

Naming, Labelling and Packaging Incident Examples

ISMP Canada

October 10, 2013

Samples of Angeliq (Drospirenone and Estradiol-17 β) Mistakenly Provided as Birth Control



- 3 incidents in which physicians gave samples of this product to patients instead of oral contraceptives
 - progestin dose used for hormone replacement therapy is substantially lower than in oral contraceptives
 - effective dose of estrogen used for hormone replacement therapy is less than that used in oral contraceptives
 - if a woman who has not yet reached menopause uses Angeliq instead of an oral contraceptive, she could become pregnant - the consequences of the mix-up could be devastating

Samples of Angeliq (Drospirenone and Estradiol-17 β) **Mistakenly Provided as Birth Control**

Potential Contributing Factors:

- progestin–estrogen combination in Angeliq appears similar to the combination of ingredients in oral contraceptives
- labelling and packaging is similar to oral contraceptives
- inner and outer package label does not specify the indication (treatment of menopausal symptoms) or the target patient population (postmenopausal women)
- prescribers stored samples of Angeliq in the same location as samples of oral contraceptives
 - Notably, during ISMP Canada’s review of these incidents, it was discovered that a community pharmacy was mistakenly storing Angeliq in the same location as oral contraceptive products.
- “Angeliq” sounds like a woman’s - many oral contraceptive products include (or sound similar to) a woman’s name (e.g., Alesse, Apri, Linessa, Portia, Yasmin, Yaz)




Potential for Confusion between Pradax and Plavix



- an otherwise healthy patient was scheduled for an endovascular coiling procedure to treat a brain aneurysm
- several days before the procedure, the neurosurgeon wrote a prescription for Plavix 150 mg daily with ASA 325 mg daily (to prevent platelet aggregation and clot formation during surgery)
- day before surgery patient admitted and during medication reconciliation, the pharmacist noticed that the patient was taking Pradax 150 mg daily instead of the intended Plavix 150 mg daily
- Order for Plavix had been misinterpreted and Pradax had been dispensed in error by community pharmacy.
- The neurosurgeon was notified of the error, and the procedure was postponed.

Potential for Confusion between Pradax and Plavix

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on Pradax® and Plavix®

November 8, 2011

Subject: Risk of potential patient harm associated with name confusion involving the prescription drugs Pradax® and Plavix®.

Boehringer Ingelheim (Canada) Ltd., and sanofi-aventis Canada Inc. (on behalf of Bristol-Myers Squibb Sanofi Canada partnership) in consultation with Health Canada, would like to alert patients to the risk of medication errors associated with the mix-up of the names of two prescription drugs, Pradax® (dabigatran) and Plavix® (clopidogrel).

Pradax® is a blood thinner prescribed to patients who have a heart condition called atrial fibrillation (irregular heartbeat) to prevent strokes as well as to patients following hip or knee replacement surgery to prevent blood clots.¹ Plavix® helps keep platelets in the blood from sticking together and forming clots that could lead to heart attack or stroke. Plavix® combined with acetylsalicylic acid (ASA), can also be prescribed to patients with an irregular heartbeat that cannot take blood thinners.²

Since January 2011, there have been a total of 5 Canadian cases involving drug name mix-ups between Pradax® and Plavix®, including 1 case that resulted in patient harm (non-serious bleeding after a medical procedure). In addition, there have been 2 reports of concerns raised by health care professionals about potential for confusion between the names of these two drugs.

- Mix-ups between the drug names Pradax® and Plavix® have been associated with similarities in the names, when spoken or written, and in their use in patients with certain heart conditions or at risk of blood clots.
- Receiving Pradax® instead of Plavix® or vice versa, may result in patient harm, including increased risk of bleeding, stroke, heart attack or blood clots.
- Pradax® and Plavix® work in different ways and are used in different circumstances. Patients are encouraged to be aware of the names and uses of the medications they are taking and to keep a list of current medications with them. Should you have any questions regarding the prescription, contact your doctor or pharmacist.



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A KEY PARTNER IN

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Brand Name Change for Dabigatran: Pradax Is Now Pradaxa

In 2011, ISMP Canada published a safety alert (based on voluntary reports received) to highlight the potential for confusion between the brand names Pradax (dabigatran etexilate) and Plavix (clopidogrel).¹ As an update, the brand name for dabigatran etexilate has recently been changed from Pradax to Pradaxa. As of January 2013, the new brand name will appear on packaging and labelling; however, any products labelled "Pradax" that are still in stock may be distributed and used as directed by a physician until the expiry date stated on the package. For additional information about the name change and transition, please visit the manufacturer's website at: http://www.boehringer-ingelheim.ca/content/dam/internet/opu/ca_EN/documents/humanhealth/Pradaxa_name_Change_HCP_Letter.pdf

Reference

1. Drug name alert: potential for confusion between Pradax and Plavix. ISMP Can Saf Bull. 2011 May 27;11(4):1-2. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPSCSB2011-04-DrugNameAlert_PotentialForConfusion_PradoxAndPlavix.pdf