CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202022Orig1s000

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 Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	May 17, 2011
Application Type/Number:	NDA 202022
Reviewer(s):	Yelena Maslov, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Zachary Oleszczuk, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist Division of Medication Error Prevention and Analysis
Drug Name(s):	Edurant (Rilpivirine) Tablets, 25 mg
Applicant/sponsor:	Tibotec, Inc
OSE RCM #:	#2011-1470

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

CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Edurant, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The proposed product characteristics are provided in Appendix B.

1.1 REGULATORY HISTORY

Edurant (Rilpivirine) Tablets, 25 mg is the subject of a 505 (b)(1) application, NDA 202022, submitted to the FDA on July 23, 2010. The name, Edurant, is the forth proposed name for this product submitted by the Applicant on May 5, 2011. (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Anti-Viral Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on May 5, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

There are no components of the proposed proprietary name that can contribute to medication error or render the name unacceptable.

2.2.3 FDA Name Simulation Studies

Twenty-eight practitioners responded DMEPA's prescription studies. See Appendix D for sample prescriptions used in the study and the complete listing of interpretations from the verbal and written prescription studies. None of responses overlapped with other drug names. Fourteen participants interpreted the proposed proprietary name correctly as

'Edurant' with two correct interpretations (n=2) occurring with inpatient orders, eleven correct interpretation (n=11) occurring with outpatient orders, and one correct interpretation (n=1) occurring with voice order. The remaining fourteen participants misinterpreted the name, Edurant. The most common interpretation occurred with four inpatient order participants misinterpreting the letter 'a' as the letter 'e' and three voice order participants misinterpreting the letter 'a' as the letter 'o'.

2.2.4 Comments from Other Review Disciplines

In response to the OSE e-mail, dated May 6, 2011, the Division of Anti-Viral Products (DAVP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Edurant. These names were identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar		**Sound Similar**		**Look and Sound Similar**	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Duract	EPD Panel	Enduron	EPD Panel	Saredutant	EPD Panel
Duoplant	EPD Panel	Imuran	EPD Panel		
Edarbi	EPD Panel	Medent	EPD Panel		
Edecrin	EPD Panel	Eluant	EPD Panel		
Etidronate	EPD Panel				
Caduet	EPD Panel				
Clinoril	EPD Panel				
Enecat	EPD Panel				
Efudex	EPD Panel				
Ethedent	EPD Panel				
Edetate	EPD Panel				
Edluar	EPD Panel				
Duravent	EPD Panel				
Durahist	EPD Panel				
Inderal	EPD Panel				
Endrate	EPD Panel				

Ethrane	EPD Panel				
Endocet	EPD Panel				
Evamist	EPD Panel				
Caziant	EPD Panel				
Cesamet	EPD Panel				
Avodart	EPD Panel				
Etodolac	Primary Safety Evaluator				
Abelcet	Primary Safety Evaluator				
Altorant	Primary Safety Evaluator				
Alamast	Primary Safety Evaluator				
Atrovent	Primary Safety Evaluator				
(b) (4)	Primary Safety Evaluator				
(b) (4)	Primary Safety Evaluator				

Our analysis of the 34 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 34 names will not pose a risk for confusion as described in Appendix E and F.

DMEPA communicated these findings to the Division of Anti-Viral Products via e-mail on May 9, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Anti-Viral Products on May 11, 2011, the Division had no additional concerns with the proposed proprietary name, Edurant.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name is acceptable from both a promotional and safety perspective. However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

The proposed proprietary name, Edurant, must be re-reviewed if NDA approval is delayed beyond 90 days.

4 REFERENCES

1. ***Micromedex Integrated Index (http://csi.micromedex.com)***

   Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)***

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

7. ***Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)***

   The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***U.S. Patent and Trademark Office (http://www.uspto.gov)***

   USPTO provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)***

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

10. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

    The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. ***Natural Medicines Comprehensive Databases (www.naturaldatabase.com)***

    Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

12. ***Access Medicine Database (http://www.accessmedicine.com/drugs.aspx)***

    Access Medicine contains full-text information from approximately 60 medical titles: it includes tables and references. Among the database titles are: Goodman and Gilman's The Pharmacological Basis of Therapeutics, Current Medical Diagnosis and Treatment, Tintinalli's Emergency Medicine, and Hurst's the Heart.

13. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

14. ***Red Book Pharmacy's Fundamental Reference***

    Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

15. ***Lexi-Comp (www.lexi.com)***

    Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

16. ***Medical Abbreviations Book***

    Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

17. ***LabelDataPlus Database (http://www.labeldataplus.com/index.php?ns=1)***

    LabelDataPlus database covers a total of 36773 drug labels. This includes Human prescription drug labels as well as Active Pharmaceutical Ingredients (APIs), OTC

(Application and Monograph) drugs, Homeopathic drugs, Unapproved drugs, and Veterinary drugs.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by DDMAC. DDMAC evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. DDMAC provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed

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

product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2] The product characteristics considered for this review appears in Appendix B1 of this review.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*

[2] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and

orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment 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.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, 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 orthographically or phonetically similar 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 primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. 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 compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

[3] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike"

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes 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 not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name 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 the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or,

inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Product Characteristics Provided for Edurant

Edurant
(ee' dur ant)
(Rilpivirine) Tablets 25 mg

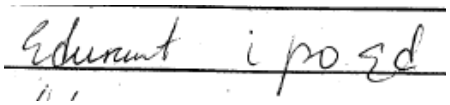
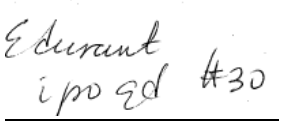
Indication: Non-nucleoside reverse transcriptase inhibitor of HIV type 1
Route: Oral
Dosage Form: Tablet
Strengths: 25 mg
Dosage/Administration: Take 1 tablet orally once daily
How Supplied: bottles of 30 tablets
Applicant: Tibotec

Appendix C: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Edurant	**Scripted May Appear as**	**Spoken May Be Interpreted as**
Capital 'E'	'a','C', 'I', 'L', 'S'	Any vowel
lower case 'e'	'a', 'c', 'i', 'l', 'o'	Any vowel
lower case 'd'	'b', 'el', 'al', 'f', 't'	't'
lower case 'u'	'n', 'v', 'w'	any vowel
lower case 'r'	n, s, or v	'w'
lower case 'a'	'el, 'd', 'o', 'u', 'n'	Any vowel
lower case 'n'	'm', 'u', 'r', 'h', 's'	'm', 'dn', 'kn', 'mn, 'pn'
Lower case 't'	'f', 'd', 'b', 'x'	'd'

Appendix D: Prescription Simulation Samples and Results

Figure 1 [redacted] (b) (4) Study (Conducted on 05/11/2011)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Edurant #30 1 po daily
Outpatient Prescription:  	

FDA Prescription Simulation Responses

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Edument	Edurant	Aderon
Edunent	Edurant	Ederant
Edununt	Edurant	Ederont
Edurant	Edurant	Ederont
Edurant	Edurant	Edurant
Edurent	Edurant	Eterant
Edurent	Edurant	Etterant
Edurunt	Edurant	
Eduscrunt	Edurant	
Eduvint	Edurant	
	Edurant	

Appendix E: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Product Name	Similarity to Edurant	Failure preventions
Duoplant (Salicylic Acid)	Looks alike	Lacks sufficient orthographic similarity
Efudex (Fluorouracil)	Looks alike	Lacks sufficient orthographic similarity
Medent	Looks and sounds alike	Lacks sufficient orthographic and phonetic similarity
Saredutant	Sounds alike	Lacks sufficient phonetic similarity
(b) (4)		(b) (4)
(b) (4)*** (Gadobutrol)	Looks alike	The proposed proprietary name for NDA 201277 was an alternate name that was not reviewed. The product was approved under the name Gadavist
Duract (Bromfenac)	Looks alike	The product is discontinued without a generic equivalent available
Enecat (Barium)	Looks alike	The product is discontinued without a generic equivalent available
Altorant (Guaifenesin)	Looks alike	The product is discontinued without a generic equivalent available
Eluant (Sodium Chloride)	Looks and sounds alike	The product is discontinued without a generic equivalent available

*** This document contains proprietary information that should not be released to the public

Appendix F: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

Proposed name: Edurant (Rilpivirine) Tablets	**Strength(s): 25 mg**	**Usual dose: Take 1 tablet (25 mg) orally once daily**
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
Edarbi (Azilsartan Medoximil) Tablets, 40 mg and 80 mg Usual Dose 40 mg to 80 mg once daily	Orthographic Both names start with the letter string 'Ed' and share the letter 'r' in similar positions. Additionally, the letter 'u' in Edurant may appear similar to the corresponding letter 'a' in Edarbi when scripted. Dosage Form Tablets Route of Administration Oral Usual Dose One tablet Frequency of Administration Once daily	Orthographic The letter string '-ant' in Edurant lacks orthographic similarity to the letter string '-bi' in Edarbi Strength 25 mg vs. 40 mg and 80 mg

Edecrin (Ethacrynic Acid) Tablets, 25 mg Usual Dose 50 mg to 100 mg orally once to twice daily up to 200 mg twice daily. Powder for Injection, 50 mg Usual Dose 50 mg or 0.5 mg/kg to 1 mg/kg intravenously injected over several minutes	Orthographic Both names start with the letter string 'Ed-'. Additionally, the letter string '-uran-' may appear similar to the letter string '-ecrin' when scripted. Dosage Form Tablets Strength 25 mg Route of Administration Oral Frequency of Administration Both product may be administered once daily	Orthographic Although both names have the same number of letters, the name Edurant is longer than the name Edecrin due to wider letters 'u' and 'a'. Additionally, the upstroke and the corss stroke letter 't' at the end of the name Edurant provides more orthographic differentiation. Usual Dose One tablet vs. two tablets to four tablets
Etidronate Disodium Tablets, 200 mg and 400 mg Usual Dose 5 mg/kg/day to 10 mg/kg/day orally once daily for no longer than 6 months or 11 mg/kg/day to 20 mg/kg/day orally once daily for no longer than 3 months.	Orthographic Both names start with the letter 'E'. Additionally, the letter 'd' and letter string '-ran-' in Edurant may appear similar to the letter 't' and letter string '-ron-' in Etidronate and these similar looking letters are located in similar positions. Dosage Form Tablets Route of Administration Oral Usual Dose Both products may be administered as one tablet Frequency of Administration Both product may be administered once daily	Orthographic The name Etidornate appears longer than the name Edurant (10 letters vs. 7 letters) Strength 25 mg vs. 200 mg and 400 mg

Caduet (Amlodipine and Atorvastatin) Tablets, 2.5 mg/10 mg, 2.5 mg/20 mg, 2.5 mg/40 mg, 5 mg/10 mg, 5 mg/20 mg, 5 mg/40 mg, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg Usual Dose 2.5 mg/10 mg to 10 mg/40 mg orally once daily	Orthographic The beginning letters 'e' and 'c' may appear similar to each otyher if scripted in a lower case. Additionally, the letter string '-dur-' in Edurant may appear similar to the letter string '-due-'. Furthermore, both names contain letter 't' at the end of the names. Dosage Form Tablets Route of Administration Oral Usual Dose Both products may be administered as one tablet Frequency of Administration Once daily	Orthographic The name Edurant appears longer than the name Caduet (7 letters vs. 6 letters). Additionally, upstrokes 'd' in both names do not correspond to each other. Strength 25 mg vs. multiple
Clinoril (Sulindac) Tablets, 150 mg and 200 mg Usual Dose 150 mg to 200 mg orally twice daily	Orthographic The letter string –durant' may appear similar to the name Clinoril when scripted. Dosage Form Tablets Route of Administration Oral Usual Dose Both products may be administered as one tablet	Orthographic The similar letter strings do not correspond to each other. Strength 25 mg vs. 150 mg and 200 mg Frequency of Administration Once daily vs. twice daily

Ethedent* (Sodium Fluoride) Chewable Tablets: 0.25 mg, 0.5 mg, and 1 mg Usual Dose 0.25 mg to 1 mg orally once daily Gel: 1.1% Cream: 1.1% *Although the proprietary name is discontinued, multiple generic products are available. Usual Dose Brush teeth once daily	Orthographic Both names start with the letter 'E' and share the letter string '-nt' at the end of the names. Additionally, the letters 'd' and 'a' in Edurant may appear similar to the corresponding letters ;t' and e' in Ethedent when scripted. Dosage Form Both products are available as tablets Strength Edurant will be available as 25 mg which is similar to Ethedent strength of 0.25 mg especially if the preceding zero is omitted (e.g., .25 mg) Route of Administration Oral Usual Dose Both products may be administered as one tablet Frequency of Administration Once daily	Orthographic The letter string '-ur-' in Edurant lacks orthographic similarity to the letter string '-hed-' when scripted. Additionally, the name Edurant contains 3 upstrokes and the name Ethedent contains 4 upstrokes.
Edetate Disodium Injection, 3 g/20 mL (150 mg/mL) Usual Dose 50 mg/kg/day up to 3 g/day administered by slow intravenous infusion	Orthographic Both names start with the letter string 'Ed-'. Additionally, both names contains letter 't' at the end of the names in similar positions.	Orthographic The name Edurant contains 3 upstrokes vs. the name Edetate contains 4 upstrokes. Additionally, the letter string '-ur-' in Edrant lacks orthographic similarity to the letter string '-et-' in Edetate. Strength 25 mg vs. 3 g/20 mL (150 mg/mL) Usual Dose 25 mg vs. 50 mg/kg/day up to 3 g/day

Edluar (Zolpidem) Sublingual Tablet, 5 mg and 10 mg Usual Dose 5 mg to 10 mg orally once daily at bedtime	Orthographic Both names start with the letter string 'Ed-'. Additionally, the letter string '-ran-' in Edurant may appear similsr to the letter string '-uar-' when scripted. Dosage Form Tablets Route of Administration Oral Usual Dose Both products may be administered as one tablet Frequency of Administration Once daily	Orthographic The name Edurant appears longer than the name Edluar (7 letters .vs 6 letters). Additionally, although both names contains 3 upsctrokes, Edurant contains 2 upstrokes in the beginning of the name and 1 at the ends vs. Edluar contains 3 upstrokes together at the beginning of the name Strength 25 mg vs. 5 mg and 10 mg
Endocet (Oxycodone and Acetaminophen) Tablet, 5 mg/325 mg, 7.5 mg/325 mg, 7.5 mg/500 mg, 10 mg/325 mg, 10 mg/650 mg Usual Dose 5 mg/325 mg to 10 mg/650 mg orally every 6 hours as needed.	Orthographic Both names start with the letter 'E' and contains upstrokes 'd' and 't'. Additionally, the letter 'n' in Edurant may appear similar to the letter string '-ce-' in Endocet when scripted. Dosage Form Tablets Route of Administration Oral Usual Dose Both products may be administered as one tablet	Orthographic The upstrokes 'd' are not located in the corresponding positions of the names. Additionally, the letter string '-ura-' in Edurant lacks orthographic similarity with the letter 'o' in Endocet when scripted. Strength 25 mg vs. multiple combinations strengths. Frequency of Administration Once daily vs. every 6 hours as needed.

Duravent (Chlorpheniramine/ Phenylephrine/ Methscopolamine) Chewable Tablets, 2 mg/10 mg/1.25 mg Usual Dose 1 tablet to 2 tablets every 4 to 6 hours Duravent DA (Chlorpheniramine/ Phenylephrine/ Methscopolamine) Extended-release Tablets, Usual Dose 1 tablet every 8 hours Duravent DPB (Chlorpheniramine/ Phenylephrine/ Methscopolamine) Extended-release Tablets, 8 mg/20 mg/2.5 mg Usual Dose 1 tablet every 8 hours	Orthographic Both names share the letter strings '-dura-' and '-nt' Dosage Form Tablets Strength Edurant will be available as 25 mg which is similar to Duravent DPB dose of Methscopolamine of 2.5 mg Route of Administration Oral Usual Dose Both products may be administered as one tablet	Orthographic The shared letter strings do not correspond to each other. Additionally, Edurant contains 3 upstrokes and Duravent contains 2 upstrokes. Furthermore, the name Edurant starts with the letter 'E' and the name Durahist starts with the letter 'D'. Frequency of Administration Once daily vs. 4 hours to 6 hours or every 8 hours as needed.
Endrate (Edetate Disodium) Injection, 3 g/20 mL (150 mg/mL) Usual Dose 50 mg/kg/day up to 3 g/day administered by slow intravenous infusion	Orthographic Both names start with the letter 'E' and share the letter string '-ra-' and the letters 'd' and 't'	Orthographic The name Edurant contains 2 upstrokes next to each other at the beginning of the name and 1 upstroke as the last letter of the name vs. Endrate contains 1 upstroke at the beginning of the name, 1 in the middle, and 1 closer to the end. Strength 25 mg vs. 3 g/20 mL (150 mg/mL) Usual Dose 25 mg vs. 50 mg/kg/day up to 3 g/day

Durahist* (Chlorpheniramine/ Pseudoephdrine/ Methscopolamine) Extended-release Tablets, 8 mg/60 mg/2.5 mg <u>Usual Dose</u> 1 tablet every 12 hours Durahist D (Dexchlorpheniramine/ Pseudoephdrine/ Methscopolamine) Extended-release Tablets, 3.5 mg/45 mg/1 mg <u>Usual Dose</u> 1 tablet every 12 hours Durahist PE (Chlorpheniramine/ Pseudoephdrine/ Methscopolamine) Extended-release Tablets, 8 mg/20 mg/1.25 mg <u>Usual Dose</u> 1 tablet every 12 hours *Proprietary name is discontinued, but generic products are available	<u>Orthographic</u> Both names share the letter string '-dura-' and the letter 't'. Additionally, the letter 'n' in Edurant may appear similar to the letter string '-is-' in Durahist when scripted. <u>Dosage Form</u> Tablets <u>Strength</u> Edurant will be available as 25 mg which is similar to Durahist's strength of Methscopolamine if 2.5 mg <u>Route of Administration</u> Oral <u>Usual Dose</u> Both products may be administered as one tablet	<u>Orthographic</u> The shared letter string '-dura-' and similar letter strings '-nt-' and '-ist' do not correspond to each other. Additionally, the name Edurant starts with the letter 'E' and the name Durahist starts with the letter 'D' that lack similarities when scripted. <u>Frequency of Administration</u> Once daily vs. every 12 hours

Inderal (Propranolol) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg Usual Dose 10 mg to 320 mg two to four times daily Inderal LA (Propranolol) Extended-release Tablets, 60 mg, 80 mg, 120 mg, 160 mg Usual Dose 80 mg to 320 mg orally once daily Inderal (Propranolol) Injection Usual Dose 1 mg to 3 mg intravenously over no faster than 1 minute	Orthographic Both names share the letter 'd' and the letter string '-ra-' in similar positions. Additionally, the letter 'e' and letter 't' in Edurant may appear similar to the letter 'i' and the letter 'l' in Inderal, if the first letters of the names are scripted in a lower case. Dosage Form Both products are available as tablets Route of Administration Oral Usual Dose Both products may be administered as one tablet Frequency of Administration Both products (i.e., Edurant and Inderal LA) may be administered once daily	Orthographic Although both names contain the same number of letters, the name Edurant appears longer due to wider letters 'u'. Additionally, the upstrokes 'd' and similar-looking upstrokes 'l' and 't' are not located in corresponding positions. Strength 25 mg. vs 20 mg, 40 mg, 6- mg, 80 mg, 120 mg, 160 mg
Ethrane (Eflurane) Liquid for Inhalation, 99.9% Usual Dose Inspire concentration of 2% to 4.5% over 7 to10 minutes to produce general anesthesia	Orthographic Both names start with the letter 'E' and share the letter string '-an' in similar positions. Additionally, the letter 'd' in Edurant may appear similar to the letter 't' in Ethrane when scripted. Route of Administration Oral Strength Both products are available in a single strength, thus, strength may be omitted	Orthographic Although both names contains 3 upstrokes, the name Edurant contains 2 upstrokes at the beginning of the name immediately next to each other and 1 upstroke at the end of the name vs. the name Ethrane contains all 3 upstrokes at the beginning of the name immediately next to each other. Usual Dose One tablet vs. 2% to 4.5%

Evamist (Estradiol) Topical Solution, 1.53 g/actuation Usual Dose 1 spray to 3 sprays to inner surface of the forearm once daily in the morning	Orthographic Both names start with the letters 'E' and 't'. Additionally, the letter string '-uran-' in Edurant may appear orthographically similar to the corresponding letter string '-amis-' in Evamist when scripted. Strength Both products are available in a single strength, thus, strength may be omitted Frequency of Administration Once daily	Orthographic The letter 'd' in Edurant lacks orthographic similarity to the corresponding letter 'v' in Evamist. Additionally, Edurant contains 3 upstrokes vs. Evamist contains 2 upstrokes. Route of Administration Oral vs. topical Usual Dose One tablet vs. one to three sprays
Caziant Desogel and Ethinyl Estadiol) Tablets, 0.125 mg/0.025 mg, 0.15 mg/0.025 mg, 0.1 mg/0.025 mg Usual Dose 1 tablet orally once daily	Orthographic Both names share the last letter string '-ant'. Additionally, the letters 'e' and 'r' in Edurant may appear similar to the letters 'c' and 'i' in Caziant, if the first letters of the names are scripted in a lower case. Dosage Form Tablets Strength Both products are available in a single strength, thus, strength may be omitted Route of Administration Oral Usual Dose One tablet Frequency of Administration Once daily	Orthographic The letter string '-du-' in Edurant lacks orthographic similarity to the letter string '-az-' in Cazient. Additionally, the name Edurant contains 3 upstrokes and the name Caziant contains 2 upstrokes and a down stroke if the letter 'z' is scripted as down stroke

Cesamet (Nabilone) Tablet, 1 mg Usual Dose 1 mg to 2 mg twice to three times daily	Orthographic Both names end with the letter 't'. Additionally, the letter 'e' and the letter string '-uran-'in Edurant may appear similar to the corresponding letter 'c' and the letter string '-same-' in Cesamet if the first letters of the names are scripted in a lower case Dosage Form Tablets Strength Both products are available in a single strength, thus, strength may be omitted Route of Administration Oral Usual Dose Both products may be administered as one tablet	Orthographic The letter 'd' in Edurant lacks orthographic similarity to the corresponding letter 'e' in Cesamet. Additionally, the name Edurant contains 3 upstrokes and the name Cesamet contains 2 upstrokes. Frequency of Administration Once daily vs. three times daily
Avodart (Dutasteride) Capsules, 0.5 mg Usual Dose 0.5 mg orally once daily	Orthographic Both names end with the letter 't'. Additionally, the letter 'E' and the letter string '-an-' in the name Edurant may appear similar to the letter 'A' and the letter string '-ar-' in Avodart when scripted. Dosage Form Single dosage form: tablets vs. capsules. Strength Both products are available in a single strength, thus, strength may be omitted Route of Administration Oral Usual Dose One tablet Frequency of Administration Once daily	Orthographic Although both names contains three upstrokes, the middle upstroke 'd' is not located in the corresponding positions of the name. Thus, the letter string '-dur-' in Edurant lacks orthographic similarity to the letter string '-vod-' in Avodart when scripted.

Etodolac Tablet, 400 mg and 500 mg Etodolac Capsule 200 mg and 300 mg Usual Dose 200 mg to 400 mg orally every 6 to 8 hours up to 1000 mg daily Etodolac Extended-release Tablet, 400 mg, 500 mg, 600 mg Usual Dose 400 mg to 1000 mg orally once daily	Orthographic Both names start with the letter 'E' and the letter string '-du-' in Edurant may appear similar to the letter string '-to-' in Etodolac when scripted. Dosage Form Both products may are available as tablets. Etodolac is also available is capsules Route of Administration Oral Usual Dose Both products may be administered as one tablet Frequency of Administration Both products may be dosed as once daily	Orthographic The name Edurant contains 3 upstrokes vs. the name Etodolac contains 4 upstrokes. Additionally, the letter string '-rant' in Edurant lacks orthographic similarity to the corresponding letter string '-dolac' in Etodolac when scripted. Strength 25 mg vs. 200 mg, 300 mg, 400 mg, 500 mg, 600 mg
Abelcet (Amphotericin B Phospholipid Complex) Injection, 100 mg/20 mg (5 mg/mL) Usual Dose 5 mg/kg/day intravenously as a single infusion at a rate of 2.5 mg/kg/hr	Orthographic Both names end with the letter 't'. Additionally, the letter string 'Ed-' and the letter 'n' in Edurant may appear similar to the letter strings 'Ab-' and '-ce-' in Abelcet when scripted. Strength Both products are available in a single strength, thus, strength may be omitted Frequency of Administration Once daily	Orthographic The name Edurant contains 3 upstrokes vs. the name Abelcet contains 4 upstrokes. Additionally, the letter string '-ura-' in Edurant lack orthographic similarity to the letter string '-el-' in Abelcet when scripted. Usual Dose One tablet (25 mg) vs. 5 mg/kg/day
Alamast (Pemirolast) Ophthalmic Solution, 0.1% Usual Dose 1 drop to 2 drops in each affected eye four times daily	Orthographic Both names share the last letter 't'. Additionally, the remaining letters in the names may appear similar when scripted, especially if the letter 'a' is scripted in a lower case.	Route of Administration Oral vs. ophthalmic Usual Dose One tablet vs. one to two drops Frequency of administration Once daily vs. four times daily

Atrovent (Ipratropium bromide) Inhalation Aerosol, 17 mcg/actuation and 18 mcg per actuation <u>Usual Dose</u> 2 sprays three to four times daily Inhalation Solution: 0.02% <u>Usual Dose</u> 1 vial three to four times daily Nasal Spray: 0.03% and 0.06% <u>Usual Dose</u> 2 sprays per nostril three to four times daily	<u>Orthographic</u> Both names share the last letter string '-nt'. Additionally, the letter string 'Ed-' and '-ra-' in Edurant may appear similar to the letter strings 'At-' and '-ve-' in Atrovent when scripted.	<u>Orthographic</u> The letter 'u' in Edurant lacks orthographic similarity to the letter string '-ro-' in Atrovent when scripted. <u>Dosage Form</u> Tablet vs. Inhalation Aerosol or Inhalation Solution or Nasal Spray <u>Strength</u> 25 mg vs. various for different dosage forms <u>Usual Dose</u> One tablet vs. two sprays or one vial <u>Frequency of Administration</u> Once daily vs. three to four times daily
Enduron* (Methylchlothiazide) Tablet, 5 mg *Proprietary name is discontinued and not prescribed, however, generic is still available <u>Usual Dose</u> 2.5 mg to 5 mg orally once daily	<u>Orthographic</u> Both names start with the letter 'E' and the letter string '-duran-' in Edurant may appear similar to the letter string '-duron' in Enduron when scripted. <u>Phonetic</u> Both names start with the letter 'E' and the letter string '-duran-' in Edurant is phonetically similar to the letter string '-duron' in Enduron. <u>Dosage Form</u> Tablets <u>Strength</u> Both products are available in a single strength, thus, strength may be omitted <u>Route of Administration</u> Oral <u>Usual Dose</u> One tablet <u>Frequency of Administration</u> Once daily	<u>Orthographic</u> Although both names start with the letter 'E' and share similar letter strings '-duran-' and '-duron', the appearance of the beginning of the name is different because of the letter 'n' that appears in Enduron. The letter 'n' separates the letter 'E' and the similar letter strings '-duran-' and '-duron'. Additionally, the name Edruant contains 3 upstrokes vs. the name Enduron contains 2 upstrokes. <u>Phonetic</u> The name Enduron contains a strong letter 'n' vs. Edurant does not and the name Edurant contains letter 't' and Enduron does not, which creates the phonetic difference between the two names.

Imuran (Azathioprine) Tablet, 50 mg <u>Usual Dose</u> 3 mg/kg to 5 mg/kg orally 1 to 3 days prior to transplantation. 1 mg/kg to 3 mg/kg orally once daily Powder for Injection, 100 mg <u>Usual Dose</u> 3 mg/kg to 5 mg/kg intravenously 1 to 3 days prior to transplantation. 1 mg/kg to 3 mg/kg intravenously once daily	<u>Orthographic</u> Both names share the letter string '-uran'. Additionally, the letter 'e' in Edurant may appear similar to the letter 'i' in Imuran if both are scripted in a lower case. <u>Phonetic</u> Both names share the letter string '-uran'. Additionally, the letter 'E-' in Edurant is phonetically similar to the letter 'I-' in Imuran. <u>Dosage Form</u> Tablets <u>Strength</u> Both products are available in a single strength, thus, strength may be omitted <u>Route of Administration</u> Both products may be administered orally <u>Usual Dose</u> Both products may be administered as one tablet <u>Frequency of Administration</u> Once daily	<u>Orthographic</u> The name Edurant contains 3 upstrokes vs. the name Imuran contains 1 upstroke. <u>Phonetic</u> The name Edurant contains letters 'd' and 't' vs. the name Imuran does not, which creates the phonetic difference between the two names.

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/s/

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