

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

Angeliq, a combination product containing progestin and estrogen, is a relatively new medication intended to relieve symptoms associated with menopause.^{1,2} ISMP Canada has been alerted to 2 incidents in which physicians gave samples of this product to patients instead of oral contraceptives (birth control). In both cases, the error was discovered when the patient went to fill her prescription for Angeliq at a community pharmacy, after completing the samples received several months before.

The dose of the progestin component used for hormone replacement therapy (i.e., in drugs like Angeliq) is substantially lower than the dose of progestin used in oral contraceptives. Similarly, the potency or effective dose of estrogen used for hormone replacement therapy is less than that used in oral contraceptives.³ If a woman who has not yet reached menopause uses Angeliq instead of an oral contraceptive, she could become pregnant, and the consequences of the mixup could be devastating. These 2 reports suggest that labelling, packaging, and patient information for Angeliq could be improved.

The following were identified as potential underlying causes of the incidents:

- The progestin–estrogen combination in Angeliq appears similar to the combination of ingredients in

birth control pills. However, Angeliq contains 1 mg each of drospirenone and estradiol-17 β , whereas for example, Yasmin oral contraceptive tablets contain 3 mg of drospirenone and 0.03 mg of ethinyl estradiol (a more potent estrogen).

- The labelling and packaging of Angeliq (Figures 1 and 2) is similar in design to the labelling and packaging for oral contraceptives, and for both types of products, a 28-day supply is provided in each package.
- Neither the label on the outer package of Angeliq nor the label on the inner package specifies the indication (treatment of menopausal symptoms) or the target patient population (postmenopausal women) (Figures 1, 2, and 3).
- 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 name, and the brand names of many oral contraceptive products include (or sound similar to) a woman’s name (e.g., Alesse, Apri, Linessa, Portia, Yasmin, Yaz).



Figure 1: The front panel of the outer package for Angeliq.

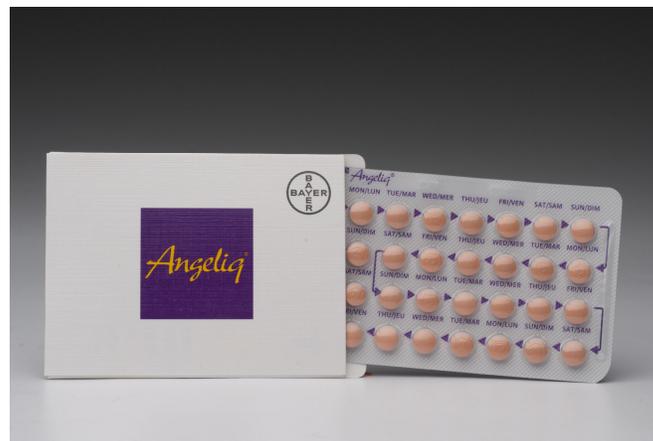


Figure 2: The main panel of the inner package for Angeliq, along with the blister pack of tablets.

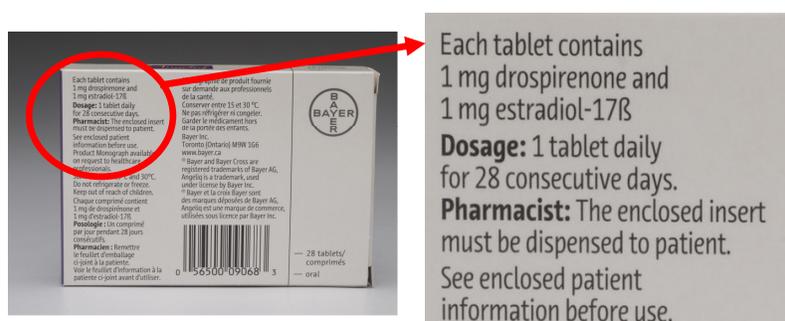


Figure 3: The back panel of the outer package for Angeliq. Neither the indication (treatment of menopausal symptoms) nor the intended patient population (postmenopausal women) is mentioned on the package label.

ISMP Canada has alerted the manufacturer and other stakeholders about the potential confusion involving Angeliq.

Packages of Angeliq should always be stored separately from oral contraceptives in prescribers' offices, clinic

settings, community pharmacies, and any other settings where both types of drugs are present. ISMP Canada encourages wide sharing of this alert among prescribers, including family practice residents, community pharmacists, and other healthcare providers.

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