is discontinued and no generic alternatives are available. |
| 24. | predacort 50 | 58 | Name identified in RxNorm and Red Book databases. Product is discontinued and no generic alternatives are available. |
| 25. | Raphtre | 58 | Name identified in RxNorm and Red Book databases. Product is discontinued and no generic alternatives are available. |
| 26. | Re Kar Ce Plus | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 27. | Renaplus | 57 | Veterinary product. |

**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 (%) |
|---|---|---|
| 28. | Addaprin | 56 |
| 29. | Ardeparin | 60 |
| 30. | Decapryn | 58 |
| 31. | Depandrate | 58 |
| 32. | Ed-Apap | 55 |
| 33. | Grapiprant | 56 |
| 34. | Pedtrace-4 | 55 |
| 35. | Prazepam | 55 |
| 36. | Tresaderm | 56 |

[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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