CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-881

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; White Oak 22; Mail Stop 4447)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**ODS CONSULT #:** 05-0189
July 6, 2005	February 10, 2006	
DATE OF DOCUMENT:		
June 10, 2005	**PDUFA DATE:** April 10, 2006	

TO: Brian Harvey, MD, PhD
Director, Division of Gastroenterology Products (HFD- 180)

THROUGH: Alina Mahmud, RPh, MS, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support (HFD-420)

FROM: Nora Roselle, PharmD, Safety Evaluator
Division of Medication Errors and Technical Support (HFD-420)

PRODUCT NAME: **Moviprep**
(PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid) for Oral Solution

NDA#: 21-881
NDA SPONSOR: Norgine International Limited

COMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Moviprep. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.

2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review to minimize potential errors with the use of this product.

3. DDMAC finds the proprietary name, Moviprep, acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; White Oak 22; Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: August 17, 2005

NDA#: 21-881

NAME OF DRUG: **Moviprep**
(PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid) for Oral Solution

NDA HOLDER: Norgine International Limited

I. INTRODUCTION:

This consult was written in response to a request from the Division of Gastroenterology Products (HFD-180), for assessment of the proprietary name "Moviprep", regarding potential name confusion with other proprietary or established drug names. Container labels and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Moviprep is indicated for bowel cleansing prior to colonoscopy ——————————————— ——————— . The recommended dose for adults is 2 liters of Moviprep solution prior to gastrointestinal examination. Oral administration is at a rate of eight ounces (240 mL) every fifteen to thirty minutes, until two liters are consumed. The first bowel movement may occur approximately one hour after the start of Moviprep administration. The dosing of Moviprep can be divided as one liter in the evening before and one liter in the early morning of the day of the clinical procedure. Likewise, Moviprep can be given as two liters in the evening preceding the clinical procedure or two liters early in the morning of the day of the clinical procedure as long as consumption is completed at least one hour before the scheduled procedure. Moviprep is supplied in a powdered form which is reconstituted as a solution for oral administration. Moviprep solution is prepared by emptying the contents of Pouch A and Pouch B into a suitable glass container or the mixer provided adding one liter of lukewarm water and mixing until the ingredients are dissolved. The solution may be refrigerated prior to drinking. After consumption of the first liter, the procedure should be repeated with the second Pouch A and Pouch B. The reconstituted solution should be refrigerated and used within 24 hours.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3] for existing drug names which sound-alike or look-alike to Moviprep to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[4]. The Saegis[5] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Moviprep. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC finds the proprietary name, Moviprep, acceptable from a promotional perspective.

2. Several product names were identified in the Expert Panel Discussion (EPD) that were thought to have potential for confusion with Moviprep. These products are listed in Table 1 (see below and page 4), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by EPD

Product Name	Established name, Dosage form(s)	Usual adult dose*	Other
Moviprep	PEG 3350 and Electrolytes for Oral Solution	Take 2 liters by mouth prior to GI exam; given at a rate of 8 oz (240 mL) every 15-30 minutes until 2 liters are consumed	
Monopril	Fosinopril Sodium Tablets, 10 mg, 20 mg, and 40 mg	Initial: 10 mg once daily; Maintenance: 20 - 40 mg once daily	Look-alike
Minipress	Prazosin HCl Capsules, 1 mg, 2 mg, and 5 mg	1 mg BID or TID	Look-alike, Sound-alike
Mifeprex	Mifepristone Tablets, 200 mg	Day 1: three 200 mg tablets as a single oral dose; if abortion has not occurred, then on Day 3 give Misoprostol two 200 mcg tablets PO	Sound-alike

[1] MICROMEDEX Integrated Index, 2005, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, 2005, Facts and Comparisons, St. Louis, MO.
[3] The Division of Medication Errors and Technical Support [DMETS] database of proprietary name consultation requests, Drugs@FDA, and the electronic online version of the FDA Orange Book.
[4] WWW location http://www.uspto.gov/tmdb/index.html.
[5] Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

Product Name	Established name, Dosage form(s)	Usual adult dose*	Other
Moviprep	PEG 3350 and Electrolytes for Oral Solution	Take 2 liters by mouth prior to GI exam; given at a rate of 8 oz (240 mL) every 15-30 minutes until 2 liters are consumed	
Movipride (foreign)	Bromopride	Antiemetic	Look-alike, Sound-alike
Movicol (foreign)	PEG 3350	Bowel cleansing/laxative prior to colonoscopy, etc.	Look-alike, Sound-alike
*Frequently used, not all-inclusive.			

B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion. The POCA did not identify any additional names considered to have significant phonetic or orthographic similarities to Moviprep.

C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Moviprep 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. These studies employed a total of 121 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. Inpatient orders and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Moviprep (see below). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were 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 sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Moviprep 4 pouches Mix with 2 liters of fluid and drink 8oz every 15 minutes until complete	Moviprep Mix with two liters of fluid and drink eight ounces every fifteen minutes until complete.
Inpatient RX: Moviprep mix with 2 liters of fluid and drink 8oz every 15m until complete	

2. Results:

None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. See appendix A for the complete listing of interpretations from the verbal and written studies.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Moviprep, the primary concerns related to look-alike and sound-alike confusion with Monopril, Minipress, Mifeprex, Movipride, and Movicol. Movipride and Movicol are both foreign names identified to have potential for look- and sound-alike confusion with Moviprep.

Movipride is an antiemetic drug marketed in the Dominican Republic and Central America. Other product information was not available and the panel did feel that the name possessed convincing look- or sound-alike potential with Moviprep.

Movicol is a PEG- 3350 product, also manufactured by the sponsor Norgine. While the name lacks convincing look- and sound-alike potential with the proposed name, it was determined that the name should be mentioned since it carries the same indication for use as Moviprep. The Movicol name is used in the UK, Spain, Australia, and many other international countries. Given the lack of convincing look- and sound-alike potential, DMETS is not concerned with confusion between Movipride and Movicol and the proposed proprietary name.

Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to small sample size. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Moviprep.

1. Look and Sound-Alike Name Confusion

   a. Monopril has a look-alike similarity to Moviprep. Monopril is indicated for the treatment hypertension and heart failure. Monopril is available in 10 mg, 20 mg, and 40 mg oral tablets. The recommended initial dose of Monopril is 10 mg once daily with a maintenance dose of 20 mg - 40 mg once daily. Monopril and Moviprep share similar orthographic characteristics in that the first seven letters of each name look similar when scripted ("Monopri-" vs. "Movipre-"). The last letter of each name differs as one is an upstroke letter ("l") and the other is a downstroke letter ("p"). Besides look-alike similarities, Monopril and Moviprep are both given by oral administration. However, there are numerous product characteristics which help differentiate one name from the other. The two products each have a different dosage form (tablet vs. powder for reconstitution), strength (10 mg, 20 mg, and 40 mg vs. multiple ingredient drug product, no single strength indicated), dosing regimen (one tablet once daily vs. drink two liters by mouth prior to GI exam at a rate of eight ounces every 15-50 minutes until gone), and indication for use (hypertension/heart failure vs. bowel cleanser). In addition, since Moviprep is a combination of PEG 3350 and several different electrolytes, a strength most likely will not be indicated on a prescription order. Monopril, on the other hand, is available in three different strengths, one of which will need to be identified prior to prescription filling and dispensing. Furthermore, Moviprep has distinct product preparation instructions which must be followed prior to use. Moviprep powder must be reconstituted to a large volume, oral solution prior to administration by the patient. Thus, even though the drug names look-alike, DMETS believes that the differences mentioned above will help minimize error between Monopril and Moviprep.

Monopril Moviprep

b. Minipress has a look and sound-alike similarity to Moviprep. Minipress is indicated for the treatment of hypertension. Minipress is available in 1 mg, 2 mg, and 5 mg oral capsules. The recommended dose of Minipress is 1 mg two or three times daily. Minipress and Moviprep share similar orthographic characteristics in that the first seven letters of each name look similar when scripted ("Minipre-" vs. "Movipre-"). However, the last letters of each name differ as the double "ss" in Minipress look different than the downstroke letter "p" in Moviprep. Minipress and Moviprep each have three syllables when spoken, but are differentiated phonetically by the beginning letters ("Mini-" vs. "Movi-"). Besides look-alike similarities, Minipress and Moviprep are both given by oral administration. However, there are numerous product characteristics which help differentiate one name from the other. The two products each have a different dosage form (capsules vs. powder for reconstitution), strength (1 mg, 2 mg, and 5 mg vs. multiple ingredient drug product, no single strength indicated), dosing regimen (one tablet two or three times daily vs. drink two liters by mouth prior to GI exam at a rate of eight ounces every 15-50 minutes until gone), and indication for use (hypertension vs. bowel cleanser). In addition, since Moviprep is a combination of PEG 3350 and several different electrolytes, a strength most likely will not be indicated on a prescription order. Minipress, on the other hand, is available in three different strengths, one of which will need to be identified prior to prescription filling and dispensing. Furthermore, Moviprep has distinct product preparation instructions which must be followed prior to use. Moviprep powder must be reconstituted to a large volume, oral solution prior to administration by the patient. Thus, even though the drug names look-alike and sound similar, DMETS believes that the differences mentioned above will help minimize error between Minipress and Moviprep.

c. Mifeprex has a sound-alike similarity to Moviprep. Mifeprex is indicated for the termination of intrauterine pregnancy. Mifeprex is available in 200 mg oral tablets. The recommended dose of Mifeprex is as follows: Day 1, three 200 mg tablets as a single oral dose; if abortion has not occurred, then on Day 3 give Misoprostol two 200 mcg tablet by mouth. Mifeprex and Moviprep have slight sound-alike characteristics in that the end of each name ("-prex" vs. "-prep") is similar and each name has three syllables. However, the beginning of each name sound completely different and help distinguish one name from the other ("Mife-" vs. "Movi-"). Besides slight sound-alike similarities, Minipress and Moviprep are both given by oral administration. However, there are numerous product characteristics which help differentiate one name from the other. The two products each have a different dosage form (tablets vs. powder for reconstitution), strength (200 mg vs. multiple ingredient drug product, no single strength indicated), dosing regimen (three 200 mg tablets as a single dose vs. drink two liters by mouth prior to GI exam at a rate of eight ounces every 15-50 minutes until gone), and indication for use (termination of pregnancy vs. bowel cleanser). Furthermore, Moviprep has distinct product preparation instructions which must be followed prior to use. Moviprep powder must be reconstituted to a large volume, oral solution prior to administration by the patient. Moreover, Mifeprex has a limited distribution and is only supplied to doctor's who sign a Physician's Agreement. Thus, Mifeprex is not available to the public through licensed pharmacies and patients are usually closely monitored by their physicians while taking Mifeprex. Based on a lack of convincing look-alike similarities and the above-mentioned product differences, we believe there is minimal risk for confusion and error between Mifeprex and Moviprep.

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X § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Appendix A. Moviprep

Verbal	Written Outpatient	Written Inpatient
MuviPrep	Moviprep	Moviprep
Movie Prep Pouches	Moviprep	Moviprep
Movieprep	Moviprep	Moviprep
Luviprep	Moviprep	Moviprep
Luviprep	Moviprep	Moviprep
Movieprip	Moviprep	Moviprep Mix
Loreetrip	Moviprep	Moviprep
Moviprep	Moviprep	Moviprep
Movi-Pred	Moviprep	Moviprep
Moviprep	Moviprep	Moviprep
Movieprep	Moviprep	Moviprep Mix
Luiprip	Moviprep	Moviprep Mix
Lurycrip	Moviprep	Moviprep
Moody Prep	Moviprep	Moviprep
Movieprep	Moviprep	Moviprep
Muviprep	Moviprep	Moviprep
	Moviprep	Moviprep mix
	Moniprep	Moviprep Mix
	Moviprep	Movipred
		Moviprep mix
		Moviprep
		Moviprep
		Moviprep
		Moviprep
		Moviprep Mix
		Moviprep
		Moviprep
		Moviprep

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DRUG SAFETY OFFICE REVIEWER

Carol Holquist
2/16/2006 06:57:15 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(WO 22, Mailstop 4447)

DATE RECEIVED: June, 16, 2006 **DATE OF DOCUMENT:** June 2, 2006	**DESIRED COMPLETION DATE:** July 13, 2006 **PDUFA DATE:** August 2, 2006	**OSE REVIEW #:** 05-0189-1

TO: Brian Harvey, MD, PhD.
Director, Division of Gastroenterology Products
HFD-180

THROUGH: Alina Mahmud, RPh., MS, Team Leader
Denise Toyer, Pharm D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Linda M. Wisniewski, RN, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: **MoviPrep**
(PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid) for Oral Solution

NDA#: **21-881**

NDA SPONSOR: Norgine International Limited

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, MoviPrep. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.

2. DMETS recommends implementation of the labels and labeling revisions outlined in section II of this review to minimize potential errors with the use of this product.

3. DDMAC finds the proprietary name, MoviPrep, acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
WO 22; Mailstop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: June 15, 2006

NDA#: 21-881

NAME OF DRUG: MoviPrep
(PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid) for Oral Solution

NDA HOLDER: Norgine International Limited

I. INTRODUCTION:

This consult was written in response to a request from the Division of Gastroenterology Products (HFD-180), for a re-assessment of the proprietary name, "MoviPrep", regarding potential name confusion with other proprietary or established drug names. The name MoviPrep was found acceptable by DMETS in ODS consult #: 05-0189, dated February 16, 2006. This application received an Approvable action on April 10, 2006. DMETS notes that the sponsor, Norgine, has granted Salix Pharmaceuticals the exclusive rights to market MoviPrep in the United States as of December 12, 2005.

PRODUCT INFORMATION

MoviPrep is indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age and older. The recommended MoviPrep dose for colon cleansing for adult patients is 2 liters (approximately 64 ounces) of MoviPrep solution (with 1 additional liter of clear fluids) taken orally prior to the colonoscopy in one of the following ways:

1) Split-dose MoviPrep regimen: the evening before the colonoscopy, take the first liter of MoviPrep solution over one hour (one 8 ounce glass every 15 minutes) and then drink 0.5 liters (approximately 16 ounces) of clear fluid. Then, on the morning of the colonoscopy, take the second liter of MoviPrep solution over one hour and then drink 0.5 liters of clear liquid at least one hour prior to the start of the colonoscopy; or

2) Evening-only (Full-dose) MoviPrep regimen: around 6 pm in the evening before the colonoscopy, take the first liter of MoviPrep solution over one hour (one 8 ounce glass every 15 minutes) and then about 1.5 hours later take the second liter of MoviPrep solution over one hour. In addition, take 1 liter (approximately 32 ounces) of additional clear liquid during the evening before the colonoscopy.

Preparation of the MoviPrep solution:

MoviPrep is supplied in powdered form. MoviPrep is administered as an oral solution after reconstitution and is supplied in a carton containing 4 pouches (2 of Pouch A and 2 of Pouch B). It is also supplied with a disposable container clearly marketed with a one liter fill line. The container contains 4 pouches (2 of pouch A and 2 of pouch B). The carton and container should be stored at 77°F. When reconstituted, store upright and keep solution refrigerated. Use within 24 hours.

MoviPrep solution is prepared by emptying the contents of 1 pouch A and 1 pouch B into a suitable glass container (or the container provided), then adding to the container 1 liter of lukewarm water. Mix the solution to ensure that the ingredients are completely dissolved. If the patient prefers, the MoviPrep solution can be refrigerated prior to drinking. The reconstituted solution should be used within 24 hours. After consumption of the first liter of MoviPrep solution, the above mixing procedure should be repeated with the second pouch A and pouch B to reconstitute the second liter of the MoviPrep solution.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3,4] for existing drug names which sound-alike or look-alike to MoviPrep to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[5]. The Saegis[6] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name MoviPrep. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC finds the proprietary name, MoviPrep, acceptable from a promotional perspective.

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[1] MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[3] AMF Decision Support System [DSS], Drugs@FDA, the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, and the electronic online version of the FDA Orange Book.
[4] Phonetic and Orthographic Computer Analysis
[5] WWW location http://www.uspto.gov/tmdb/index.html.
[6] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

2. The Expert Panel identified one additional name that was thought to have the potential for confusion with MoviPrep. This product is listed in Table 1 (page 4), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel.

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
MoviPrep	PEG 3350 and Electrolytes for Oral Solution	Take 2 liters by mouth prior to exam: given at a rate of 8 oz (240 mL) every 15-30 minutes until 2 liters are consumed.	N/A
Univasc	Moexipril Hydrochloride Tablets: 7.5 mg and 15 mg	7.5 mg once daily to 30 mg daily in one or two divided doses one hour before meals.	LA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name MoviPrep, the primary concern relating to look-alike and/or sound-alike confusion with Moviprep is Moexipril.

Moexipril was thought to have potential look-alike similarities to MoviPrep. Moexipril is an established name for Univasc. Moexipril is indicated in the treatment of hypertension.

The orthographic similarity stems from the similar beginning and middle letters of each name (Movi vs. Moex and pre vs. pri). However, the last letter of each name is orthographically different. Where MoviPrep has a downstroke for the letter 'p', Moexipril has an upstroke for the letter 'l'. This orthographic difference may help to differentiate these two names when written. There are also some differentiating product characteristics, such as dose (8 oz vs. 7.5 mg to 30 mg), frequency of administration (every 15-30 minutes vs. once or twice daily), strength (multiple ingredient product with no single strength vs. 7.5 mg and 15 mg), and dosage form (powder for oral solution vs. tablet). In addition, since MoviPrep is a combination of PEG 3350 and several different electrolytes, a strength most likely will not be indicated on a prescription order. Moexipril, on the other hand, is available in two different strengths, one of which will need to be identified prior to prescription filling and dispensing.

The orthographic differences between Moexipril and MoviPrep, in addition to differentiating product characteristics, decrease the potential for confusion involving this name pair.

Moexipril
Moviprep

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