

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-993**

**PROPRIETARY NAME REVIEW(S)**

**CONSULTATION RESPONSE**  
**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT**  
**OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY**  
**(DMETS; WO 22, MAIL STOP 4447)**

<b>DATE RECEIVED:</b> May 12, 2006	<b>DESIRED COMPLETION DATE:</b> October 01, 2006	<b>OSE REVIEW #:</b> 06-0172
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**TO:** Andrea Leonard-Segal, MD  
Director, Division of Nonprescription Clinical Evaluation  
HFD-560

**THROUGH:** Alina Mahmud, R.Ph., M.S., Team Leader  
Denise Toyer, Pharm.D., Deputy Director  
Carol Holquist, R.Ph., Director  
Division of Medication Errors and Technical Support

**FROM:** Kimberly Pedersen, R.Ph., Safety Evaluator  
Division of Medication Errors and Technical Support

**PRODUCT NAME:**  
**Claritin® RediTabs™**  
(Loratadine Orally Disintegrating Tablets)  
5 mg

**SPONSOR:** Schering-Plough HealthCare Products, Inc.

**NDA#:** 21-993

**RECOMMENDATIONS:**

1. DMETS has no objections to the use of the "12 Hour" descriptor in conjunction with the Claritin® RediTabs™ proprietary name. This is considered a final decision. However, if 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 prior to NDA approval will rule out any objections based upon approvals of other proprietary and established names from the signature date of this document.
2. DMETS recommends implementation of the label revisions outlined in section III to minimize potential errors with the use of this product.
3. DDMAC does not provide comments on the promotional aspects of over-the-counter products. The Federal Trade Commission regulates the advertising of these products.

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

**Division of Medication Errors and Technical Support (DMETS)  
Office of Surveillance and Epidemiology  
WO 22, MAIL STOP 4447  
Center for Drug Evaluation and Research**

**PROPRIETARY NAME, LABEL AND LABELING REVIEW**

**DATE OF REVIEW:** August 4, 2006

**NDA #:** 21-993

**NAME OF DRUG:** **Claritin® RediTabs™**  
(Loratadine Orally Disintegrating Tablets)  
5 mg

**NDA SPONSOR:** Schering-Plough HealthCare Products, Inc.

**I. INTRODUCTION**

This consult was written in response to a request from the Division of Nonprescription Clinical Evaluation (HFD-560), for an assessment of the descriptor "12 Hour" in conjunction with the proprietary name, Claritin® RediTabs™, with regard to potential name confusion with other proprietary or established drug names. Container label (blister foils) and carton labeling were provided for review and comment from a medication error perspective.

**PRODUCT INFORMATION**

Claritin® RediTabs 12 Hour contains 5 mg of loratadine as an orally disintegrating tablet for the relief of sneezing, runny nose, itchy/watery eyes, itchy throat or itchy nose. The recommended dosing is one tablet with or without water every 12 hours, not to exceed two tablets in 24 hours. This is the first proposed loratadine 5 mg disintegrating tablet. The sponsor currently markets loratadine 10 mg disintegrating tablets with three product line names (Claritin Reditabs, Claritin Hives Relief Reditabs, and Claritin Pediatric Reditabs). In addition, the sponsor markets Claritin syrup, which contains 5 mg of loratadine per teaspoonsful. They previously marketed Claritin-D 12 hour containing 5 mg loratadine and 120 mg pseudoephedrine, but this is currently listed as discontinued. The remaining marketed Claritin products contain 10 mg of loratadine with or without pseudoephedrine in a tablet formation (Claritin-D, Claritin 24-hour, and Claritin Hives Relief).

## II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts<sup>i,ii</sup> as well as several FDA databases<sup>iii,iv</sup> for existing drug names which sound-alike or look-alike to Claritin RediTabs 12 Hour to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted<sup>v</sup>. The SAEGIS<sup>vi</sup> Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

### A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the addition of the descriptor "12 Hour" to the proprietary name of Claritin RediTabs. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff with 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 does not provide comments on the promotional aspects of over-the-counter products.
2. The Expert Panel identified the currently marketed Claritin and Clarinex drug product lines as having the potential for confusion with Claritin® RediTabs 12 Hour™. These products are listed in Table 1 (see page 4), along with the dosage forms available and usual dosage.

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<sup>i</sup> MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

<sup>ii</sup> Facts and Comparisons, online version, Facts and Comparisons, St. Louis, Missouri.

<sup>iii</sup> AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.

<sup>iv</sup> Phonetic and Orthographic Computer Analysis (POCA)

<sup>v</sup> www location <http://www.uspto.gov/tmdb/index.html>.

<sup>vi</sup> Data provided by Thomson & Thomson's SAEGIS™ Online service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com)

**Table 1: Potential Look-Alike Names Identified for Claritin RediTabs 12 Hour**

Product Name	Established name/ Dosage form(s)	Usual adult dose*	Other**
Claritin RediTabs 12 Hour	Loratadine Capsules, 5 mg Orally Disintegrating Tablets	One Capsule every 12 hours.	N/A
Claritin RediTabs 24 Hour	Loratadine Orally Disintegrating Tablets, 10 mg	One tablet daily.	LA/SA
Claritin	Loratadine Tablets, 10 mg	One tablet daily	LA/SA
Claritin-D (12 hour and 24 hour)	Loratadine/Pseudoephedrine Sulfate 5 mg/120 mg (12 hour, discontinued) 10 mg/240 mg (24 hour)	(24 hour), one tablet daily. (12 hour listed as discontinued in the orange book), one tablet every 12 hours.	LA/SA
Children's Claritin Oral Solution and Syrup	Loratadine Syrup 5 mg/mL	Children 2 years to 6 years: 5 mg daily. Children and adults 6 years and over: 10 mg daily.	LA/SA
Children's Claritin Chewable Tablets***	Loratadine Chewable Tablets, 5 mg	Children 2 years to 6 years: 5 mg daily. Children and adults 6 years and over: 10 mg daily.	LA/SA
Clarinet	Desloratadine Tablets, 5 mg Syrup, 0.5 mg/1 mL	1 tablet daily. Children 8 to 11 months: 2 mL daily. Children 12 mos to 5 years: 2.5 mL daily. Children 6 years to 11 years: 5 mL daily. Adults: 10 mL daily.	LA/SA
Clarinet RediTabs	Desloratadine Orally Disintegrating Tablets: 2.5 mg and 5 mg	5 mg daily. Children 6 to 11 years: 2.5 mg daily.	LA/SA
Clarinet D 12 Hour	Desloratadine and Pseudoephedrine Extended Release Tablets, 2.5 mg/120 mg	One tablet twice daily.	LA/SA
Clarinet D 24 Hour	Desloratadine and Pseudoephedrine Extended Release Tablets, 5 mg/240 mg,	One tablet daily.	LA/SA

\*Frequently used, not all-inclusive.  
\*\*LA (look-alike)/SA (sound-alike).

**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 Claritin RediTabs 12 Hour with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 123 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and an outpatient prescription were written, each consisting of a combination of marketed and unapproved drug products with a prescription for Claritin RediTabs 12 Hour (see below). These prescriptions were optically scanned and one prescription was delivered to a random sample of participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail and sent to a random sample of participating health professionals for their

interpretation and review. After receiving either written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p><u>Outpatient RX:</u></p> <p><i>Claritin Reditabs 12 hour # 180 1 Tablet bid</i></p>	<p><u>Claritin Reditabs 12 hours</u> <u>Number 180</u> <u>One tablet BID</u></p>
<p><u>Inpatient RX:</u></p> <p><del><i>Claritin Reditabs 12 hr 1 tablet BID</i></del></p>	

2. Results:

The interpretations of the proposed name overlap with other Claritin line products that include Claritin and Claritin Reditabs (24 hour). See Appendix A (page 7) for the complete listing of interpretations from the verbal and written studies.

C. FDA AERS and DQRS DATABASE SEARCHES

To thoroughly review this proposed name, DMETS must consider if there currently exists confusion with the other Claritin drug products and their tradename extensions and the loratadine isomer of desloratadine (Clarinet). In addition, DMETS must consider if the labeling is sufficient for adequate consumer/patient understanding. Since the Claritin product line is currently marketed, DMETS conducted a search of the post-marketing safety reports in the FDA Adverse Event Reporting System (AERS) database. DMETS used the tradename and verbatim letter string of “Clari%” and the High Level Group Term (HLGT) of “medication errors.” In addition, the Drug Quality Reporting System (DQRS) database was also searched for similar reports with “Claritin.” These searches revealed one complaint (2006) of potential confusion with the “Children’s Claritin” packaging; implicating that the “up to 24 days of relief Children’s Claritin 24 hours” was misleading to how long the medication would last. However, this confusion does not appear to have resulted in an actual error with a patient; thus, DMETS will continue to monitor for further confusion or error. The proposed labeling does not appear to have such “days supply” statements. As for the marketed tablet formulations, there were no errors involving confusion with the nomenclature, labels, or labeling of the current non-prescription Claritin product line.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the addition of the descriptor “12 Hour” to the proprietary name of Claritin Reditabs, the primary concerns relating to look-alike and sound-alike confusion with currently marketed Claritin product line.

DMETS conducted prescription studies to simulate the prescription ordering process. In this case,

there was confirmation that the proposed name could be confused with the existing Claritin product line. One participant in the voice study identified the product as “Claritin” omitting the modifier “Reditabs 12 hour.” Omission of the 12 Hour modifier was also seen with two voice, two outpatient, and seven inpatient participants. These results are anticipated when a new product is introduced into the marketplace.

Currently, there is an approved 10 mg Claritin Reditabs 24 hour marketed to adults and pediatric patients. Since this proposed 12 hour formulation is for twice daily usage, DMETS is concerned for the potential for confusion. The potential for harm would result in a patient who used the 24-hour formulation twice daily in lieu of the 12 hour formulation. The adverse events seen in doses above 10 mg were somnolence, tachycardia, and headache. The 12 and 24 hour formulations are both marketed for children six years of age and above, thus the adverse events of extrapyramidal signs and palpitations that were reported in doses above 10 mg in children are applicable. Due to the potential severity in outcomes, the labeling of these two products must be sufficient to inhibit confusion and error between Claritin Reditabs 24 hour and Claritin Reditabs 12 hour. In addition to the label and labeling recommendations outlined in Section III of this review, DMETS also recommends that educational measures be taken to emphasize the difference between the 24 hour and 12 hour formulation. This plan should be executed before and after product launch.

### **III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES**

In review of the Claritin® RediTabs 12 Hour container label (blister foils) and carton labeling, DMETS has focused on safety issues relating to possible medication errors. DMETS has identified the following areas of improvement, which might minimize potential user error.

#### **A. GENERAL COMMENTS**

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#### **B. CONTAINER LABEL (Individual Blisters)**

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C. CARTON LABELING

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ON ORIGINAL**

Appendix A: Prescription Study Results for Claritin Redi-Tabs 12 Hour

<b>Inpatient</b>	<b>Outpatient</b>	<b>Voice</b>
Claritin Redi-Tabs 12 hr	Claritin Reditabs 12-hour	Claritin Redi-Tabs 12 hr.
Claritin Red tabs 12 hour	Claritin RediTabs 12 hour	Claritin Reditabs 12-hour
Claritin Redi-Tabs 12 hour	Claritin Reditabs 12 hours	Claritin redi-tabs 12-hour
Claritin rédi-tabs 12 hr	Claritin Redi-Tabs 12 hour	Claritin Reditabs 12 hr
Claritin Redi-Tabs	Claritin Redi-tabs 12 hour	Claritin RediTabs 12 Hour
Claritin Redi Tabs	Claritin Reditab 12 hour	Claritan Ready Tabs 12-hr
Claritin Redi Tabs 12 hour	Claritin Reditabs	Claritin Reditabs 12 hour
Claritin Reditabs	Claritin Reditabs 12 hour	Claritin RediTab
Claritin Reditabs	Claritin Reditabs 12 hour	Clariten
Claritin Rech-tabs 12 hr	Claritin Reditabs 12 hour	Claritin Redi-tabs
Claritin Redi Tabs	Claritin Redi-tabs 12h	Claritin Redi-Tabs 12 Hr
Claritin Reditabs	Claritin Redi-tabs	Claritin Ready Tabs 12 hour
Claritin Redi-tabs	Claritin Redtabs 12 hr	Claritin Redi-Tabs 12-hour
Clarintin Redi-Tabs 12 hr		Claritin Reditabs 12 hour
Claritin Redi-tabs 12 hr		Claritin Reditab 12 hour
		Claritin ready tabs 12-hour
		Claritin Readytab-12 hours

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/s/  
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