

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-711

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: December 19, 2008
To: Rafel D. Rieves, M.D., Director
Division of Medical Imaging and Hematology Products, HFD-160
From: Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis, HFD-420
Subject: Proprietary Name Review
Drug Name(s): Vasovist (Gadofosveset Trisodium) Injection
244 mg/mL
Application Type/Number: NDA 21-711
Applicant/sponsor: Epix Pharmaceuticals, Inc.
OSE RCM #: 2008-1333

1 INTRODUCTION

This memorandum is written in response to resolve the differences in opinion between the Division of Medication Error Prevention and Analysis (HFD-420) and the Division of Medical Imaging and Hematology Products (HFD-160) on the acceptability of the proposed proprietary name Vasovist.

2 MATERIAL REVIEWED

I have reviewed and considered the comments provided by the DMEPA review team in OSE Review 2008-1333, information about the use of gadolinium contrast agents provided by the Division of Medical Imaging and Hematology Products, information provided by Applicant on December 18, 2008, and information I have obtained from discussions with the Joint Commission, members of the American Society of Medication Safety Officers, and member organizations of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP).

3 DISCUSSION

The name, Magnevist, was identified by the DMEPA review team as a name that was thought to look similar to Vasovist when scripted and shares a number of overlapping product characteristics. (See Appendix A for detail). The FDA prescription studies returned a positive interpretation of Vasovist as Magnevist. Additionally, the web-based drug information handbook, Lexi-Comp, indicates "Vasovist may be confused with Magnevist or Gadovist".

The DMEPA safety evaluator determined that pharmacy departments do not have consistent oversight of contrast agents. She noted that pharmacy departments may become more involved in reviewing medication orders for these products due to the inclusion of contrast media in the Joint Commissions Medication Management (MM) standards and the National Patient Safety Goals (NPSG). The safety evaluator determined that the inclusion of contrast media in the Standards and NPSGs has caused these agents to be ordered and prescribed in a manner similar to other medications used in hospitals. This causes orthographic similarity of the names Magnevist and Vasovist creating the possibility for confusion. The December 18, 2008, correspondence from the applicant states that they are confident confusion with Vasovist will not occur based on their "post-marketing experience in over 10 years in Europe and other ex-US countries where language and dialect issues could have also led to errors." They reported no medication dispensing errors to date.

Historically, contrast agents have been stored, ordered verbally, and administered without a prospective review by pharmacy within the area where the procedure is performed (i.e. radiology suite, emergency room, etc.). The Applicant has provided information that contrast agents continue to be ordered in this manner, and when orders are issued for prospective review by a pharmacist, the orders tend to be electronic or on preprinted order/protocols minimizes the possibility that the name "Vasovist" could be scripted and misinterpreted. The Division of Medical Imaging and Hematology Products (DMIHP) has advised us that these agents are not routinely ordered by name or by handwritten communication, and has disagreed with the safety concerns expressed by the DMEPA review team. However, I have learned through discussions with Medication Safety Officers and the Joint Commission, that self-selection is not the standard of care for these products. In fact, there is no consistent standard of care for these products causing each institution to interpret the Joint Commission Standard differently. Certain institutions order these products by protocol; some self-select in the Radiology department; some stock these contrast agents in Automated Dispensing Cabinets (i.e. Pyxis) in Radiology; some

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stock these agents in the pharmacy and receive a written requisition for the agent that is not patient specific. Additionally, some institutions anticipate that pharmacy will be expected to review written orders of gadolinium-containing products in the near future because of the differences in dosing and clinical issues with use of these agents in renally impaired patients.

Collectively, these considerations have led me to conclude the written prescriptions or requisitions for contrast agents may not be the usual practice in the current medication use process but are plausible.

4 CONCLUSIONS AND RECOMMENDATIONS

DMEPA will align with the Division of Medical Imaging and Hematology Products decision to allow the use of the name Vasovist for this product. This alignment is based on the agreement that the proprietary name will be revised if postmarketing medication errors occur as the result of proprietary name confusion.

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/s/

Carol Holquist
12/19/2008 04:26:42 PM
DRUG SAFETY OFFICE REVIEWER



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: December 17, 2008

To: Rafel D. Rieves, M.D., Director
Division of Medical Imaging and Hematology Products, HFD-160

Thru: Kellie Taylor, Pharm.D., MPH, Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis, HFD-420

From: Tara Turner, Pharm.D., Safety Evaluator
Division of Medication Error Prevention and Analysis, HFD-420

Subject: Proprietary Name Review

Drug Name(s): Vasovist (Gadofosveset Trisodium) Injection
244 mg/mL

Application Type/Number: NDA 21-711

Applicant: Epix Pharmaceuticals, Inc.

OSE RCM #: 2008-1333

CONTENTS

EXECUTIVE SUMMARY	1
1 INTRODUCTION	1
1.1 Background	1
1.2 Regulatory History	1
1.3 Product Information	2
2 METHODS AND MATERIALS.....	2
2.1 Adverse Event Reporting System (AERS) Database.....	2
2.2 Safety Evaluator Risk Assessment – Vasovist and Magnevist	2
3 RESULTS	3
3.1 Adverse Event Reporting System (AERS) Database.....	3
3.2 Safety Evaluator Risk Assessment – Vasovist and Magnevist	4
4 DISCUSSION.....	4
5 CONCLUSIONS AND RECOMMENDATIONS	5
5.1 Comments to the Division	5
5.2 Comments to the Applicant	5
6 REFERENCES	7

EXECUTIVE SUMMARY

The findings of the Failure Mode and Effects Analysis (FMEA) indicates that the proposed name Vasovist is vulnerable to name confusion with Magnevist that could lead to medication errors in the usual practice setting. Thus, the Division of Medication Error Prevention and Analysis maintains its objection to the use of the proprietary name, Vasovist, for this product (see full comments in Section 4).

5 INTRODUCTION

This memorandum was written in response to a request from the Division of Medical Imaging and Hematology Products (DMIHP) for re-assessment of the proposed proprietary name, Vasovist, regarding potential name confusion with other proprietary or established drug names.

5.1 BACKGROUND

Given the fact that the product under review is a contrast agent, we think it is important to provide some background on the medication use system for these agents. In the past it has been customary for imaging agents to be ordered by, stored, prepared, and administered in radiology clinics with little or no interaction with hospital pharmacy departments. However, the Joint Commission medication management (MM) standards and the National Patient Safety Goal (NPSG) for medication reconciliation have changed the dynamic and resulted in a more collaborative approach between radiology and pharmacy departments. The Joint Commission included contrast media in the definition of a medication in its MM standards in 2004, and the following standards appear:

MM 4.10 – Pharmacist review of orders (may be performed by pharmacist or licensed independent practitioner)

MM 2.20 – Storage of medications (formulary management, security and temperature control, ordering, authorized access)

MM 4.30 – Medication labeling (administered in the radiology department, sent home with the patient)

NPSG 8 – Medication reconciliation (inpatient, outpatient)

Currently, it is our understanding that pharmacy departments do not consistently have oversight of contrast agents. Only recently have radiology departments begun to send orders routinely to the pharmacy for review prior to use. Similarly, although many pharmacies are becoming involved in the ordering and review of orders for these products, the storage is frequently in the radiology department.

5.2 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis (DMEPA) originally reviewed and objected to the proposed proprietary name, Vasovist in OSE Review # 04-0026, dated May 28, 2004. Our objections were based on look-alike concerns with Magnevist, a currently marketed contrast agent in the United States. Of particular concern was the fact that there was a positive hit for Magnevist in the CDER prescription studies that were conducted.

Subsequent to this objection, the applicant submitted a rebuttal which DMEPA evaluated. We indicated that the applicant had not provided persuasive evidence to diminish our concerns and therefore upheld our original decision in OSE Review # 04-0026-1, dated October 15, 2004. Based on review of the Division Director's memorandum dated January 11, 2005, we note that

DMIHP did not agree with our assessment. However, the Director's memo deferred the final recommendation on the acceptability of the name due to approvability issues associated with the application. Subsequently, two approvable letters were issued followed by a lengthy appeals process. The application was re-submitted to FDA on June 30, 2008.

In a letter dated August 14, 2008, the applicant indicates that at this time they are "seeking confirmation that Vasovist is an acceptable proprietary tradename for gadofosveset trisodium". They note that in a December 7, 2004 teleconference Dr. Mills stated that he "did not have a reason to not accept Vasovist". They further note that since 2004, gadofosveset trisodium has been approved for marketing in 33 countries outside the United States utilizing the proprietary name Vasovist.

5.3 PRODUCT INFORMATION

Vasovist (gadofosveset trisodium) Injection is a gadolinium-based blood pool contrast agent proposed to be indicated for use with magnetic resonance angiography (MRA) to evaluate aortoiliac occlusive disease in adults with known or suspected peripheral vascular disease. Vasovist should be administered to adults as an intravenous bolus injection, manually or by power injection, at a dose of 0.12 mL/kg body weight over a period of time up to 30 seconds followed by a 25-30 mL normal saline flush. Vasovist Injection is a sterile solution for intravenous injection, containing 244 mg/mL of gadofosveset trisodium. The product is packaged in 10 mL and — single use glass vials in shrink-wrapped packages of 10 vials. Vasovist should be stored at room temperature and should be protected from light and freezing.

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6 METHODS AND MATERIALS

6.1 ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

On October 22, 2008, the Division of Medication Error Prevention and Analysis searched the FDA Adverse Event Reporting System (AERS) database to retrieve any medication errors relating to Vasovist, given that the product is currently approved and marketed in countries outside the United States. AERS was searched using the trade name term "*Vasovist*", the active ingredient term "*gadofosveset trisodium*", and the verbatim term "*Vasovist*" with the MedDRA high level group term "Medication Errors" and preferred term "Pharmaceutical Product Complaint".

Similarly, we searched AERS for cases of name confusion between Vasovist and Magnevist, given that both products are currently approved and marketed in countries outside the United States. An interaction search was performed using the trade name terms "*Vasovist*" and "*Magnevist*", the active ingredient terms "*gadofosveset trisodium*", "*gadopentetate*", and "*gadopentetate dimeglumine*", and the verbatim terms "*Vasovist*" and "*Magnevist*" with the MedDRA high level group term "Medication Errors" and preferred term "Pharmaceutical Product Complaint".

6.2 SAFETY EVALUATOR RISK ASSESSMENT – VASOVIST AND MAGNEVIST

The primary Safety Evaluator applies their individual expertise, gained from evaluating medication errors reported to FDA, to conduct a Failure Modes and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic

tool for evaluating a process and identifying where and how it might fail.¹ When applying FMEA to assess the risk of a proposed proprietary name, we seek to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator identifies potential failure modes by asking: "Is the name Vasovist convincingly similar to Magnevist, which may cause practitioners to become confused at any point in the usual practice setting?" An affirmative answer indicates a failure mode and represents a potential for Vasovist to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking "Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?" The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would ultimately not be a source of medication errors in the usual practice setting, the name is eliminated from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

7 RESULTS

7.1 ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

The individual search of the AERS database for medication errors relating to "Vasovist" retrieved no cases. Similarly, the interaction search for cases of name confusion between "Vasovist"/"gadofosveset" and "Magnevist"/"gadopentetate" retrieved no cases.

¹ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

7.2 SAFETY EVALUATOR RISK ASSESSMENT – VASOVIST AND MAGNEVIST

We identified the following factors that may contribute to medication errors involving Vasovist and Magnevist: orthographic similarity between the proprietary names, orthographic similarity between the established names, similar indications and setting of use, numerically similar dosing, same dosage form and route of administration, overlapping vial sizes, same storage requirements, and the same distributor (see Appendix A for details).

8 DISCUSSION

The names “Vasovist” and “Magnevist” are convincingly similar to one another. The orthographic similarity of this name pair stems from the similar appearance of the first letters (‘Va’ vs. ‘Ma’) when scripted. Additionally, the ending letters overlap and look similar (‘ovist’ vs. ‘evist’). The only letter that may help to differentiate the names is the lower case ‘g’ in Magnevist; however it can resemble a lower case ‘s’ when scripted (see samples below). Further, the names have a comparable number of letters (8 for Vasovist vs. 9 for Magnevist), which makes them look similar in length.



The image shows two handwritten samples of the drug names. On the left, 'Magnevist' is written above 'Vasovist', with a horizontal line between them. On the right, 'Magnevist' is written above 'Vasovist'. The handwriting is cursive and demonstrates how the 'g' in 'Magnevist' can look like an 's' and how the 'v' in 'Vasovist' can look like a 'g', making the two names appear very similar when written quickly.

Vasovist and Magnevist share the following overlapping product characteristics: indication of use (MRA vs. MRI), setting of use (radiology clinic), dosage form (solution for injection), route of administration (intravenous bolus), vial sizes (10 mL ——— single use), and storage requirements (controlled room temperature). The products also share numerically similar dosing (0.12 mL/kg vs. 0.2 mL/kg). As described in Section 1 on page 1 of this review, imaging agents are typically ordered, stored, prepared and administered in the radiology clinic without pharmacist intervention, which increases our level of concern given these similarities.

b(4)

Additionally, these products have similar established names (gadofosveset vs. gadopentetate) and the same distributor (Bayer), and may therefore be stored near each other. Although the carton labeling for these products is relatively well differentiated (see Appendix B), this does not eliminate the risk of selection errors. For example, in pharmacy computer systems or computerized physician order entry systems these products may be represented by a similar mnemonic (‘gado’) in a drop-down menu.

In addition, we note that LexiComp indicates that “Vasovist may be confused with Magnevist, Gadovist”. LexiComp also states that “The ISMP includes this medication among its list of drug classes which have a heightened risk of causing significant patient harm when used in error.” LexiComp is a company that produces drug information references, in both print and on-line formats. Their information is collected and validated by an in-house team comprised of advanced-degree pharmacists with clinical and academic experience. Their in-house team also works with external clinical reviewers and editors. Decisions involving incorporation of content are based on levels of evidence and peer-review consensus.

Lastly, although our searches of the AERS database retrieved no medication error reports, we do not believe this finding is indicative of the potential risk of confusion in the U.S. market for

several reasons. First, the medication use system for contrast agents in the U.S. may differ from foreign markets, particularly given the recent JCAHO initiatives. As stated in Section 1.1 (Background), these initiatives encourage a more collaborative approach in the management of contrast agents, including pharmacist review of orders, storage, labeling, and reconciliation. Secondly, post-marketing evidence suggests that medication errors involving imaging agents are under-reported, and thus errors involving these products may not be identified.

9 CONCLUSIONS AND RECOMMENDATIONS

The Division of Medication Error Prevention and Analysis maintains its objection to the use of the proprietary name, Vasovist, for this product because it is vulnerable to name confusion with Magnevist. This confusion could lead to medication errors in the usual practice setting.

We will proceed with the safety review of the labels and labeling under separate cover.

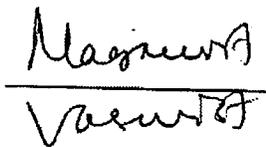
9.1 COMMENTS TO THE DIVISION

We would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy us on any communication to the applicant with regard to this review. If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

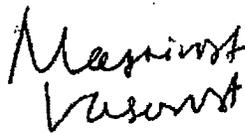
9.2 COMMENTS TO THE APPLICANT

We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable for the following reasons:

The names "Vasovist" and "Magnevist" are convincingly similar to one another. The orthographic similarity of this name pair stems from the similar appearance of the first letters ('Va' vs. 'Ma') when scripted. Additionally, the ending letters overlap and look similar ('ovist' vs. 'evist'). The only letter that may help to differentiate the names is the lower case 'g' in Magnevist; however it can resemble a lower case 's' when scripted (see samples below). Further, the names have a comparable number of letters (8 for Vasovist vs. 9 for Magnevist), which makes them look similar in length.



Handwritten comparison of 'Magnevist' and 'Vasovist'. The word 'Magnevist' is written above 'Vasovist', with a horizontal line between them. The letters 'M' and 'V' are written in a similar, cursive style, and the ending letters 'nevist' and 'sivist' are also written in a similar style, illustrating the orthographic similarity.



Handwritten comparison of 'Magnevist' and 'Vasovist'. The word 'Magnevist' is written above 'Vasovist'. The letters 'M' and 'V' are written in a similar, cursive style, and the ending letters 'nevist' and 'sivist' are also written in a similar style, illustrating the orthographic similarity.

Vasovist and Magnevist share the following overlapping product characteristics: indication of use (MRA vs. MRI), setting of use (radiology clinic), dosage form (solution for injection), route of administration (intravenous bolus), vial sizes (10 mL single use), and storage requirements (controlled room temperature). The products also share numerically similar dosing (0.12 mL/kg vs. 0.2 mL/kg). As described in Section 1 on page 1 of this review, imaging agents are typically ordered, stored, prepared and administered in the radiology clinic without pharmacist intervention, which increases our level of concern given these similarities.

Additionally, these products have similar established names (gadofosveset vs. gadopentetate) and the same distributor (Bayer), and may therefore be stored near each other. Although the carton

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labeling for these products is relatively well differentiated (see Appendix B), this does not eliminate the risk of selection errors. For example, in pharmacy computer systems or computerized physician order entry systems these products may be represented by a similar mnemonic ("gado") in a drop-down menu.

In addition, we note that LexiComp indicates that "Vasovist may be confused with Magnevist, Gadovist". LexiComp also states that "The ISMP includes this medication among its list of drug classes which have a heightened risk of causing significant patient harm when used in error." LexiComp is a company that produces drug information references, in both print and on-line formats. Their information is collected and validated by an in-house team comprised of advanced-degree pharmacists with clinical and academic experience. Their in-house team also works with external clinical reviewers and editors. Decisions involving incorporation of content are based on levels of evidence and peer-review consensus.

Lastly, although our searches of the AERS database retrieved no medication error reports, we do not believe this finding is indicative of the potential risk of confusion in the U.S. market for several reasons. First, the medication use system for contrast agents in the U.S. may differ from foreign markets, particularly given the recent JCAHO initiatives. As stated in Section 1.1 (Background), these initiatives encourage a more collaborative approach in the management of contrast agents, including pharmacist review of orders, storage, labeling, and reconciliation. Secondly, post-marketing evidence suggests that medication errors involving imaging agents are under-reported, and thus errors involving these products may not be identified.

We note that you have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, a new request for a proposed proprietary name review should be submitted. If you have any questions on this letter or the proprietary name review process, please call Janet Anderson, Project Manager, Office of Surveillance and Epidemiology, at (301) 796-0675.

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10 REFERENCES

1. **Cohen H. Medication Management and Contrast Media: Discussion Guide.**
<http://www.ashp.org/DocLibrary/Policy/ContrastMedia/ContrastMediaDiscussionGuide.aspx>
Accessed 11/13/2008
2. **Adverse Events Reporting System (AERS) Database**
AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufactures that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS; is to identify potential postmarketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.
3. **Lexi-Comp (<http://online.lexi.com/crlsql/servlet/crlonline>)**
A web-based searchable version of the Drug Information Handbook.
4. **OSE Review # 04-0026**
Wisniewski L. Proprietary Name Review, Division of Medication Errors and Technical Support, FDA; dated May 28, 2004.
5. **OSE Review # 04-0026-1**
Wisniewski L. Proprietary Name Rebuttal, Division of Medication Errors and Technical Support, FDA; dated October 15, 2004.

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APPENDICES

Appendix A: FMEA Table Comparing Vasovist and Magnevist

Proprietary Name	Established Name	Dosage Form/ How Supplied	Indication(s)	Dosing	Storage	Distributor
Vasovist	gadofosveset trisodium	solution for injection (clear, colorless to pale yellow) containing 244 mg/mL 10 mL and _____ single use vials	For use with magnetic resonance angiography (MRA) to evaluate aortoiliac occlusive disease in adults with known or suspected peripheral vascular disease	0.12 mL/kg body weight via intravenous bolus injection over a period of time up to 30 seconds followed by a 25-30 mL normal saline flush	Controlled room temp.; protect from light and freezing	Bayer
Magnevist	gadopentetate dimeglumine	solution for injection (clear, colorless to slightly yellow) containing 469.01 mg/mL 50 mL and 100 mL pharmacy bulk package 5 mL, 10 mL, 15 mL, 20 mL single-dose vial 10 mL, 15 mL, 20 mL pre-filled disposable syringe	For use with magnetic resonance imaging (MRI) in adults and pediatric patients (2 years of age and older) to visualize lesions with abnormal vascularity in the brain, spine and associated tissues; to facilitate the visualization of lesions with abnormal vascularity in the head and neck; to facilitate the visualization of lesions with abnormal vascularity in the body (excluding the heart)	0.2 mL/kg body weight administered intravenously at a rate not to exceed 10 mL per 15 seconds followed by a 5 mL normal saline flush	Controlled room temp.; protect from light and freezing	Bayer

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 Trade Secret / Confidential (b4)

 ✓ Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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Carol Holquist
12/19/2008 04:26:42 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)**

DATE RECEIVED: August 30, 2004	DESIRED COMPLETION DATE: October 1, 2004 PDUFA DATE: October 15, 2004	ODS CONSULT #: 04-0026-1
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TO: George Q. Mills, M.D.
Director, Division of Medical Imaging and Radiopharmaceutical Drug Products
HFD-160

THROUGH: James Moore, R.Ph.
Project Manager
HFD-160

PRODUCT NAME: Vasovist (Gadofosveset Trisodium Injection) 244 mg/mL NDA#: 21-711	NDA SPONSOR: Epix Medical, Inc.
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SAFETY EVALUATOR: Linda M. Wisniewski, RN

RECOMMENDATIONS:

DMETS does not recommend the use of the proprietary name, Vasovist. Epix Medical has not provided persuasive evidence, at this time, to diminish our concerns with potential confusion between Vasovist and Magnevist. Therefore, as noted in our previous reviews, DMETS does not recommend use of the proprietary Vasovist.

Carol Holquist, RPh
Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664

**Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research**

PROPRIETARY NAME REBUTTAL

DATE OF REVIEW: September 13, 2004
NDA #: 21-711
NAME OF DRUG: Vasovist
(Gadofosveset Trisodium Injection) 244 mg/mL
NDA HOLDER: Epix Medical, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Medical Imaging and Radiopharmaceutical Drug Products (DMIRDP), to reconsider the acceptability of the proprietary name Vasovist, based on the sponsor's submission dated August 20, 2004.

Previously, the sponsor submitted the name Vasovist, which was the subject of ODS Consult 04-0026, dated May 28, 2004. DMETS did not recommend use of this name due to look-alike similarities with the currently marketed product, Magnevist.

This submission includes a request for reconsideration of the DMETS recommendation. The firm submitted a rebuttal for the proprietary name Vasovist and an independent analysis of the proprietary name conducted by b(4)

PRODUCT INFORMATION

Vasovist™ (gadofosveset trisodium) is a formulation of a stable gadolinium diethylenetriaminepentaacetic acid (GdDTPA) chelate substituted with a diphenylcyclohexylphosphate group, for use in magnetic resonance angiography b(4)

in adults with suspected or known vascular disease. Vasovist™ Injection is provided as a sterile, nonpyrogenic, clear, colorless to pale yellow aqueous solution of gadofosveset trisodium. Each mL of Vasovist™ contains 244 mg of gadofosveset trisodium (0.25 mmol), 0.27 mg of fosveset, and water for injection. Following intravenous injection, gadofosveset binds reversibly to endogenous serum albumin resulting in longer vascular retention (plasma half-life) than non-protein bound MRI contrast agents, allowing for imaging up to one hour following injection. Gadofosveset is predominantly cleared via the kidneys. Vasovist™ should be administered as an intravenous bolus injection, manually or by power injection, at a dose of 0.12 mL/kg (0.03 mmol/kg) over a period of time up to 30 seconds followed by a 25-30 mL normal saline flush. It is supplied in 10 mL vials containing 10 mL of solution and 20 mL vials containing either 15 mL of solution. Vials are contained in shipping cartons of 10 vials. Vasovist™ should be stored at 25°C and protected from light and freezing.

II. RISK ASSESSMENT:

The sponsor has requested a re-consideration of the proprietary name Vasovist for Gadofosveset. This rebuttal included a cover letter and four appendices: Vasovist Draft 10 mL Label (Appendix A), Vasovist™ (MS-325) (Appendix B), Name submission for Schering MS-325: Justification for re-submitting VASOVIST (Appendix C), and a Proposed Test (Appendix D). DMETS will evaluate each attachment separately. The sponsor's comments will be italicized.

A. COVER LETTER:

- An important consideration is that VASOVIST and MAGNEVIST, while used by radiologists in an MR suite, are quite different in their indications and packaging. VASOVIST has a proposed indication as an MRA contrast agent for the brain, head and neck, spine and body lesions. Another key distinction between the two products is that VASOVIST is packaged with a white stopper dust cover while MAGNEVIST utilizes a purple stopper dust cover and purple and white label. Please note that EPIX and Berlex will commit to change the packaging for VASOVIST so that it is more readily differentiated from MAGNEVIST.*

b(4)

DMETS response: DMETS evaluates the orthographic and phonetic characteristics of each proposed proprietary name, irrespective of their indications of use. DMETS acknowledges that the packaging and indications of use of each product is different. See Appendix A. However, DMETS is concerned with the orthographic presentation of the name Vasovist and its potential to look similar to the orthographic presentation of the name Magnevist. The differentiation between the packaging and labels of these two products does not prevent one from making an error when interpreting a scripted order.

- The EPIX position is also supported by the conclusion of a name validation study commissioned by Schering and conducted in May/June of 2003 by [redacted]. That study was designed specifically to assess the potential for medication error and subsequent misprescription in regard to the broad range of presently available prescription products, and presented the following conclusions....*

b(4)

DMETS response: Since the appendices address the labels and labeling and the [redacted] study in detail, DMETS will address the conclusions presented from the study separately in this consult.

b(4)

B. Appendix A: VASOVIST DRAFT 10 mL Label

DMETS acknowledges that the VASOVIST Draft 10 mL label is different from the Magnevist label. However, our concern is not with selection errors resulting from similar container labels and carton labeling. DMETS' is concerned with the orthographic similarity between Vasovist and Magnevist. If a practitioner has misinterpreted a Vasovist prescription as Magnevist, the differences in the presentation of the labels and labeling may not prompt them that an error has occurred.

C. **Appendix B: VASOVIST™ (MS-325)**

1. *Although the scope of the MS-325 name validation study was global, for the purpose of this report the specific findings and conclusions will be limited to the candidate name "VASOVIST" and the U.S. market.*

DMETS Response: DMETS is concerned that only European countries (Germany, France, United Kingdom, Italy, and Spain) participated in this fieldwork study. The scope indicates that the study was global and the findings and conclusions will be limited to the candidate name (Vasovist) and the U.S. market. However, the participants are from the European community and not the U.S. market. Differences in healthcare scenarios, dispensing, and administration of drug products in these foreign countries make it difficult to extrapolate these results to the U.S. market.

2. *During a 4-week period in May and June 2003, ——— undertook fieldwork with 121 pharmacists (100 hospital pharmacists and 21 retail pharmacists). (20 respectively in Germany, France, U.K., Italy and Spain, and 8 per remaining E.U. market, 80% hospital-based and 20% retail-based) and in addition 30 physicians 18 radiologists, 6 vascular surgeons and 6 hospital cardiologists) were included in the field work.*

b(4)

DMETS Response: See comment II-C-1 above.

3. *Fieldwork Outcomes: There was not a single misinterpretation of VASOVIST for an existing or generic pharmaceutical product in the verbal order interpretation test undertaken by 59 pharmacists and 30 physicians. There was not a single misinterpretation of VASOVIST for an existing branded or generic pharmaceutical product in the written order interpretation test undertaken by 62 pharmacists.*

DMETS response: Although there were no misinterpretations of Vasovist for another branded product, DMETS is unaware if Magnevist is marketed in any of these countries. Therefore, the potential for confusion could not exist, if practitioners are unaware of the product. Additionally, orthographic differences (e.g., accents, symbols, diacritics¹) that appear in the orthographic presentations of different languages' terms may increase the potential for look-alike similarities between these two products.

4. *DISPENSER (Verbal Assessment) Primary Research Findings:*

Masavist, Masamist, Mazepist, Mazavist, Mazivist, Masovist, Mazevist, Mazovist, Mazomist, Mazapis, Masaist, and Metazoprist

DMETS Response: Despite the location where the study was conducted, DMETS has concern with the results. DMETS is concerned with the orthographic similarity between Vasovist and Magnevist. We acknowledge none of the orthographic interpretations from the study included confusion with Magnevist or any existing branded or generic pharmaceutical product (see II-C-3). We also acknowledge the

¹ A mark, such as the cedilla of *façade* or the acute accent of *résumé*, added to a letter to indicate a special phonetic value or distinguish words that are otherwise graphically identical. Source: <http://dictionary.reference.com/search?q=diacritic>

same results in the verbal studies. However, DMETS notes in the sponsor's verbal studies, nineteen (16%) of the respondents interpreted Vasovist as a name beginning with the letter 'M' (see below).

Spelling Interpretations by Pharmacists of Simulated Verbal Order		
Spelling Variations	Percentage of Respondents	Number of Respondents
Masavist	8%	5
Masamist	3%	2
Mazepist	3%	2
Mazavist*	3%	2
Mazivist*	2%	1
Masovist	2%	1
Mazevist*	2%	1
Mazovist*	2%	1
Mazomist*	2%	1
Mazapist	2%	1
Masapist	2%	1
Metazoprist	2%	1

In particular, the five starred (*) responses (Mazavist, Mazivist, Mazevist, Mazomist, and Mazovist) are of concern to DMETS since they have orthographic similarity to Magnevist. Although these responses were from the verbal assessment section, the results indicate that in this study, participants misinterpreted Vasovist as names similar to Magnevist. In cases where a nurse or pharmacist receive a verbal order for Vasovist and hear one of the responses above, their orthographic documentation (e.g., patient chart, floor stock requisition, etc) of the name would only increase the potential for confusion with Magnevist. These study results indicate there is the potential for verbal confusion between Magnevist and Vasovist in addition to the potential for orthographic confusion.

D. **Appendix C: Name submission for Schering MS-325: Justification for re-submitting Vasovist.**

The objective of this study was to determine the specific dispensing and administration environment of Magnetic Resonance (MR) contrast agents and identify possible issues associated with the co-existence of VASOVIST (to be supplied in vials) within Schering's portfolio of "-vist" products, with specific reference to GADOVIST (supplied in prefilled syringes and vials) and RESOVIST (supplied in prefilled syringes only).

DMETS Response: DMETS has concerns that this study is not applicable to the United States, which may have a different dispensing and administration environment when compared to the countries studied (i.e., Denmark, Austria, Germany and Italy). Additionally, DMETS' concern of potential orthographic similarity with Magnevist was not addressed in this study. Therefore, we have no comment with regard to this study.

E. **Appendix D: Proposed Test**

Objective: To determine the dispensing and administration environment of MR products and identify possible issues associated with the co-existence of Vasovist within Schering's portfolio of the "-vist" family, with specific reference to Magnevist.

Methodology: Telephone/Fax or Online quantitative survey

Geographies: United States

Timeline: 4 weeks

Sample: 120 respondents, as follows:

- 60 radiology radiologists (hospital or private practice) administering Magnevist*
- 30 hospital nurses handling or administering Magnevist*
- 30 MR technicians handling or administering Magnevist*

DMETS response:

DMETS notes that the proposed start date of this study was approximately September 7, 2004 which was one week after DMETS' received the rebuttal. DMETS did not have sufficient time to review this study prior to the start date. Therefore, we do not have any comments on the proposed study format. However, we note that the proposed study involved only 120 respondents. Thus, negative findings from this study may not be predicative as to what may occur once the drug is widely prescribed, as this study may have limitations primarily due to the small sample size. Finally, we note that the proposed final report on this study is expected to arrive at the Agency approximately six weeks (October 19, 2004) after the start date. Since the PDUFA date is October 15, 2004, the results could not be used to support the acceptability of the proposed proprietary name prior to the PDUFA date.

In summary, the data submitted by Epix Medical, Inc. has not provided persuasive evidence to diminish our concerns with potential orthographic confusion between Magnevist and Vasovist. As concluded in our previous review, DMETS does not recommend the use of the proprietary name Vasovist.

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III. RECOMMENDATIONS:

DMETS does not recommend the use of the proprietary name, Vasovist. Epix Medical has not provided persuasive evidence, at this time, to diminish our concerns with potential confusion between Vasovist and Magnevist. Therefore, as noted in our previous reviews, DMETS does not recommend use of the proprietary Vasovist.

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 Sammie Beam, Project Manager, at 301-827-2102.

Linda M. Wisniewski, R.N.
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur: _____
Denise P. Toyer, PharmD.
Deputy Director
Division of Medication Errors and Technical Support
Office of Drug Safety

Appendix A: Comparison of Vasovist and Magnevist

Proprietary Name	Vasovist	Magnevist
Scripted name	<i>Vasovist 5mL</i>	<i>Magnevist</i>
Established Name	Gadofosveset	Gadopentetate Dimeglumine
Approval Date	Pending	6/2/88 & 3/10/00
Sponsor	Berlex	Berlex
Indication	MRA: Magnetic Resonance Angiography	MRI: Magnetic Resonance Imaging
Patient Population	Adults	Adults and pediatric patients.
Dosage Strength	244 mg/mL	469.01 mg/mL
How Supplied	Vials: 10 mL, 20 mL	Vials: 5 mL, 10 mL, 15 mL, 20 mL Prefilled syringes: 10 mL, 15 mL, 20 mL
Usual Dose and Range	0.12 mL per kg over 30 seconds followed by 25 mL to 30 mL normal saline flush.	0.2 mL/kg not to exceed 10 mL per 15 seconds.
Frequency	Once.	Once.
Route	Intravenous.	Intravenous.
Dosage formulation	Injection.	Injection.
Storage conditions	25°C, protect from light and freezing	15-30° C, protect from light and freezing

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/s/

Linda Wisniewski
10/15/04 03:07:54 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
10/15/04 04:10:28 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)**

DATE RECEIVED: January 30, 2004	DESIRED COMPLETION DATE: June 30, 2004 PDUFA DATE: October 15, 2004	ODS CONSULT #: 04-0026
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TO: George Q. Mills
Director, Division of Medical Imaging and Radiopharmaceutical Drug Products
HFD-160

THROUGH: James W. Moore
Project Manager
HFD-160

PRODUCT NAME: Vasovist (Gadofosveset Trisodium Injection) NDA#: 21-711	NDA SPONSOR: Epix Medical, Inc.
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SAFETY EVALUATOR: Linda M. Wisniewski, RN

DMETS RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name, Vasovist.
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 Vasovist acceptable from a promotional perspective.

Carol Holquist, RPh
Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: March 1, 2004
NDA#: 21-711
NAME OF DRUG: Vasovist™ (Gadofosveset Trisodium Injection)
NDA HOLDER: Epix Medical, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Medical Imaging and Radiopharmaceutical Drug Products (HFD-160) for assessment of the proprietary name "Vasovist", regarding potential name confusion with other proprietary or established drug names. Draft container labels, carton and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Vasovist™ (gadofosveset trisodium) is a formulation of a stable gadolinium diethylenetriaminepentaacetic acid (GdDTPA) chelate substituted with a diphenylcyclohexylphosphate group, for use in magnetic resonance angiography

in adults with suspected or known vascular disease. Vasovist™ Injection is provided as a sterile, nonpyrogenic, clear, colorless to pale yellow aqueous solution of gadofosveset trisodium. Each mL of Vasovist™ contains 244 mg of gadofosveset trisodium (0.25 mmol), 0.27 mg of fosveset, and water for injection. Following intravenous injection, gadofosveset binds reversibly to endogenous serum albumin resulting in longer vascular retention (plasma half-life) than non-protein bound MRI contrast agents, allowing for imaging up to one hour following injection. Gadofosveset is predominantly cleared via the kidneys. Vasovist™ should be administered as an intravenous bolus injection, manually or by power injection, at a dose of 0.12 mL/kg (0.03 mmol/kg) over a period of time up to 30 seconds followed by a 25-30 mL normal saline flush. It is supplied in 10 mL vials containing 10 mL of solution and 20 mL vials containing either 15 mL — of solution. Vials are contained in shipping cartons of 10 vials. Vasovist™ should be stored at 25°C and protected from light and freezing.

b(4)

b(4)

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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 databases³ for existing drug names which sound-alike or look-alike to Vasovist 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 conducted⁴. The Saegis⁵ 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 Vasovist. 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 Vasovist acceptable from a promotional perspective.
2. The Expert Panel did not identify any proprietary names that were thought to have the potential for confusion with Vasovist.

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. The phonetic search module returns a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. The POCA identified Nasonex, Osmovist, Viracept and Renovist which were considered to have significant phonetic or orthographic similarities to Vasovist. These products are listed in Table 2 (see page 4), along with the dosage forms available and usual dosage.

¹ MICROMEDEX Integrated Index, 2004, 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], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-04, 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

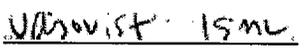
Table 2: Potential Sound-Alike/Look-Alike Names Identified by POCA

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Vasovist	Gadofosveset Injection	0.12 mL per kg over 30 seconds followed by 25 mL to 30 mL normal saline flush.	N/A
Nasonex	Mometasone furoate 50 mcg/actuation	2 sprays (50 mcg/spray) in each nostril once daily (total daily dose, 200 mcg).	LA
Osmovist	Iotrolan 190 (40.6%) Iotrolan 240 (51.3%) Injection	Based on concentration used. Ranges from 8 mL to 15 mL. For intrathecal use only. NDA withdrawn by the commissioner on 10 June 1999.	LA
Viracept	Nelfinavir Mesylate Tablets 250 mg Powder 50 mg/g of powder Orally	750 mg t.i.d. or 1,250 mg b.i.d.	LA
Renovist	Diatrizoate Meglumine; Diatrizoate Sodium 34.3% and 35% Injection	No dosing information available. Appears in the discontinued section of the Orange Book.	LA
Magnevist	Gadopentetate Dimeglumine 469.01 mg/mL	0.2 mL/kg at a rate not to exceed 10 mL per 15 seconds.	LA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

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 Vasovist with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten samples of the drug name. These studies employed a total of 124 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. Two handwritten samples were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Vasovist (See below). These samples were optically scanned and one handwriting sample was delivered to a random sample of the participating health professionals via e-mail. In addition, the 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
<p>Sample #1:</p> 	<p>Vasovist 15 mL</p> <p>#2</p>
<p>Sample #2:</p> 	

Moreover, both products have the same sponsor (Berlex), are packaged similarly (e.g. 10 mL, 15 mL, ^r), and if stored by established name, would be in close proximity to each other on pharmacy shelves. Thus, the orthographic similarities and product characteristics increases the potential for confusion and subsequent error involving these two products.

b(4)

Nasonex
vasovist

2. Nasonex may look similar to Vasovist when scripted. Nasonex is indicated for use in patients that experience seasonal and allergic perennial allergic rhinitis. The first three letters of each name look similar when scripted (nas vs. vas). Additionally, the next three letters 'aso' are the same (see page 6). Despite these similarities, there are product characteristics that will help to distinguish the two products: strength (50 mcg per spray vs. 244 mg/mL), dose (2 sprays in each nostril vs. 0.12 mL/kg), dosage form (nasal spray vs. injection), route of administration (intranasal vs. intravenous), dosing frequency (x1 vs. qd) and indication of use (seasonal or allergic rhinitis vs. contrast agent for MRI). Although a Nasonex "use as directed" order could potentially be misinterpreted as Vasovist, the order would need to be clarified because the volume to be administered is required. Additionally, if a patient is on both drugs, a discontinue Nasonex order could be misinterpreted as Vasovist or vice versa. If an order for Nasonex was interpreted as Vasovist, further investigation regarding rescheduling or revising the MRI will be needed. Moreover, if an order for Vasovist were interpreted as Nasonex, the concurrent orders for rescheduling or canceling the MRI would prompt reassessment of the interpretation of the original order. Despite the orthographic similarities, the product characteristics will help to minimize confusion with these two products.

nasonex
vasovist

3. Viracept may look similar to Vasovist. Viracept is indicated for treatment of HIV infection when anti-retroviral therapy is warranted. The first four letters of each name appear similar when scripted (e.g. vira and vaso) (see below). Additionally, the latter half of the name may also look similar when scripted if the downstroke of the 'p' is not prominent. Despite these orthographic similarities, there are product characteristics that will help differentiate the two products, such as: strength (250 mg or 50 mg vs. 244 mg/mL), dose (750 mg to 1,250 mg vs. 0.12 mL/kg), dosage form (tablet or oral powder for reconstitution vs. injection), route of administration (orally vs. intravenously), dosage frequency (b.i.d. or t.i.d. vs. one time), location of use (home, hospital or HIV clinic vs. radiology department), and indication of use (HIV infection vs. contrast for MRI enhancement). These differences will help to distinguish the two products and minimize potential errors.

viracept
vasovist

4. Increase the prominence of the net volume on the principal display panel.

C.

D. CONTAINER (20 mL)

See General Comments A1 through A3 and comments B2 and B3.

E. CARTON LABELING (20 mL)

See General Comments A1 through A3 and comments B3, and C2.

F. INSERT LABELING

1. See General Comment A3.

2. DOSAGE AND ADMINISTRATION SECTION, Table 11:

The dosing of Vasovist appears to be dosed primarily on mL/kg. However, the second set of dosing units '0.03 mmol/kg' in the header may be confusing and increases the potential for medication errors. DMETS recommends deleting "0.03 mmol/kg" from the header of Table 11, Dosage Chart for VASOVIST Injection.

IV. RECOMMENDATIONS:

- A. DMETS does not recommend the use of the proprietary name Vasovist.
- B. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review that might lead to safer use of the product. We would be willing to revisit these issues if the Division receives another draft of the labeling from the manufacturer.
- C. DDMAC finds the proprietary name Vasovist 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 Sammie Beam, project manager, at 301-827-3242.

Linda M. Wisniewski, RN
Safety Evaluator
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Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

Appendix A:

NDA: 21-711

Vasovist

Inpatient	Outpatient	Verbal
Vasonist	Magnavist	Adevist
Vasovist	Not interpretable would need to recontact physician	Asovist
Vasovist	Vagavist	Atavist
Vasovist	Vagavist	Azavid
Vasovist	Vagavist	Azovisc
Vasovist	Vagavist	Azovisc
Vasovist	Vagavist	Dasovisc or Vasovisc
Vasovist	Vagavist	Vasobid
Vasovist	Vagovist	Vasovasc
Vasovist	Vagovist	Vasovib
Vasovist	Vagovist	Vasovif
Vasovist	Vasavist	Vasovis
Vasovist	Vasavist	Vasovis
Vasovist	Vasavist	Vasovisc
Vasovist	Vasovist	Vasovisc
Vasovist	Vasovist	Vasovisk
Vasovist	Vasovist	VasoVist
Vasovist	Vasovist	Vasovist
Vasovist	Vorgovist	Vasovist
Vasovist	Vorgovist	Vasovist
Vasovist	Vorzavist	Vasovist
Vasovist		Vogavist
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Linda Wisniewski
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