

ABOUT ANNOVERA

ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system) is the only long-lasting, reversible contraceptive that delivers 1-year (13 cycles) of birth control, is patient-controlled and procedure-free.¹

Just one prescription of ANNOVERA offers month-to-month protection from pregnancy for an entire year (13 cycles), so there's no need to make frequent visits to a healthcare provider or pharmacy.

ANNOVERA is as effective as a pill without the daily hassle.

The ring is soft and flexible and is designed to fit comfortably inside a woman's body, allowing for easy insertion and removal. ANNOVERA is the same size as a tampon and most women don't feel ANNOVERA once it is correctly in place. For additional information on how to use ANNOVERA, please refer to the [educational video](#).

ANNOVERA's long-lasting reversible option gives women complete control over when and for how long they want to use contraception. ANNOVERA is entirely procedure free, so the patient can control both her fertility and menstruation (inserted for 21 continuous days and removed for 7 days each cycle) and can choose to stop using it at any time if she changes her mind about birth control.



ANNOVERA releases an average continuous daily dose of 150 mcg/day of a novel non-androgenic progestin, segesterone acetate, and 13 mcg/day of estrogen (ethinyl estradiol), making it one of the lowest dose combination hormonal contraceptives on the market.¹

Segesterone acetate demonstrated no androgenic, estrogenic, or glucocorticoid activity at contraceptive doses* and has the highest anti-ovulatory potential of available progestins.²

If you are using ANNOVERA, you can download the ANNOVERA mobile app that will allow you to track your insertion and removal dates and receive reminders for when refills are due. The app also includes a how-to video and frequently asked questions. The app is available for download via the usual app portals, including the Apple App Store and Google Play.

*Based on pharmacological studies in animals and in vitro studies. The clinical significance of these data is not known.

Please see Indication and Important Risk Information, including Boxed Warning, on the following pages

ANNOVERA CLINICAL DATA

Based on data from two clinical trials, ANNOVERA was shown to be 97.3% effective in preventing pregnancy when used as directed.

Overall, nearly 90% of women in a global clinical trial were satisfied with ANNOVERA as form of contraception.[†] Most women ranked ANNOVERA highly in characteristics related to ease-of-use, comfort, expulsion, and physical effects during sexual activity.[‡]

In clinical trials, ANNOVERA showed high rates of adherence[‡], low rates of discontinuation due to irregular bleeding and expulsion[§], and no alteration of the vaginal microbiome or increased vaginal infections with 13 cycles of use.[¶]

ACCESS TO ANNOVERA



ANNOVERA has unrestricted access on a variety of health plans, including the public health sector, as well as for women in the military. Most have no out-of-pocket costs.⁴



We are working with healthcare providers to ensure they are aware of the brand, and with leading online birth control prescription and delivery services, such as **Pill Club**, **PillPack**, **PlushCare**, **Simple Health** and **Nurx**, to help ensure wide availability of ANNOVERA.



While the majority of women who get ANNOVERA don't have a co-pay, with the ANNOVERA Savings Program, those with a co-pay could pay as little as \$60 for a year of birth control.^{**}



ANNOVERA is available in public health clinics, college and university health clinics, and city, county, state and federal facilities, including many state Medicaid programs.

[†]In an ANNOVERA Phase 3 study, a product acceptability questionnaire was administered and completed at the end of Cycle 3 (n=1036). Results based on data from 905 subjects in the areas of ease of use, expulsion, side effects, and sex/intercourse.

[‡]Adherence is defined as following the 21-day-in/7-day-out cyclic regimen and not removing the vaginal system >2 hours in the preceding cycle.

[§]In clinical trials (N=2308), 12% of participants discontinued ANNOVERA due to an adverse reaction: Metrorrhagia/menorrhagia (1.7%), Headache, including migraine (1.3%), Vaginal discharge/vulvovaginal mycotic infections (1.3%), and Nausea/vomiting (1.2%). In addition, 1.4% of participants discontinued ANNOVERA due to vaginal system expulsion.

[¶]In a sub-study of 110 women, ANNOVERA showed no increase in vaginitis, bacterial vaginosis, or yeast infections and no changes in the vaginal flora after 13 cycles of use. In clinical studies of 2308 women, vulvovaginal infections and vaginal discharge were common adverse reactions, leading to discontinuation in 1.3% of women.

^{**}Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Please see Program Terms, Conditions, and Eligibility Criteria at savings.annovera.com.

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INDICATION

ANNOVERA is a progestin/estrogen combination hormonal contraceptive (CHC) indicated for use by females of reproductive potential to prevent pregnancy.

Limitation of use: Not adequately evaluated in females with a BMI of $> 29 \text{ kg/m}^2$.

IMPORTANT RISK INFORMATION

Do not use ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious heart and blood vessel (cardiovascular) side effects from hormonal birth control methods, including death from heart attack, blood clots, or stroke. This risk increases with age and the number of cigarettes you smoke.

ANNOVERA does not protect against HIV infection (AIDS) and other sexually transmitted infections.

DO NOT USE ANNOVERA IF YOU

- have or have had a blood clot in your arms, legs, lungs, or eyes.
- have had a stroke.
- have reduced blood flow to your brain (cerebrovascular disease).
- have reduced blood flow or blockage in 1 or more of the arteries that supply blood to your heart (coronary artery disease).
- have had a heart attack.
- have heart rhythm or heart valve problems that increase your risk of having blood clots, such as an infection of the inner lining of the heart and heart valves or a type of irregular heartbeat called
- atrial fibrillation.
- have a problem with your blood that makes it clot more than normal.
- have high blood pressure that is not controlled with medicine or have high blood pressure with blood vessel damage.
- have diabetes and are over 35 years old; have diabetes with high blood pressure or problems with your kidneys, blood vessels, eyes, or nerves; or have had diabetes for longer than 20 years.
- have headaches with changes in vision, numbness or weakness, have migraine headaches with aura, or are over age 35 years old and have any type of migraine headaches.
- have liver disease or liver tumors.
- have or have had breast cancer or any cancer that is sensitive to the female hormones estrogen or progesterone.
- have unexplained vaginal bleeding.
- are allergic to segesterone acetate, ethinyl estradiol, or any of the ingredients in ANNOVERA.
- take any Hepatitis C drug combination medicine containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

WARNINGS

ANNOVERA can cause serious side effects, including: blood clots; toxic shock syndrome (TSS); liver problems, including liver tumors; high blood pressure; gallbladder problems; changes in the sugar and fat (cholesterol and triglycerides) levels in your blood; headache; irregular or unusual vaginal bleeding and spotting between your menstrual periods; depression; possible cancer in your cervix; swelling of your skin especially around your mouth, eyes, and in your throat (angioedema); dark patches of skin on your forehead, cheeks, upper lip, and chin (chloasma). **Call your healthcare provider or get emergency medical care right away if any of these serious side effects occur.**

THE MOST COMMON SIDE EFFECTS OF ANNOVERA INCLUDE:

- headache, including migraine
- nausea/vomiting
- vaginal yeast infection (candidiasis)
- lower/upper abdomen pain
- painful periods
- vaginal discharge
- urinary tract infection
- breast pain/tenderness
- irregular vaginal bleeding
- diarrhea
- genital itching

USE

ANNOVERA is a ring-shaped vaginal system with hormones used by females to prevent pregnancy.

ANNOVERA has not been adequately studied in females with a body mass index >29 kg/m².

The risk information provided here is not complete. To learn more, review the ANNOVERA Patient Information and talk with your healthcare provider or pharmacist. The FDA-approved product labeling, including Patient Information, can be found at ANNOVERA.com.

You may report side effects to the FDA at www.fda.gov/medwatch or by calling 1-800-FDA-1088. You may also report side effects to TherapeuticsMD at 1-888-228-0150.

REFERENCES

1. ANNOVERA® Full Prescribing Information. Boca Raton, FL; TherapeuticsMD Inc. 2020.
2. Kumar N, Koide SS, Tsong Y, Sundaram K: Nestorone: a progestin with a unique pharmacological profile. *Steroids*. 2000 Oct-Nov;65(10-11):629-36.
3. Merkatz RB, Plagianos M, Hoskin E et al. Acceptability of the Nestorone®/ethinyl estradiol contraceptive vaginal ring: development of a model; implications for introduction." *Contraception*. 2014;90(5):514-521.
4. Planned Parenthood. About Health Insurance. Available at: <https://www.plannedparenthood.org/get-care/health-insurance/about-health-insurance>.