

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-083

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; White Oak 22, Mail Stop 4447)**

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TO: Russell Katz, MD
Director, Division of Neurology Products
HFD-120

THROUGH: Denise Toyer, Pharm.D., Deputy Division Director
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Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME:

Primary Name: Exelon® Patch
(Rivastigmine) Transdermal System
Patch 5 (4.6 mg/24 hours); Patch 10 (9.5 mg/24 hours)

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NDA#: 22-083

SPONSOR: Novartis

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, **Exelon Patch**. This is considered a final decision. However, if the Sponsor intends to use a numeral to modify the proposed proprietary name (e.g. "Exelon Patch 5", "Exelon Patch 10", _____), the Sponsor should resubmit the proprietary name for evaluation since the scope of this review did not encompass the inclusion of a numerical modifier. DMETS would request that the Sponsor provide reasoning to explain the inclusion of a numeral in the proprietary name, and the Sponsor should be made aware that re-evaluation of the proprietary name with inclusion of numeral modifiers could render the name objectionable. Lastly, 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 that the Sponsor express the strength of the patch in terms of drug released per 24 hours, as is the convention with other commercial transdermal patches marketed in the United States. DMETS believes that the Sponsor's proposed use of patch size (particularly without inclusion of unit of measurement) to express strength is likely to be confusing and may represent a potential source of error. DMETS considered two presentations of strength: the Sponsors proposed designation of strength based on patch size (5, 10 _____) and DMETS recommended presentation as dose release rate (4.6 mg/24 hours, 9.5mg/24 hours. _____) to identify any potential safety concerns with either presentation. Thus, the Sponsor is able to modify the designation of the strength without having to re-submit the proprietary name for evaluation.
3. DMETS requests that the Sponsor consider reformulating the transdermal Exelon Patch so that the product strengths (whether expressed in mg/24 hours as DMETS recommends or cm² as proposed by the Sponsor) do not overlap numerically with the oral dosage form of Exelon. DMETS concern is that oral and transdermal numerical overlap with the oral Exelon capsules will increase the potential for medication errors involving confusion between these oral and transdermal Exelon products. Although, DMETS request represents the ideal approach to minimizing this source of potential confusion, DMETS acknowledges that the reformulation of the product to adjust the dosage delivered may not be feasible. In the event that the Sponsor is willing to reformulate the patch to modify the proposed product strength, DMETS can provide the Sponsor, if requested, with information obtained from the Proprietary Name Risk Assessment that may be useful in guiding the process. DMETS reminds the Division and the Sponsor that if the strength should change as a result of product reformulation prior to approval, this would require re-evaluation of the proprietary name, Exelon Patch, and could render the name objectionable.
3. DMETS identified several areas of risk that could lead to medication errors with the proposed Exelon Patch product, and recommends that the Sponsor educate patients and practitioners on the following aspects: the between patch size, drug release rate, and the absorption of the drug from the patch; the existence of the transdermal formulation as it relates to dosage differences between the oral and transdermal formulations; and the potential risk of inadvertent use of the oral and transdermal formulation concurrently. (See Section II, Part D for rationale).
4. DMETS recommends the implementation of the label and labeling revisions outlined in Section III of this review to minimize potential errors with the use of this product.
5. DDMAC finds the proprietary Exelon Patch 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 301-796-0080

**Division of Medication Errors and Technical Support
Office of Surveillance and Epidemiology
(DMETS; White Oak 22, Mail Stop 4447)
Center for Drug Evaluation and Research**

PROPRIETARY NAME, LABEL AND LABELING REVIEW

DATE OF REVIEW: December 8, 2006

NDA NUMBER: 22-083

NAME OF DRUG: **Exelon® Patch**
[Rivastigmine] Transdermal System
5 (4.6 mg/24 hours)
10 (9.5 mg/24 hours)

b(4)

NDA HOLDER: Novartis

*****NOTE:** This review contains proprietary and confidential information that should not be released to the public.***

I. INTRODUCTION:

This consult was written in response to a request from the Division of Neurology Products (HFD-150), for assessment of the proprietary name, Exelon® Patch, regarding potential name confusion with other proprietary or established drug names. The proprietary name, Exelon, is currently used to market solid and liquid formulations of Rivastigmine.

The container label and package insert labeling were provided for review and comment.

PRODUCT INFORMATION

Exelon® Patch is a system that delivers Rivastigmine, a cholinesterase inhibitor, transdermally. Other Exelon products are marketed in the use as capsules (1.5 mg, 3 mg, 4.5 mg, and 6 mg) and oral solutions (2 mg/mL).

Exelon Patch is indicated for the treatment of mild to moderate dementia of **Alzheimers' disease or Parkinson's disease**. According to the prescribing information provided, Exelon Patch should be applied "once daily to clean, dry, hairless intact health skin on the lower back, upper arm, or chest in a place that will not be rubbed by tight clothing." After application, the Exelon Patch is intended to be worn for 24 hours, and replaced with a new patch after 24 hours. The new patch should be applied to a new spot each day to avoid irritation, although consecutive patches can be applied to the same anatomical site (e.g., another spot on the upper arm). According to the prescribing information, Exelon Patch can be used in "everyday situations," including "bathing and during hot weather".

The Sponsor proposes to market Exelon Patch as the following strengths: Exelon® Patch 5 (delivers 4.6 mg of Rivastigmine per 24 hours) ; Exelon® Patch 10 (delivers 9.5 mg of Rivastigmine per 24 hours);

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The numeral portion modifying the proposed name correlates to the size of the patch in cm²; not the dosage delivered (see Table 1 below).

Table 1. Proposed dosages and sizes for Exelon Patch

Proposed strengths	Patch size	Dosage of Rivastigmine Delivered
Exelon Patch 5	5 cm ²	4.6 mg per 24 hours
Exelon Patch 10	10 cm ²	9.5 mg per 24 hours

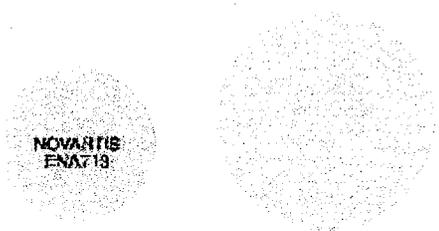
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Patients are instructed to apply one patch to skin on the lower back, upper arm, or chest every 24 hours. The transdermal absorption of Rivastigmine from Exelon Patch is slow, and maximum plasma concentrations are often not reached for 10-16 hours. Treatment should be initiated with Exelon Patch 5, and after a minimum of four weeks, the dose should be increased to Exelon Patch 10, which is the recommended maintenance dose.

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The Exelon Patch is composed of four layers containing a backing layer, drug matrix, adhesive matrix and overlapping release liner. The patches are circular in shape, tan-colored, and vary in size (see image below).

Figure 1. Exelon Patch 5, 10. from left to right.



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NOTE: Markings on Patch represent Sponsor's internal tracking codes for samples, and are not representative of the commercial product markings.

Appears This Way
On Original

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of the internet, 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 Exelon Patch 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 conducted⁵. The Saegis⁶ 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. Following completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a drug must be considered in the overall safety evaluator risk assessment.

*****NOTE: This review contains proprietary and confidential information that should not be released to the public.*****

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary names Exelon. Potential concerns regarding drug marketing and promotion related to the proposed names 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 names Exelon® acceptable from a promotional perspective.
2. The Expert Panel identified 22 proprietary names that were thought to have the potential for confusion with Exelon. Because the proprietary name Exelon® is in use for the capsule formulation of Rivastigmine Tartrate, the Expert Panel recommended reviewing post-marketing safety reports submitted to the Agency. The Expert Panel expressed overall safety concerns with the expression of strength of the proposed product, in

¹ MICROMEDEX Integrated Index, 2007, 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 98-07, and the electronic online version of the FDA Orange Book.

⁴ Phonetic and Orthographic Computer Analysis (POCA)

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

particular the discrepancy between the deliverable strength (4.6 mg/24 hours, 9.5 mg/24 hours, _____) and the proposed strength designations (5, 10, _____). The Panel also noted that postmarketing experience with other transdermal patch delivery systems has indicated that the color of the patch, inclusion of the drug name on the patch, dosing interval, and heat exposure as sources of medication error with these products.

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B. 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 Exelon 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 Exelon study employed a total of 123 healthcare professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process.

An inpatient order and outpatient prescription were written, each consisting of a combination of marketed and unapproved drug products and prescriptions for Exelon (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.

Figure 1. Exelon Study

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p><u>Outpatient RX:</u></p> <p><i>Exelon 5mg #1 box Apply 1 patch topically daily</i></p>	<p>Exelon 5 mg Apply 1 patch topically daily. Dispense 1 box</p>
<p><u>Inpatient RX:</u></p> <p><i>6. Exelon 5mg App 1 patch QD</i></p>	

2. Results for Exelon Patch:

In the Exelon Patch study, none of the 35 interpretations of the proposed name overlap with any currently marketed U.S. other than the currently marketed Exelon. DMETS notes that the prescription studies incorrectly presented the strengths with units of “mg” instead of “cm²”, but that this error did not appear to impact the interpretation of the name. Appendix A contains a complete listing of interpretations from the verbal and written studies.

C. ADVERSE EVENT REPORTING SYSTEM (AERS)

Exelon Patch is an addition to the Exelon product line. The immediate-release capsule and the solution formulation of Exelon were approved on April 21, 2000. Therefore, the FDA Adverse Event Reporting System (AERS) was searched for all post-marketing safety reports concerning medication errors associated with Exelon. The MEDDRA High Level Group Term (HLGT) “Medication Errors” and the product name “Exelon” and established names “Rivastigmine Tartrate” and “Rivastigmine” were used as search criteria. A total of 49 reports involving Exelon medication errors were retrieved and reviewed to identify issues related to the naming or labeling of the product. The AERS search revealed only one medication error report concerning name confusion between Exelon and another product, Effexor XR. Several reports related concerns regarding the use of terminal zeros in the numeral portion of the strengths (i.e. 3.0 mg), but none of these reports indicated an actual error as a result of this error-prone expression (n=5; ISR# 389536-6, ISR # 3829199-2, ISR#3815575-0, ISR#3780110-2, ISR# 3762575-5). However, the proposed Exelon Patch labeling will be reviewed to ensure terminal zeros are not present.

D. SAFETY EVALUATOR RISK ASSESSMENT

The primary safety concerns from a medication errors perspective identified in the review of the proposed Exelon Patch product concern the Sponsor’s proposal to express the strength as a function of patch size instead of the conventional dosage delivered; the risk of medication errors resulting from the extension of the Exelon product line; and the potential for name confusion with the proposed proprietary name, Exelon Patch.

1. Exelon Patch Strength Designation

DMETS is concerned that the Sponsor proposes to express the strength of the Exelon Patch in terms of patch size (cm²), rather than the conventional expression of strength as amount of drug released over a period of time. Nearly all of the commercially available transdermal delivery systems express the strength as a function of dosage delivered; and DMETS is not aware of *any* transdermal delivery system that uses the physical size of the patch to designate strength. DMETS believes this could be a cause of confusion in practice for the following reasons:

- The Sponsor does not designate a unit of measure to indicate that the numeral corresponds to patch size. In doing so, the Sponsor has introduced ambiguity, and the practitioner could misinterpret the numeral as a representation of the amount of drug released (in milligram), total drug content of the patch, the number of patches in a carton, or apply an American measurement to the size of the patch (e.g., square inches). Adding to the risk of misinterpretation is the fact that the strength appears to

approximate the total drug released by the patch (i.e. Exelon Patch 5 releases 4.6 mg per 24 hours), which could mistakenly lead practitioners to believe that the Sponsor has simply 'rounded up' to then nearest increment of '5'. Ambiguous expressions are, by definition, error-prone, and should be avoided when possible.

- The patch size does not appear to have a linear relationship to the release of drug from the patch, thereby complicating practitioner understanding of the patch size and dose-delivered relationship. Exelon Patch 5 delivers 0.92 mg per 1 cm² of the patch, Exelon Patch 10 delivers 0.95 mg per 1 cm² of the patch.

Further complicating this relationship between patch size and dosage delivered the absorption of the drug increases over-proportionally with rising patch doses. Collectively, DMETS believes that prescribers will have difficulty understanding and remembering the complex relationship between patch size, dosage delivered, and drug absorption, and as such, the designation of strength on the basis of patch size is likely to represent a source of prescribing error in practice.

- In the future, applicants of generic versions of this product will be required to show bio-equivalency. Currently, applicants of generic transdermal system products are not required to make the patch the same size as the reference listed drug. Applicants are required, however, to demonstrate that the drug release rate from the patch is the same as the reference listed drug. Since generic versions of this product will have the same release rates but not necessarily the same patch size, it is conceivable that future generic versions could have different strengths depending on how the product is formulated and how the Sponsor chooses to designate the strength

DMETS believes that the use of patch size (particularly without inclusion of unit of measurement) is likely to be confusing and may represent a potential source of error. DMETS recommends that the Sponsor express the strength of the patch in terms of drug released per 24 hours, as is the convention with other commercial transdermal patches marketed in the U.S. This will also help to minimize confusion in the future when generic products become available. DMETS also recommends that the Sponsor educate practitioners about the relationship between patch size, drug release rate, and the absorption of the drug from the patch to minimize the potential for medication errors.

2. Extension of the Existing Product Line

Post-marketing experience has shown that the introduction of product line extensions result in medication errors especially when there is a knowledge deficit with respect to the introduction of the new formulation. In this case we can anticipate error between Exelon capsules and Exelon Patch due to omission or oversight of the "Patch" modifier, prescribing errors due to dosage differences between the oral and transdermal delivery system, and the concomitant use of the oral and transdermal delivery systems.

a) Modifier omission or oversight

It is common for modifiers to be omitted⁷. In this case, if the dosage form modifier is not specified (i.e. "Patch") there is potential that the capsule formulation could be

⁷ Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

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dispensed, particularly with the 5 cm² size of the proposed Exelon Patch _____
_____. Exelon capsules are marketed in a variety of strengths, including 4.5 mg and 1.5 mg. If the Sponsor expresses the strength of the 5 cm² size of the Exelon Patch as 4.6 mg/24 hours, DMETS believes that "4.6 mg" is likely to be confused with 4.5 mg in practice, which could increase the potential for confusion with the oral and transdermal dosage forms. On the other hand, if the strength of the Exelon Patch product line continues to be expressed on the basis of patch size against DMETS's recommendation, a practitioner could misinterpret the _____ designation to represent the _____ capsule, and thereby increase the potential for confusion between the oral and transdermal dosage forms. DMETS also has concern that prescriptions or medication orders for oral Exelon _____ could be misinterpreted as Exelon Patch _____ if the decimal point is overlooked, resulting in overdose if the Exelon Patch _____ is applied in error to the patient. b(4)

Exelon Patch and Exelon capsules have several different product characteristics including the dosing interval (twice daily versus once every 24 hours) and route of administration (oral versus topical application), but these characteristics may not be sufficient to avoid product confusion. The ideal approach to minimizing confusion between the oral and transdermal Exelon products would be to request that the Sponsor reformulate the transdermal patch so that the product strengths (whether expressed in mg/24 hours as DMETS recommends or cm² as proposed by the Sponsor) do not overlap numerically with the oral dosage form of Exelon.

However, DMETS acknowledges that the reformulation of the product to adjust the dosage delivered may not be feasible. As such, DMETS believes that it is imperative that healthcare practitioners are educated about the existence of the patch formulation. Even with this education, we will likely see errors.

In the event that the Sponsor is willing to reformulate the patch to modify the proposed product strength, DMETS can provide the Sponsor, if requested, with information obtained from the Proprietary Name Risk Assessment that may be useful in guiding the process. DMETS reminds the Division and the Sponsor that if the strength should change as a result of product reformulation prior to approval, this would require re-evaluation of the proprietary name, Exelon Patch, and could render the name objectionable.

b) Dosage differences between the formulations

The dosage differences between the oral and transdermal formulations may also represent a potential source of error. Specifically, the differences may increase the risk for Exelon Patch to be prescribed at incorrect doses and frequency, and the product may be susceptible to errors when converting from the oral capsules to patch formulation. Exelon Patch has different dosing recommendations with respect to frequency and target dosage than the oral formulation of the product. In addition, the dosage conversion from the oral formulation to the transdermal formulation is not 1:1, that is a person taking a total daily dosage of Exelon 6 mg orally, would not receive a 6 mg Exelon Patch. DMETS has recommended modifications to the proposed labeling of Exelon Patch to help minimize some of these risks (see Section III), and recommends that education efforts by the Sponsor also emphasize these differences.

c) Concomitant use of oral and transdermal Exelon products

DMETS is also concerned that the introduction of the patch formulation could lead to inadvertent use of the oral and transdermal formulation concurrently. In a hospital setting, research has shown the prescribing the same or similar medication to be given concurrently by two routes of administration to be a common source of medication error.⁸ The same study indicated the prescribing of the same or similar medication to be given concurrently via the transdermal and oral route of administration as the second most common type of prescribing error (the most common type was concurrent prescribing of same/similar medication by IV and oral routes).

To some extent, DMETS believes that this risk is reduced by using the same proprietary name to identify the product line. This allows patients and practitioners to more readily identify the commonality of the medications, even when given by different routes. However, the Sponsor should attempt to make patients, caregivers, and practitioners aware of this risk in their educational efforts. Additionally, DMETS has recommended modifications in (Section III) to further minimize the risk of concomitant use of the Exelon products.

3. Exelon Patch Name Evaluation

*****NOTE: This review contains proprietary and confidential information that should not be released to the public.*****

A total of twenty-two names were identified as having the potential to look and sound-alike similar to Exelon. These names are _____, Enlon, Insulin, Execof, Tessalon, Exidine, Exefen, Oxylone, _____ Oxilan, _____, Exelon, Emsam, Esclim, Evoclin, Exsel, Elocon, Exelderm, and Effexor XR.

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DMETS conducted prescription studies to simulate the prescription ordering process for Exelon. In this case, there was no confirmation that the proposed name could be confused with the aforementioned names, with the exception of Exelon. Respondents did not indicate the formulation of the product in their responses, only their interpretation of the proprietary name component (e.g. "Exelon"). Negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Exelon.

Fourteen of the aforementioned 23 names will not be reviewed further including:

_____, Enlon, Insulin, Execof, Tessalon, Exidine, Exefen, Oxylone _____ Oxilan, and _____ Six of these 14 names

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_____ correspond to products that are not in use in the US marketplace. For the remaining nine names that will not be reviewed further (but are available in the US market), there have been no reported cases in AERS of confusion between the proprietary names and Exelon capsules. Additionally, these products have numerous differentiating product characteristics

⁸ Lesar TS. Medication Prescribing Errors Involving Route of Administration. Hosp Pharmacy. 2006; 41(11): 1053-1066.

compared to Exelon Patch, which DMETS believes should minimize the potential for medication error.

In total, eight proprietary names identified, warrant further analysis including: Exelon (capsule dosage form), Emsam, Elocon, Exsel, Exelderm, Evoclin, Effexor XR and Esclim. In order to determine if name confusion exists with the currently marketed formulations of Exelon and the proprietary names identified; an AERS search was also conducted using the proprietary name “Exelon” and each of the seven proprietary names (Emsam, Esclim, Evoclin, Exsel, Elocon, Effexor XR and Exelderm) as interaction terms and “medication errors”. One case of name confusion was identified between Effexor XR and Exelon (See Appendix B for the full narrative of this case). No other reports of name confusion or medication errors were returned from these targeted searches for the remaining six names.

The eight products are listed are listed in Table 1 (see below), along with the dosage forms available and usual dosage, and are discussed in detail below.

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

Product Name	Established name, Dosage form(s), strengths	Usual adult dose*	Other**
Exelon® Patch	Rivastigmine Transdermal System: 5 (4.6 mg/24 hours); 10 (9.5 mg/24 hours), 	Initial: Apply Exelon Patch 5 to skin on the lower back, upper arm, or chest every 24 hours. Maintenance: After a minimum of four weeks on Exelon Patch 5, and if well tolerated, the dose should be increased to Exelon Patch 10 applied every 24 hours.	
Exelon	Rivastigmine Tartrate Capsules: 1.5 mg, 3 mg, 4.5 mg, and 6 mg Oral Solution: 2 mg/mL	Take 3 to 6 mg twice daily.	LA/SA
Emsam	Selegiline Transdermal System: 6 mg/24 hours; 9 mg/24 hours; 12 mg/24 hours.	Initial doses is 6 mg/24 hours applied once daily; may titrate based on clinical response in increments of 3 mg/day every 2 weeks up to a maximum of 12 mg/24 hours	LA
Effexor XR	Venlafaxine Extended-Release Capsule: 37.5 mg, 75 mg, 150 mg	75 mg once daily taken with food; for some new patients, it may be desirable to start at 37.5 mg/day for 4-7 days before increasing to 75 mg once daily; dose may be increased by up to 75 mg/day increments every 4 days as tolerated, up to a recommended maximum of 225 mg/day.	LA
Esclim	Estradiol Transdermal System: 0.025 mg/24 hours; 0.0375 mg/24 hours; 0.05 mg/24 hours; 0.075 mg/24 hours; 0.1 mg/24 hours	Apply topically twice weekly.	LA
Evoclin	Clindamycin phosphate Topical Foam 1%	Apply topically to affected area once daily	LA
Exsel	Selenium Sulfide Topical Shampoo/Lotion 2.5%	Apply topically to scalp or affected area. Rinse thoroughly.	LA/SA
Elocon	Mometason Furoate Cream/Ointment: 0.1% (15 g, 45 g) Lotion 0.1% (30 mL, 60 mL)	Cream, ointment: Children ≥2 years and Adults: Apply a thin film to affected area once daily; do not use in pediatric patients for longer than 3 weeks Lotion: Children ≥12 years and Adults: Apply a few drops to affected area once daily	LA
Exelderm	Sulconazole Nitrate Cream, as nitrate: 1% (15 g, 30 g, 60 g) Solution 1% (30): \$31.32	Adults: Topical: Apply a small amount to the affected area and gently massage once or twice daily for 3 weeks (tinea cruris, tinea corporis, tinea versicolor) to 4 weeks (tinea pedis).	LA

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Product Name	Established name, Dosage form(s), strengths	Usual adult dose*	Other**
Exelon® Patch	Rivastigmine Transdermal System: 5 (4.6 mg/24 hours); 10 (9.5 mg/24 hours), <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto;"> 7 </div>	Initial: Apply Exelon Patch 5 to skin on the lower back, upper arm, or chest every 24 hours. Maintenance: After a minimum of four weeks on Exelon Patch 5, and if well tolerated, the dose should be increased to Exelon Patch 10 applied every 24 hours.	
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

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DMETS has the following comments on the eight names listed in Table 1:

Because modifiers are known to be omitted or overlooked when prescribing, transcribing, and interpreting prescription and medication orders, DMETS evaluated the presentation of the proprietary name with and without the “Patch” modifier concurrently. In addition, DMETS considered two presentations of strength: the sponsors proposed designation of strength based on patch size (5, 10, _____ and DMETS recommended presentation as dose release rate (4.6 mg/24 hours, 9.5mg/24 hours, _____). The intent of this undertaking was to generate a robust proprietary name risk assessment that would enable DMETS to identify any potential safety concerns with either presentation, and thus enable the Sponsor to modify the designation of the strength without having to re-submit the proprietary name for evaluation.

Although DMETS believes that the Proprietary Name Risk Assessment was robust, the scope of the assessment did have limits. Most notably, the risk assessment did not evaluate the proprietary name as “Exelon Patch 5,” “Exelon Patch 10,” _____ since it was our understanding that the numeral portion corresponded to strength (in cm²) and was not intended as a modifier of the proposed proprietary name. DMETS noted, with concern, that in many instances within the labeling the Sponsor references the proprietary name with the numeral (e.g. “Exelon Patch 5”) as if the numeral were in fact a designated portion of the proprietary name. If the Sponsor does intend to use a numeral to modify the proposed proprietary name, this would undermine the entire premise of the Proprietary Name Risk Assessment, and the Sponsor would have to re-submit the proprietary name for evaluation. DMETS would request that the Sponsor provide reasoning to explain the inclusion of a numeral in the proprietary name, and the Sponsor should be made aware that re-evaluation of the proprietary name with inclusion of numeral modifiers could render the name objectionable.

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- a) Emsam and Exelon Patch may look similar to one another when scripted. Emsam and Exelon Patch both begin with the letter ‘E’ and are approximately the same length. Exelon does have an upstroke introduced by the letter ‘l’ which may help to differentiate the names, but in some handwriting samples this difference may be minimized by a short upstroke. In addition, Emsam and Exelon Patch are both formulated as patches, and if the dosage form is included with the name, this overlap is likely to increase the orthographic similarity of the names.

Both products are also applied topically once daily. Additionally, Emsam and Exelon Patch could have some numerical overlap in strength (9 mg versus 9.5 mg respectively), and this overlap is likely to increase the potential for confusion between these two strengths.



 Exelon Patch 9.5mg
 Emsam Patch 9mg

A search of AERS was unable to identify any medication errors resulting from Emsam and Exelon name confusion, which may indicate that the names are sufficiently differentiated. However, DMETS remains concerned that the orthographic similarity of the names may be a potential source of medication error, particularly since the Exelon Patch will introduce overlap in the product characteristics of Emsam that does not presently exist with Exelon Capsules.

Normally, this finding would be sufficient cause for DMETS to object to the use of the proposed proprietary name. However, in this instance, DMETS believes that the risk of potential name confusion between Ensam and Exelon Patch is less imminent than the errors that could result from the inadvertent duplicate therapy of the transdermal and oral dosage forms (see page 9). Furthermore, there have been no reports of Emsam and Exelon name confusion reported to the Agency, while the risk of concomitant therapy of medication administered by different routes is well documented in the literature.⁹ Based on these findings, DMETS concludes that the proposed name, Exelon Patch, may help to minimize the risk for medication errors, although we remain concerned about the potential for confusion with Emsam. As such, DMETS does not object to the use of the proprietary name, Exelon Patch, at this time.

- b) Effexor XR has been confused with Exelon capsules, and the confusion resulted in a dispensing error (See Appendix B). The reporter noted that the similarity of the names as a factor contributing to this error. Further detail regarding the underlying similarity of the names was not provided.

Effexor XR and Exelon both begin with the letter 'E' and contain the letter 'x'. Effexor XR is considerably longer than Exelon (9 versus 6 letters), and has two upstrokes in the beginning of the name that Exelon lacks (see below).

Exelon Exelon 1.5mg
Effexor XR Effexor XR 37.5mg

Overall, DMETS is not convinced that names Exelon and Effexor XR have strong orthographic or phonetic similarity. However, both products are available in strengths that have '.5' mg increments (i.e. Exelon capsules come as 1.5 mg and 4.5 mg, and Effexor XR has a 37.5 mg strength). In the error report, the prescription was written for "Effexor XR 37.5 mg," but was filled with Exelon 1.5 mg capsules. When presented in conjunction with the name, the similarity of the strengths and common letters of the names may have led to confusion.

Unlike the capsule formulation of Exelon, Exelon Patch and Effexor XR will overlap in frequency of administration with once daily dosing. The proposed strengths of Exelon Patch are different than Effexor XR (see Table 1), although overlap with the _____ capsules of Effexor XR could be introduced if practitioners express the strength of _____ with a terminal zero (i.e. _____ and the period is overlooked. However, the use of terminal zeros when prescribing and ordering drugs is discouraged by safety organizations (ISMP) and regulatory authorities (FDA, JCAHO), which may lessen the frequency of _____ being written with a terminal zero. Additionally, Exelon Patch and Effexor XR have several different product characteristics including dosage form (patch versus capsule), route of administration (oral including strengths (5, 10. _____ versus 37.5 mg, 75 mg, 150 mg). Overall, DMETS believes

b(4)

⁹ Lesar TS. Medication Prescribing Errors Involving Route of Administration. Hosp Pharmacy. 2006; 41(11): 1053-1066.

that the product difference will help to minimize the risk of medication errors that is introduced by similarity of the names.

- c) Esclim may look similar to Exelon when written. Esclim is a transdermal estradiol patch used in the treatment of moderate-to-severe vasomotor symptoms associated with menopause. Esclim patches are applied topically twice weekly. Esclim appears in the discontinued section of FDA's Orange Book.¹⁰ However, several other manufacturers produce estradiol patches that could be used in place of the Esclim patch. References commonly used by practitioners (e.g. Micromedex, Lexi-Comp Online) cross-reference this discontinued product to other biweekly estradiol patches (e.g. Vivelle®, Vivelle-Dot®, Alora®, Estraderm®) currently marketed in the US. This could perpetuate an error if Exelon was misinterpreted as Esclim, and a practitioner referred to one of these sources to find a similar product that could be used in place of Esclim.

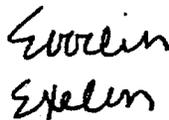
Look-alike similarities between Esclim and Exelon may be attributed primarily to the shared letters "E" and "I" and the identical length of the names. The upstroke of the letter "I" is similarly placed in both names, and the remaining lower case letters have orthographic similarity to one another when handwritten (see writing sample).

Handwritten samples of the names 'Esclim' and 'Exelon'. The 'Esclim' sample shows a cursive 'E' with a vertical upstroke that is similar in placement to the 'I' in 'Exelon' below it. The 'Exelon' sample shows a cursive 'E' and 'I' that are orthographically similar to the 'E' and 'I' in 'Esclim'.

In addition, Esclim and Exelon are both formulated as patches, which could increase the orthographic similarity of the products. However, they do not appear to share any other notable product characteristics, including strength (see table 1), frequency (twice weekly versus once daily), and indication for use. A search of AERS was unable to identify any medication errors resulting from Esclim and Exelon name confusion. Overall, DMETS believes that the discontinued status of Esclim along with the product differences will minimize the potential for error.

- d) Evoclin may look similar to Exelon when written. Evoclin is a topical antibiotic used to treat acne.

Look-alike similarities between Evoclin and Exelon may be attributed primarily to the shared letters in similar ordering (highlighted below) and similar length of the names (6 versus 7 letters). Evoclin and Exelon also owe a portion of the orthographic similarity to the similar appearance of the letters 'v' and 'x', and 'i' and 'o' when handwritten (see writing sample)

Handwritten samples of the names 'Evoclin' and 'Exelon'. The 'Evoclin' sample shows a cursive 'E' and 'V' that are orthographically similar to the 'E' and 'X' in 'Exelon' below it. The 'Exelon' sample shows a cursive 'E' and 'X' that are orthographically similar to the 'E' and 'V' in 'Evoclin'.

Like Exelon Patch, Evoclin is administered topically once daily. However, Exelon Patch will be available in several strengths, while Evoclin is formulated as a single strength (1%) that does not overlap with the proposed strengths of Exelon Patch. In the context of a medication order or prescription for Exelon Patch, prescribers will designate the strength in order for the medication to be dispensed or administered. Because Evoclin is available in a single strength (1%) that does not overlap with Exelon, DMETS believes that the inclusion of the Exelon Patch strength will help to avoid name confusion. In addition, Evoclin and Exelon have other dissimilar product

¹⁰ Web Reference: Electronic online version of the FDA Orange Book: <http://www.fda.gov/cder/ob/>

characteristics including dosage form (foam versus patch) and indications for use (acne versus mild to moderate dementia). A search of AERS was unable to identify any medication errors resulting from Evoclin and Exelon name confusion. Overall, DMETS believes that product differences minimize the potential for error.

- e) Exsel may look similar to Exelon when written and sound similar when spoken. Exsel is a topical product used to treat an itchy and flakey scalp associated with dandruff, to control scalp seborrheic dermatitis; and treatment of tinea versicolor. Exsel is formulated as a 2.5% topical lotion/shampoo.

Look-alike and sound-alike similarities between Exsel and Exelon may be attributed primarily to the shared letters 'Ex-' 'l'. When scripted, Exelon may look similar to Exsel, particularly if the "Patch" dosage form designation is not presented adjacent to the name (see writing sample below).



When spoken, Exelon has one more syllable than Exsel, which may help to differentiate the names. However, in the context of a verbal prescription or medication order for Exsel, the name may sound nearly identical to Exelon if the prescriber specifies the directions beginning with the word "on". For example, a spoken order "I'd like to apply Exsel on each evening," could be misinterpreted as "I'd like the patient to apply Exelon each evening." Given that both products are used topically, DMETS believes this could present an opportunity for the products to be confused.

However, Exelon Patch will be available in several strengths, which means that prescribers will have to designate the strength to be dispensed when ordering or prescribing Exelon Patch. Because Exsel is available in a single strength (2.5%) that does not overlap with Exelon, DMETS believes that the inclusion of the Exelon Patch strength will help to avoid name confusion. Additionally, the inclusion of the modifier "Patch" with the proprietary name "Exelon" would lessen the orthographic and phonetic similarity of the name "Exelon Patch" and "Exsel."

In addition, Exelon and Exsel have several different product characteristics including form (shampoo/lotion versus patch), indication for use, and usual adult dosing instructions. Furthermore, Exsel appears in the discontinued section of FDA's Orange Book¹¹ and is not listed in the 2005 RedBook¹² or the online drug source, Destination Rx¹³. Other references commonly used by practitioners (e.g. Micromedex, Lexi-Comp Online) cross-reference this discontinued product to other selenium sulfide 2.5% lotions/shampoo products currently marketed in the US. This could perpetuate an error if Exelon was misinterpreted as Exsel, and a practitioner referred to one of these sources to find a similar product that could be used in place of Exsel. However, a search of AERS was unable to identify any medication errors resulting from Exsel and Exelon name confusion. DMETS believes that the collective differences in the length of the names and product characteristics, along with the discontinued status of the Exsel product, minimizes the potential for error.

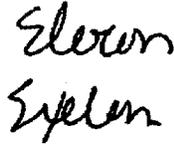
¹¹ Web Reference: Electronic online version of the FDA Orange Book: <http://www.fda.gov/cder/ob/>

¹² 2005 Red Book, Thomson PDR.

¹³ Web Reference: http://destinationrx.com/default_firstvisit.asp

- f) Elocon may look similar to Exelon when written. Elocon is a topical product used to relieve inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Look-alike similarities between Elocon and Exelon may be attributed to the identical length of the names and the shared letters 'E-' and '-on' (see below).

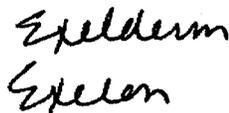


Although both names have the letter 'l', the **positioning of the letter** differs, and introduces an upstroke difference that help practitioners to distinguish the names.

Like Exelon Patch, Elocon is administered topically once daily. However, Exelon Patch will be available in several strengths, while Elocon is formulated as a single strength (1%) that does not overlap with the proposed strengths of Exelon Patch. In the context of a medication order or prescription for Exelon Patch, prescribers will designate the strength in order for the medication to be dispensed or administered. Because Elocon is available in a single strength (1%) that does not overlap with Exelon, DMETS believes that the inclusion of the Exelon Patch strength will help to avoid name confusion. In addition, Elocon and Exelon have other dissimilar product characteristics including dosage form (cream, lotion, and ointment versus patch) and indications for use (relief of skin inflammation and pruritis versus mild to moderate dementia). A search of AERS was unable to identify any medication errors resulting from Elocon and Exelon name confusion. Overall, DMETS believes that product differences minimize the potential for error.

- g) Exelderm may look similar to Exelon Patch when written. Exelderm is a topical product used to treat superficial fungal infections of the skin.

Look-alike similarities between Exelderm and Exelon may be attributed to the shared letters 'Exel-' (see below).



However, Exelderm is considerably longer than Exelon (8 versus 6 letters), a difference which may help practitioners to distinguish the names.

Like Exelon Patch, Exelderm is administered topically once daily. However, Exelon Patch will be available in several strengths, while Exelderm is formulated as a single strength (1%) that does not overlap with the proposed strengths of Exelon Patch. In the context of a medication order or prescription for Exelon Patch, prescribers will designate the strength in order for the medication to be dispensed or administered. Because Exelderm is available in a single strength (1%) that does not overlap with Exelon, DMETS believes that the inclusion of the Exelon Patch strength will help to avoid name confusion. In addition, Exelderm and Exelon have other dissimilar product characteristics including dosage form (cream, solution versus patch) and indications for use (antibiotic versus mild to moderate dementia). A search of AERS was unable to identify any medication errors resulting from Exelderm and Exelon name confusion. Overall, DMETS believes that product differences minimize the potential for error.

2. The Sponsor educate practitioners about the relationship between patch size, drug release rate, and the absorption of the drug from the patch to minimize the potential for medication errors.

B. Insert Labeling

1. Highlights of Prescribing Information

- a) Under **“DOSAGE AND ADMINISTRATION”** please modify the table. DMETS finds the statement in the third row particularly confusing, and recommends that the Sponsor use a combination of paragraph and tables to more clearly indicate the dosage and administration information.
- b) Under **“DOSAGE AND ADMINISTRATION”** or **“WARNINGS AND PRECAUTIONS”** consider adding a statement alerting practitioners that the patch and capsules are not substitutable on a mg per mg basis. DMETS believes this could help minimize potential prescribing errors.

2. Full Prescribing Information

- a) Under **“2.1 Maintenance Dose”** and **“5. WARNINGS AND PRECAUTIONS”** the Sponsor states **“Patch treatment can be resumed at the same doses if treatment is not interrupted for more than several days.”** DMETS believes that **“several”** is ambiguous, and that the Sponsor should express the number of days in discrete terms if possible (e.g., **“3”**) to avoid misinterpretation of the information.
- b) DMETS notes that the Prescribing Information includes **“Switching from Capsule or Oral Solution”** dosing information. Please ensure that similar information on **“Switching from Transdermal to Capsule or Oral Solution”** is provided in the prescribing information for Exelon capsules and solution. The Sponsor may also wish to reference this information in the Exelon Patch Prescribing Information.
- c) DMETS notes that the Prescribing Information does not specify a dosage of Exelon Patch that could be administered to patients who previously received oral dosages of Exelon greater than 12 mg. If this information is available, please include in the prescribing information. If there is no data available for this patient population, DMETS would recommend that this be specified.
- d) Under **“2.1. Method of Administration”** the sponsor notes that the Patch **“can be used in everyday situation, including bathing and hot weather.”** DMETS requests that the Sponsor submit data to support the inclusion of this statement, as heat and water exposure have been known to affect the absorption and adhesion of other transdermal patches. From a safety perspective, DMETS believes that these actions could result in adverse outcomes if the Sponsor does not have data to support such conditions of use. Also, please specify the source of heat exposure (e.g. sun, exercise, heated blankets) and duration, and include this information in the labeling.
- e) Under **“3.2 Dosage Strengths”**, DMETS recommends that the sponsor revise the wording of the table’s column headings. Use language that more clearly conveys to practitioners that the **“rivastigmine base dose load”** column represents total drug content of the patch.

- f) In Section “14. CLINICAL STUDIES,” DMETS did not see any reference to Patch adhesion rates. DMETS questions if this information was captured in clinical trials, and if so, requests that the Sponsor submit the data to the Agency for review and include in the Prescribing Information for the product.
- g) DMETS notes that the Contents of the Prescribing Information is missing section “15” (14 included, and then jumps to section 16). If this is an oversight, please adjust numbering accordingly.
- h) Under “17. Patient Counseling Information: How to Use the Exelon Patch,” the Sponsor states “Do not cut this patch into pieces.” DMETS recommends that the information be given greater prominence, and that the Sponsor consider including this information elsewhere in the Prescribing information (e.g. Under “5. Warnings and Precautions”). Also, please consider describing why patches should not be cut to convey more clearly to patients the risk.
- i) Under “17. Patient Counseling Information: How to apply Exelon Patch,” the Sponsor describes the patch as “a thin, opaque, plastic patch.” DMETS recommends that the Sponsor consider replacing the word “opaque” with the actual color of the patch.
- j) Under “17. Patient Counseling Information: How to apply Exelon Patch,” the Sponsor states that “You may write (e.g., the day of the week) on the Exelon Patch with a ball point pen. “ However this statement appears after the application instructions, which may inadvertently suggest to patients that the writing on the patch should be performed after application. DMETS recommends that the Sponsor move this statement before the application instructions, and qualify the statement with “Before applying the patch,” or some other similar language, to communicate that this action should occur prior to patch application.
- k) Under “17. Patient Counseling Information: How to apply Exelon Patch,” DMETS recommends that the application instructions conclude with “Wash your hands with soap and water after applying the patch” and that the Sponsor include a picture of this action, if space allows. DMETS is aware of accidental caregiver exposure to medication subsequent to patch application.
- l) Under “17. Patient Counseling Information: Can Exelon Patch be worn when bathing, swimming, or in the sun?” the Sponsor states “Make sure the patch does not loosen during these activities.” DMETS objects to the wording of this statement, as it may inadvertently encourage patients to use overlays (e.g. bandages, tape) to “make sure” patches do not loosen. Post-marketing surveillance of other transdermal patches has shown such efforts to secure patches that have loosened to be problematic. DMETS recommends that the Sponsor modify the wording “Check to see if the patch is loosened,” (or similar) and provide clear, concise instructions for the patients regarding what steps should be taken in the event that the patch loosens.
- m) Under “17. Patient Counseling Information: Can Exelon Patch be worn when bathing, swimming, or in the sun?” the Sponsor that the patch should not be exposed to any external heat sources. DMETS believes that this information should be given greater prominence by creating a new sub-section (e.g. “Avoid heat exposure”). DMETS

recommends the Sponsor link this to an outcome, which is that heat increases the absorption of medicine from the patch. DMETS also believes that the effects of heat exposure is an important clinical consideration, and should be clearly delineated for practitioners in “5. WARNINGS AND PRECAUTIONS”. If pharmacokinetic data is available regarding the effect of heat exposure, consider including in section “12.3 Pharmacokinetics” to detail the extent of this issue to practitioners. At minimum, DMETS believes that the Sponsor should state in general terms that heat exposure effects the delivery of drug from the patch in the Pharmacokinetics section.

- n) Under “17. Patient Counseling Information: What to do if Exelon Patch falls off?,” DMETS recommends that the Sponsor direct the patient to dispose of patches that have fallen off. Furthermore, DMETS recommends that the Sponsor consider warning against the use of overlays to secure patches that have loosened or re-apply patches that have fallen off.

C. Carton

1. The Carton does not have adequate space to affix a pharmacy label without covering important product information. DMETS requests that the Sponsor modify the carton design to accommodate a pharmacy-generated patient label.
2. The circle graphic around the strength is distracting and makes the number appear as a superscript, please omit.
3. DMETS believes that the statement “Includes 30 10 cm² systems” is confusing and redundant. Please delete, and increase the size of “Contents: 30 systems” statement.
4. Please modify the color of the cartons in non-overlapping color scheme. The Sponsor’s current proposal utilizes similar colors for the  and 10 cm² strengths and the  and 5 cm² strengths. Combined with similarities introduced by the Sponsor’s trade dress, DMETS believes there is an increased the potential for selection errors within the product line (see images below).



b(4)

D. Pouch

1. See Comments C2, C3, and C4.
2. When modifying the pouch color, please use contrasting colors for the text and background. DMETS finds the contrast of the blue text and purple background of the _____ pouch particularly poor, and thereby decreases the readability of critical information. b(4)
3. DMETS recommends that the Sponsor increase the darkness of the text used to display the established name, dosage form, and delivery rate of the patch. The current font has very thin lettering and fades into the background.
4. If space allows, DMETS recommends a statement be added to the pouch to advise the patient to retain the pouch for patch disposal as recommended in the prescribing information.

E. Patch

1. DMETS notes that the patches are beige in color. Although this does provide a level of privacy for Caucasian patients with similar skin tones, it also poses a problem for patients and caregivers when trying to locate a patch that is currently applied or when applying a replacement. DMETS recommends that the Sponsor choose a color that is easily seen on patients of all skin tones, and by a Healthcare Practitioner in an emergency. DMETS does not recommend the use of clear patches for similar reasons.
2. The proprietary name, identification of strength, and established name should be displayed in text that contrasts with the background color to improve the readability of this information once applied to the patient. The four-letter codes used by the Sponsor should be given as little prominence as possible since this information is not of use to patients or practitioners, and thus can be displayed in text that has little contrast with the background.
3. Please include the release rate of the patch (mg/24 hour), if possible, on the patch itself. DMETS is concerned that in the event of an emergency, practitioners may not be able to readily quantify the amount of drug a patient is exposed to based on patch size alone.

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Appendix A. Prescription Studies for Exelon

Verbal (n=11)	Inpatient (n=12)	Outpatient (n=12)
Exalon	Eselan	Exelon
Exalon	Eselar	Exelon
Excelon	Exclar	Exelon
Excelon	Exelac	Exelon
Exelan	Exelac	Exelon
Exelon	Exelac	Exelon
Exelon	Exelon	Exelon
Exelon	Exelon	Exelon
Exelon	Exelon	Exelon
Exolon	Exselan	Exelon
Excelon	Exslar	Exelon
	Exslar	Exelon

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Appendix B. Effexor XR –Exelon name confusion

ISR # Date Setting Outcome	Narrative
5119371-6 July 2006 Outpatient Pharmacy Vomiting, nausea, dizziness	A 25 year-old female patient was prescribed Effexor XR 37.5 mg for depression. The prescription was filled with Exelon 1.5 mg, and dispensed to the patient. The patient ingested Exelon 1.5 mg in error (unknown duration) and experienced vomiting, nausea, and dizziness. The report noted name similarity as a contributing factor.

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/s/

Kellie Taylor
5/24/2007 11:48:32 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
5/24/2007 01:27:21 PM
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