

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-386**

**PROPRIETARY NAME REVIEW(S)**

**From:** Marchick, Julie  
**To:** "SSIK (Sabina Sheikh)";  
**CC:**  
**Subject:** NDA 22-232 PrandiMet Proprietary Name Review Comments  
**Date:** Friday, March 07, 2008 8:03:51 AM  
**Attachments:** Proprietary Name Review Comments.pdf

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Good Morning Sabina,

Please see the attached document containing comments regarding your proposed tradename.

Feel free to contact me if you have any questions.

Thanks,  
Julie

**Julie Marchick**  
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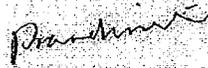
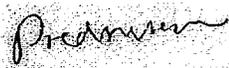
**Comments Regarding NDA 22-232**  
**Proprietary Name Review for PrandiMet**

The findings of our Proprietary Name Risk Assessment indicate that the proposed name, Prandimet, has similarity to other proprietary and established drug names and appears to be vulnerable to name confusion that could lead to medication errors with Prednisone, Prandin and Avandamet. These concerns are described in detail below.

As such, the Division of Medication Error Prevention objects to the use of the proprietary name, Prandimet for this product. We recommend the Applicant submit two alternate proprietary names and identify their primary and secondary choice. We strongly recommend that the alternate names avoid the root 'Prandi-' given the existing medication errors associated with Prandin name confusion.

**1. Prednisone**

Prednisone was identified through postmarketing surveillance as a name that was orthographically confused with the root name, Prandin. Although only one case of name confusion occurred between these two products, we believe there may be greater risk of medication errors between Prednisone and Prandimet. The names Prednisone and Prandimet have greater orthographic similarity due to the elongated ending of Prandimet, and because the names are closer in length (10 letters versus 9 letters). The beginning of each name may appear similar when scripted ('Pred-' versus 'Prand-'), and the letter 'i' appears in a similar position. If the endings of the names trail off the names may be difficult to distinguish from one another. Since the metformin strength of Prandimet is constant (500 mg), it may be omitted from prescriptions. In this case, Prednisone and Prandimet overlap in strength (1 mg), in addition to overlapping dosage form (tablet), route of administration (oral), and achievable dose (up to 10 mg). Therefore, in addition to the increased potential for orthographic confusion, the aforementioned overlapping product characteristics enhance the risk of medication errors between Prednisone and Prandimet.



**2. Avandamet**

The proposed Prandimet product could be confused with Avandamet because of their similarity in nomenclature (both share similar syllables '-andimet' versus '-andamet'), which causes the names to look and sound similar to one another. Additionally, the beginning portion of each name may appear orthographically similar (Pr- versus Av-) when scripted. We believe these similarities could lead to confusion and medication errors when interpreting a prescription.

In addition to orthographic and phonetic similarities, Prandimet and Avandamet share several overlapping product characteristics. Both drugs are indicated for the same patient population: patients with type 2 diabetes mellitus. Additionally, Avandamet and

Prandimet share overlapping strengths (1 mg/ 500 mg and 2 mg/500 mg), the same route of administration (oral), dosage form (tablet), and frequency of administration (twice daily).

Postmarketing evidence supports the FMEA findings. Medication errors have occurred between Prandin and Avandia, and factors contributing to confusion between Prandin and Avandia include orthographic similarity, overlapping indication (type 2 diabetes), strength (2 mg), achievable dose (2 mg to 16 mg), dosage form (tablets), and frequency of administration (twice daily). Since errors have occurred between Prandin and Avandia, it is likely that medication errors will also occur between Prandimet and Avandamet because the root names of these products have already been confused with one another, and they also share several overlapping product characteristics that contribute to the overall risk of error. Therefore, due to the strong orthographic similarity and phonetic similarity, along with the overlapping product characteristics, we believe that confusion and medication errors will occur between Prandimet and Avandamet.

*Avandamet  
Prandimet*

### 3. Prandin

The Division of Medication Error Prevention believes that medication errors will occur between Prandin and Prandimet. Prandin is the root name of Prandimet. It contains one of the active ingredients present in Prandimet (repaglinide). Prandin and Prandimet share orthographic and phonetic similarities as they both contain the same prefix (Prandi-). Similar to Prandimet, Prandin is also indicated for patients with type 2 diabetes. Additionally, since the metformin dose is constant for Prandimet (500 mg), Prandimet may be prescribed based upon the repaglinide dose (1 mg or 2 mg), which overlaps with Prandin. Furthermore, both drugs also share an overlapping dosage form (tablet), route of administration (oral), frequency of administration (2-3 times daily with meals), and overlapping achievable repaglinide dose (up to 10 mg).

We are concerned that medication errors are likely to occur upon computer order entry, especially if the short mnemonic is used such as 'PRAND'. Both names will show up on the screen, and since they share the same active ingredient (repaglinide) and have overlapping repaglinide strengths (1 mg and 2 mg), the potential exists for practitioners to select the wrong product. Therefore, a patient prescribed Prandin may actually be dispensed Prandimet or vice versa. Either way a patient may become hypoglycemic or not receive the adequate treatment to regulate their blood glucose levels. Therefore, due to orthographic and phonetic similarities, and due to the potential for computer order entry selection errors, we find that medication errors will likely occur between Prandin and Prandimet.

*Prandimet  
Prandin*

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/s/

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3/7/2008 08:06:11 AM  
CSO