

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-840**

**PROPRIETARY NAME REVIEW(S)**





The Saegis<sup>5</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 for Seasonique and ~~\_\_\_\_\_~~, consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. Since ~~\_\_\_\_\_~~ and ~~\_\_\_\_\_~~ are closely related, an additional prescription study for ~~\_\_\_\_\_~~ was not performed. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary names Seasonique, ~~\_\_\_\_\_~~. 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 Seasonique ~~\_\_\_\_\_~~ acceptable from a promotional perspective.
2. The Expert Panel identified one proprietary name that was thought to have the potential for confusion with Seasonique, ~~\_\_\_\_\_~~. The product is listed in table 1 (see below), along with the dosage forms available and usual dosage.

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

Product Name	Established name (Dosage forms)	Usual adult dose	Other**
Seasonique	Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol Tablets: 0.15 mg/0.03 mg and 0.03 mg	Take one tablet by mouth once daily.	
Seasonale	Levonorgestrel and Ethinyl Estradiol Tablets: 0.15 mg/ 0.03 mg	Take one tablet by mouth once a daily.	SA/LA

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

B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to Seasonique, ~~\_\_\_\_\_~~ were discussed by the Expert Panel (EPD).

<sup>5</sup> Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

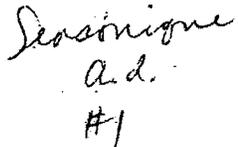
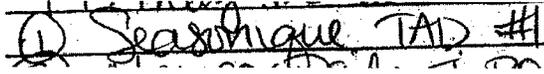
C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Six separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Seasonique 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 122 health care professionals (pharmacists, physicians, and nurses) for each. This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Seasonique (see below)

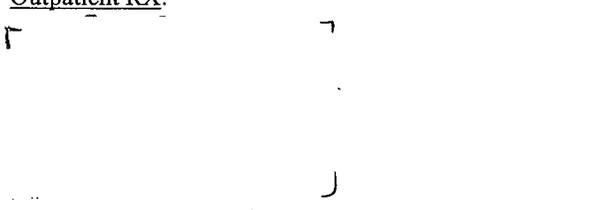
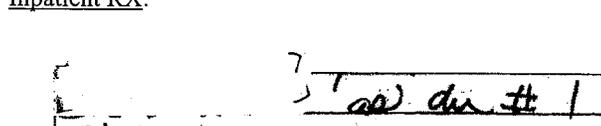
These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health 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.

**Seasonique**

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p>Outpatient RX:</p> 	<p>Seasonique Take as directed Dispense 1</p>
<p>Inpatient RX:</p> 	

2. Results:

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

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p>Outpatient RX:</p> 	<p>Take as directed Dispense 1</p>
<p>Inpatient RX:</p> 	

3. Results:

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

D. SAFETY EVALUATOR RISK ASSESSMENT

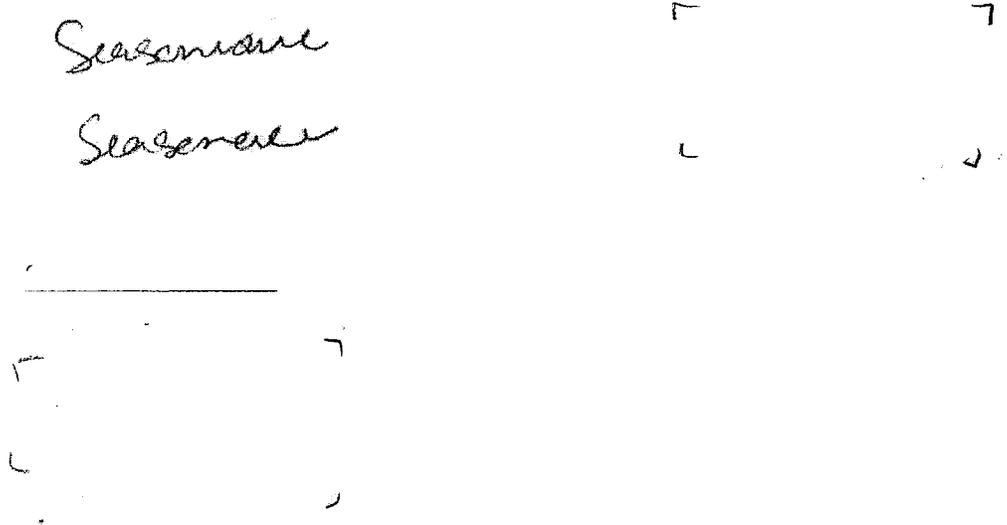
In reviewing the proprietary names Seasonique, ~~Seasonique~~, the primary concerns related to look-alike and sound-alike confusion with Seasonale. Since Seasonique, ~~Seasonique~~ are essentially phonetically and orthographically identical, all drug names were reviewed simultaneously.

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

Seasonale may look and sound similar to Seasonique; ~~Seasonique~~. Seasonale is an oral contraceptive that consists of a 91-day regimen of 84 active tablets (levonorgestrel/estradiol) and 7 inert tablets. Seasonale is taken once daily, and it extends a woman's menstrual cycle to just four times per year. Seasonique, ~~Seasonique~~ are orthographically and phonetically similar to Seasonale because they all share the same root name "Season", and they contain 3 syllables. The endings are slightly phonetically different ("ale" vs. "ique", ~~Seasonique~~). However, on scripted prescriptions, it is common for prescribers to trail off the last letters of a name. In which case, the "que" ending of Seasonique can look like the "ale" ending of Seasonale if the letter "q" is written in upper case letters. Furthermore, under the same circumstances, the endings ~~Seasonique~~ may resemble the "ale" ending of Seasonale. Since the Seasonique/ ~~Seasonique~~ is available in one strength just as Seasonale is available in only one strength, a prescription can be written without the product strength. Seasonique, ~~Seasonique~~ share many overlapping characteristics such as active ingredients, indication for use, usual dose, frequency of administration, route of administration, dosage form and sponsor. In addition, since both products are oral contraceptives, the medications would be

prescribed in the same patient population by the same health care providers (specialists-OB/GYN physicians or general practitioners). The multitude of overlapping characteristics, a common route name and orthographic similarities may increase the risk of confusion and medication errors between these products.

Seasonique/Seasonale



The potential exist for selection errors between Seasonale and Seasonique ~~\_\_\_\_\_~~. Since all of the drug products share the same root name and active ingredients, they will appear adjacent to one another on computer order entry screens and they will be side-by-side on the pharmacy shelf. This will highly increase the likelihood of selection errors. Postmarketing surveillance has shown that there have been numerous selection errors between oral contraceptives with the same root name and active ingredients (Ortho Cyclen, Ortho Tricyclen, Othro Tricyclen Lo). Therefore, DMETS has strong concerns about the potential for selection errors between the drug products.

Moreover, Seasonique ~~\_\_\_\_\_~~ and Seasonale are all 91-day cycle dosing regimens. The last seven days of Seasonale are white inert tablets, whereas the last seven days of Seasonique, ~~\_\_\_\_\_~~ and ~~\_\_\_\_\_~~ are seven yellow tablets containing 0.01 mg of ethinyl estradiol. Many patients do not take the last seven inert tablets in their birth control pack. DMETS is concerned that patients may also omit the last seven tablets of this new product formulation, not realizing that the last seven tablets actually contain medication. In this case, the patient would not receive the benefits of the last seven days of low dose ethinyl estradiol.

**III. COMMENTS TO THE SPONSOR:**

DMETS does not recommend the use of the proprietary names Seasonique, ~~\_\_\_\_\_~~. In reviewing the proprietary names, the primary concerns related to look-alike and/or sound-alike confusion with Seasonale.

Seasonale may look and sound similar to Seasonique, ~~\_\_\_\_\_~~. Seasonale is an oral contraceptive that consists of a 91-day regimen of 84 active tablets (levonorgestrel/estradiol) and 7 inert tablets. Seasonale is taken once daily, and it extends a woman's menstrual cycle to just four times per year. Seasonique, ~~\_\_\_\_\_~~ are orthographically and phonetically similar to Seasonale

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Seasonique/Seasonale

*Seasonique*

*Seasonale*

\_\_\_\_\_

*Seasonique*

*Seasonale*

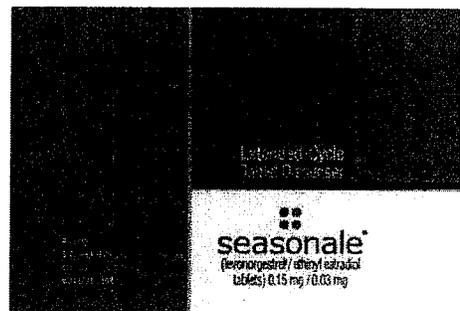
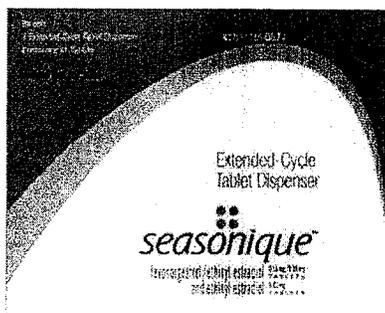
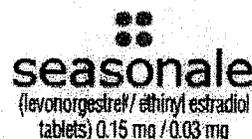
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Additionally, DMETS reviewed the labels and labeling from a safety perspective. DMETS has identified the following areas of possible improvement, which may minimize potential user error.

#### A. GENERAL COMMENT

1. The sponsor currently markets Seasonale, another extended-cycle oral contraceptive. We note that the sponsor has elected to use the same logo in the labeling of Seasonale on the labeling of Seasonique. The four pink dots in a square formation appear above the middle of each name. Although Seasonique is slightly italicized, the names appear almost identical (see example below). We recommend removing the four dot logo and differentiating the names more prominently to ensure that the potential for confusion is minimized. In addition, both product labeling contains a raspberry, blue, green and white colored panel on the carton and pouch. Although the design layout of the primary display panel of Seasonique and Seasonale appears to be different, the colors apparent on the Seasonique panel may be a cognitive reminder to the health care provider that the product is Seasonale. Therefore, we recommend using an entirely different color scheme to differential these products.



2. DMETS does not have a sample of the proposed blister pack container for Seasonique. Therefore, we recommend significantly differentiating the color of the blister pack container in order to alert the user that the product is different from Seasonale.
3. The term "extended-cycle" is used on the blister label and carton labeling. DEMTS is concerned the terminology "extended-cycle" implies these oral contraceptive tablets or dosing schedule provides an additional benefit over other oral contraceptive tablets or dosing schedules. DMETS recommends the removal of the terminology "extended-cycle".

#### B. BLISTER LABEL (Physician sample and Commercial product)

Please ensure the lot number and expiration date are located on the blister label.

#### C. CARTON LABELING (Physician sample and Commercial product)

See General Comment A1.



Appendix A. Seasonique Prescription Study Results

<b>Written Inpatient</b>	<b>Written Outpatient</b>	<b>Verbal</b>
Seasonique	Seasonique	C-Vonique
Seasonique	Seasonique	Evaleave
Seasonique	Seasonique	evenique
Seasonique	Seasonique	Fevanique
Seasonique	Seasonique	Kevaneke
Seasonique	Seasonique	Seasonique
Seasonique	Seasonique	Seasonique
Seasonique	Seasonique	Seevanique
Seasonique	Seasonique	Seeveniz
Seasonique	Seasonique	Sudanique
Seasonique	Seasonique	Susinique
Seasonique	Seasonique	Zevenique
Seasonique	Seasonique	
Seasonique	Sensinique	
	Sensonique	
	Seosonigne	
	Seosonique	

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Alina Mahmud  
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DRUG SAFETY OFFICE REVIEWER

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