

## New Drug Approvals

### Generic Name (Trade Name) Company

August 16, 2018

### **Segesterone acetate and ethinyl estradiol vaginal system**

### Uses/Notes

FDA has [approved](#) segesterone acetate and ethinyl estradiol vaginal system under the trade name Annovera. The combined hormonal contraceptive is the first vaginal ring contraceptive that can be used for an entire year.

Annovera is a reusable donut-shaped (ring), nonbiodegradable, flexible vaginal system that is placed in the vagina for 3 weeks, followed by 1 week out of the vagina, at which time women may experience a period (a withdrawal bleed). This schedule is repeated every 4 weeks for 1 year (thirteen 28-day menstrual cycles).

The ring is washed and stored in a compact case for the 7 days not in use. It does not require refrigeration prior to dispensing and can withstand storage temperatures up to 30° C (86° F).

Efficacy and safety of Annovera were studied in three open-label clinical trials that included healthy women ranging in age from 18 to 40 years. The results showed that about 2 to 4 women out of 100 may get pregnant during the first year they use Annovera.

Annovera carries a boxed warning on cigarette smoking and serious cardiovascular events. Women older than 35 who smoke should not use Annovera. Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use.

Annovera also is contraindicated and should not be used in women with a high risk of arterial or venous thrombotic diseases; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; liver tumors, acute hepatitis, or severe (decompensated) cirrhosis; undiagnosed abnormal uterine bleeding; hypersensitivity to any of the Annovera components; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

The most common adverse effects are similar to those of other combined hormonal contraceptive products,

***(Annovera—The Population Council)***

**New vaginal ring provides 1 year of birth control**

such as headache/migraine, nausea/vomiting, yeast infections, abdominal pain, dysmenorrhea, breast tenderness, irregular bleeding, diarrhea, and genital itching.

FDA is requiring postmarketing studies to further evaluate the risks of venous thromboembolism and the effects of CYP3A-modulating drugs and tampon use on the pharmacokinetics of Annovera.

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<http://www.aphanet.org/new-drug-approvals/new-vaginal-ring-provides-1-year-birth-control>

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