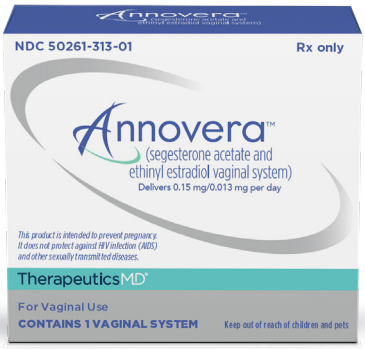
Annovera™
(segesterone acetate and ethinyl estradiol vaginal system)
Delivers 0.15 mg/0.013 mg per day

NOW AVAILABLE



The first and only long-lasting†, patient-controlled, reversible birth control[1] that does not require a medical procedure or repeat doctor visits

†1 year (13 cycles) when left in place 21 days and removed 7 days per cycle.

NATIONAL DRUG CODE

NDC#: 50261-313-01

ANNOVERA DOSAGE FORM & STRENGTH

Silicone elastomer vaginal system containing 103 mg segesterone acetate (SA) and 17.4 mg ethinyl estradiol (EE), which releases on average 0.15 mg/day of SA and 0.013 mg/day of EE

ANNOVERA PATIENT SAVINGS

Eligible patients **pay as little as $60 per year** for one 12-month ANNOVERA — about $5 per month for 13 cycles

Patients text **YEAR** to **38745**** or go to **savings.ANNOVERA.com** to register and receive an activated e-card by text or email

*Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state health care programs. Program Terms, Conditions, and Eligibility Criteria apply. Visit savings.ANNOVERA.com for complete details.
**Message and data rates may apply. Reply HELP for help; reply STOP to cancel at any time. Up to 20 messages per month per request.

IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS
See full prescribing information for complete boxed warning.

- Females over 35 years old who smoke should not use ANNOVERA.
- Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use.

Please see additional Important Safety Information on the following page and Full Prescribing Information, including BOXED WARNING, at www.ANNOVERA.com.

IMPORTANT SAFETY INFORMATION (CONT'D)

CONTRAINDICATIONS

ANNOVERA 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 components of ANNOVERA; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- Stop ANNOVERA if a thrombotic or thromboembolic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years.
- Discontinue if jaundice occurs.
- Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir. ANNOVERA can be restarted 2 weeks following completion of this regimen.
- Do not prescribe ANNOVERA for females with uncontrolled hypertension or hypertension with vascular disease. Monitor blood pressure and stop use if blood pressure rises significantly in females with well-controlled hypertension.
- Monitor glucose in pre-diabetic or diabetic females taking ANNOVERA. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias.
- Patients using ANNOVERA who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated. ANNOVERA should be discontinued if indicated.
- Other warnings include: gallbladder disease; depression; cervical cancer; increased serum concentrations of binding globulins; hereditary angioedema; chloasma (females who tend to develop chloasma should avoid exposure to the sun or UV radiation while using ANNOVERA); toxic shock syndrome (TSS) (if a patient exhibits symptoms of TSS, remove ANNOVERA, and initiate appropriate medical treatment); vaginal use (ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration).

ADVERSE REACTIONS

The most common adverse reactions reported in at least 5% of women who received ANNOVERA were: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, lower/upper abdominal pain, dysmenorrhea, vaginal discharge, urinary tract infection, breast pain/tenderness/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with ANNOVERA.

INDICATION

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

Limitation of Use: ANNOVERA has not been adequately studied in females with a body mass index of >29 kg/m^2.

Please note that this information is not comprehensive. Please click here for the Full Prescribing Information, including BOXED WARNING.

Reference: 1. ANNOVERA [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2019.

TherapeuticsMD®

For Her. For Life.

This article is sponsored by TherapeuticsMD®.

Important Education for Patients Regarding a Long-Lasting Reversible Contraceptive

ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system) is a progestin/estrogen combined hormonal contraceptive indicated for use by females of reproductive potential to prevent pregnancy. ANNOVERA is the only FDA-approved long-lasting reversible contraceptive that does not require a procedure. ANNOVERA contains a novel progestin, segesterone acetate.[1] Unlike other progestins, segesterone acetate has demonstrated no androgenic activity.[2a] The 13 mcg ethinyl estradiol daily dose is one of the lowest doses on the market. A single ANNOVERA prescription provides fertility and menstruation control for 13 consecutive 28-day cycles (1 year), and pharmacists can provide counseling support with just a single conversation, either during the initial pharmacy visit or over the phone if the prescription is not used immediately. Pharmacists have an important role in counseling patients on birth control. Patient understanding should be confirmed prior to dispensing self-administered birth control. Counseling can involve answering patient questions and educating on product-specific features, administration, storage, and expiration.[1]

DOSING AND ADMINISTRATION

ANNOVERA is a nonbiodegradable, soft, flexible ring that patients can fold into a size no wider than a tampon for the simple, 6-step insertion and removal process (TABLE). It is inserted for 21 continuous days and removed for 7 days each cycle for 13 cycles. Counsel on the 6-step insertion and removal process and the 28-day cycle, emphasizing the importance of maintaining a calendar of insertion and removal dates to optimize adherence.[1,3]

EXPIRATION

The first insertion of ANNOVERA must be prior to the 18-month expiration date that is printed on the packaging. Show patients where the expiration date is printed. Advise them that if the first insertion of ANNOVERA is prior to the date of expiration, contraception will be provided for a full 13 cycles (1 year).[1] Offer availability to answer future questions via phone.

STORAGE

Counsel patients that, before and after each use, ANNOVERA should be washed and dried. During each 7-day vaginal system-free interval, ANNOVERA should be stored in its black compact case at 20°C to 25°C (68°F to 77°F). Excursions are permitted to 15°C to 30°C (59°F to 86°F). It should not be stored in direct sunlight, exposed to excessive heat, or put in the refrigerator or freezer. After 13 cycles of use, ANNOVERA should be discarded in its case via a drug take-back option if possible. By counseling on ANNOVERA, pharmacists can help patients adhere to guidelines for optimal efficacy.[1]

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

REFERENCES

1. ANNOVERA [Prescribing Information]. Boca Raton, Florida: TherapeuticsMD, Inc; 2020. 2. Kumar N, Koide SS, Tsong Y, Sundaram K. Nestorone: a progestin with a unique pharmacological profile. Steroids. 2000;65(10-11):629-636. doi:10.1016/s0039-128x(00)00119-7 3. Carlin EP, Spielmann HM, inventors; The Proctor & Gamble Company, assignee. Tampon. US Patent 7,338,483 B2. March 4, 2008.

IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

See full prescribing information for complete boxed warning.

- **Females over 35 years old who smoke should not use ANNOVERA.**
- **Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use.**

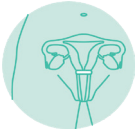
CONTRAINDICATIONS

ANNOVERA 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 components of ANNOVERA; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- Stop ANNOVERA if a thrombotic or thromboembolic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years.
- Discontinue if jaundice occurs.
- Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir. ANNOVERA can be restarted 2 weeks following completion of this regimen.
- Do not prescribe ANNOVERA for females with uncontrolled hypertension or hypertension with vascular disease. Monitor blood pressure and stop use if blood pressure rises significantly in females with well-controlled hypertension.
- Monitor glucose in pre-diabetic or diabetic females taking ANNOVERA. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias.

TABLE. INSERTING AND REMOVING ANNOVERA®[1]

	**STEP 1:**	Clean the ring	First wash and dry hands. Then remove ANNOVERA from the package and wash and dry the ring with mild soap and water and pat dry.
	**STEP 2:**	Prepare to insert	Using thumb and index finger, squeeze the ANNOVERA ring into a narrow oval shape.
	**STEP 3:**	Choose a comfortable position	The ANNOVERA ring can be inserted while lying down, squatting, or standing with 1 leg up.
	**STEP 4:**	Insert ANNOVERA into vagina	The ring should be inserted as far as possible into the vagina, and should not be felt. If the ring feels uncomfortable, it may not have been inserted far enough. ANNOVERA does not need to be in an exact position to work. Note: Be sure to record the date of insertion.
	**STEP 5:**	Ensure ANNOVERA is in place	Once in place, ANNOVERA sits in the vagina (as pictured), without obstructing the vaginal canal.
	**STEP 6:**	Removing the ring	Wash and dry hands and assume a comfortable position (see Step 3). Then reach into the vagina, hook the ring using the index finger, and pull downward and forward to remove. Wash the ANNOVERA ring with mild soap and lukewarm water, pat dry, and store it in the case provided. Note: Be sure to record the date of removal.

This cycle can be repeated 13 times with 1 prescription.

IMPORTANT SAFETY INFORMATION (*continued*)
WARNINGS AND PRECAUTIONS (*continued*)

- Patients using ANNOVERA who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated. ANNOVERA should be discontinued if indicated.
- Other warnings include: gallbladder disease; depression; cervical cancer; increased serum concentrations of binding globulins; hereditary angioedema; chloasma (females who tend to develop chloasma should avoid exposure to the sun or UV radiation while using ANNOVERA); toxic shock syndrome (TSS) (if a patient exhibits symptoms of TSS, remove ANNOVERA, and initiate appropriate medical treatment); vaginal use (ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration).

ADVERSE REACTIONS

The most common adverse reactions reported in at least 5% of women who received ANNOVERA were: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, lower/upper abdominal pain, dysmenorrhea, vaginal discharge, urinary tract infection, breast pain/tenderness/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with ANNOVERA.

INDICATION

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

Limitations of Use: ANNOVERA has not been adequately studied in females with a body mass index >29 kg/m^2.

Please note that this information is not comprehensive. Please see Brief Summary of Prescribing Information, including BOXED WARNING on the adjacent pages. For the Full Prescribing Information, please go to ANNOVERA.com.

ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use ANNOVERA safely and effectively. Please visit **ANNOVERA.com/pi.pdf** for Full Prescribing Information (PI).

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive (CHC) use. This risk increases with age, particularly in females over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs should not be used by females who are over 35 years of age and smoke.

INDICATIONS AND USAGE

ANNOVERA is indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use: ANNOVERA has not been adequately studied in females with a BMI >29 kg/m^2.

DOSAGE AND ADMINISTRATION

One ANNOVERA is inserted in the vagina. The vaginal system must remain in place continuously for 3 weeks (21 days) followed by a 1-week (7-day) vaginal system-free interval. One vaginal system provides contraception for thirteen 28-day cycles (1 year). Follow instructions for starting ANNOVERA, including switching from other contraceptive methods, and use after abortion, miscarriage, or childbirth *[see How to Start ANNOVERA (2.2) in PI]*.

Contraceptive efficacy of ANNOVERA may be reduced if a woman deviates from the recommended use. If ANNOVERA is out of the vagina for more than 2 continuous hours or more than 2 cumulative hours during the 21 days of continuous use, then back-up contraception, such as male condoms or spermicide, should be used until the vaginal system has been in the vagina for 7 consecutive days.

CONTRAINDICATIONS

ANNOVERA is contraindicated in females who are known to have the following conditions: • A high risk of arterial or venous thrombotic diseases. Examples include females who are known to: smoke, if over age 35; have current or history of deep vein thrombosis or pulmonary embolism; have cerebrovascular disease; have coronary artery disease; have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation); have inherited or acquired hypercoagulopathies; have uncontrolled hypertension or hypertension with vascular disease; have diabetes mellitus and are over age 35, diabetes mellitus with hypertension or vascular disease, or other end-organ damage, or diabetes mellitus of >20 years duration; have headaches with focal neurological symptoms, migraine headaches with aura, or are over age 35 with any migraine headaches. • 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 components of ANNOVERA. Hypersensitivity reactions reported include: throat constriction, facial edema, urticaria, hives, and wheezing. • Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for alanine transaminase (ALT) elevations.

WARNINGS AND PRECAUTIONS

Thromboembolic Disorders and Other Vascular Conditions

Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.

Stop ANNOVERA if a thrombotic or thromboembolic event occurs, or unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately. Stop ANNOVERA at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery in females who are not breastfeeding. Before starting ANNOVERA, consider history and risk factors of thrombotic or thromboembolic disorders. ANNOVERA is contraindicated in females with a high risk of arterial or venous thrombotic/thromboembolic diseases.

Arterial Events

Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years. CHCs increase the risk of cardiovascular events and cerebrovascular events, such as stroke and myocardial infarction. The risk is greater among older females (>35 years of age), smokers, and females with hypertension, dyslipidemia, diabetes, or obesity.

Venous Events

The use of CHCs increases the risk of VTE, such as deep vein thrombosis and pulmonary embolism. Risk factors for VTEs include smoking, obesity, and family history of VTE, in addition to other factors that contraindicate use of CHCs. The rates of VTE are even greater during pregnancy, and especially during the postpartum period. The risk of VTE is highest during the first year of CHC use and when restarting hormonal contraception following a break of 4 weeks or longer. The risk of VTE due to CHCs gradually disappears after use is discontinued.

Liver Disease

Impaired Liver Function

ANNOVERA is contraindicated in females with acute hepatitis or severe (decompensated) cirrhosis of the liver. Discontinue ANNOVERA if jaundice develops. Acute liver test abnormalities may necessitate the discontinuation of ANNOVERA use until the liver tests return to normal and ANNOVERA causation has been excluded.

Liver Tumors

ANNOVERA is contraindicated in females with benign or malignant liver tumors. Hepatic adenomas are associated with CHC use (estimated 3.3 cases/100,000 CHC users). Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir. ANNOVERA can be restarted 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

Hypertension

ANNOVERA is contraindicated in females with uncontrolled hypertension or hypertension with vascular disease. For all females, including those with well-controlled hypertension, monitor blood pressure at routine visits and stop ANNOVERA if blood pressure rises significantly.

Age-Related Considerations

The risk for cardiovascular disease and prevalence of risk factors for cardiovascular disease increase with age. Certain conditions, such as smoking and migraine headache without aura, that do not contraindicate CHC use in younger females, are contraindications to use in women over 35 years of age. Consider the presence of underlying risk factors that may increase the risk of cardiovascular disease or VTE, particularly before initiating ANNOVERA for women over 35 years, such as hypertension, diabetes, dyslipidemia, and obesity.

Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among CHC users. Use of CHCs may also worsen existing gallbladder disease. A past history of CHC-related cholestasis predicts an increased risk with subsequent CHC use. Females with a history of pregnancy-related cholestasis may be at an increased risk for CHC-related cholestasis.

Adverse Carbohydrate and Lipid Metabolic Effects

Hyperglycemia

ANNOVERA is contraindicated in diabetic females over age 35, or females who have diabetes with hypertension, nephropathy, retinopathy, neuropathy, other vascular disease, or females with diabetes of >20 years duration. ANNOVERA may decrease glucose tolerance. Carefully monitor prediabetic and diabetic females who are taking ANNOVERA.

Dyslipidemia

Consider alternative contraception for females with uncontrolled dyslipidemia. ANNOVERA may cause adverse lipid changes. Females with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using ANNOVERA.

Headache

ANNOVERA is contraindicated in females with certain headaches. Evaluate new or significant changes in headaches, including migraines, and discontinue ANNOVERA if indicated.

Bleeding Irregularities and Amenorrhea

Females using ANNOVERA may experience unscheduled (breakthrough) bleeding and spotting, especially during the first month of use. If unscheduled bleeding occurs or persists, check for causes such as pregnancy or malignancy.

Based on subject diaries from the two clinical efficacy trials of ANNOVERA, 5–10% of females experienced unscheduled bleeding per 28-day cycle. A total of 41 subjects (1.7%) discontinued use due to menstrual disorders including metrorrhagia, menorrhagia, and abnormal withdrawal bleeding. Females who are not pregnant and use ANNOVERA may experience amenorrhea. Based on subject diary data from two clinical trials for up to 13 cycles, amenorrhea occurred in 3–5% of females per cycle using ANNOVERA and in 0.9% of females in all 13 cycles. If scheduled bleeding does not occur, consider the possibility of pregnancy.

Depression

Carefully observe females with a history of depression and discontinue ANNOVERA if depression recurs to a serious degree.

Cervical Cancer

Some studies suggest that CHCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia.

Effect on Binding Globulins

The estrogen component of ANNOVERA may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

Hereditary Angioedema

In females with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

Chloasma

Chloasma may occur with ANNOVERA use, especially in females with a history of chloasma gravidarum. Advise females who tend to develop chloasma to avoid exposure to the sun or ultraviolet radiation while using ANNOVERA.

Toxic Shock Syndrome (TSS)

If a patient exhibits signs/symptoms of TSS, consider the possibility of this diagnosis, remove ANNOVERA, and initiate appropriate medical evaluation and treatment.

Vaginal Use

Some females are aware of the vaginal system on occasion during the 21 days of use or during coitus, and partners may feel the vaginal system during coitus. ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration. Vaginal and cervical erosion and/or ulceration has been reported in females using other contraceptive vaginal devices. In some cases, the ring adhered to vaginal tissue, which necessitated removal by a healthcare provider.

ADVERSE REACTIONS

Clinical Trial Experience

Most Common Adverse Reactions

In clinical trials, adverse reactions reported in by ≥5% of ANNOVERA-treated subjects include: headache, including migraine (38.6%); nausea/vomiting (25.0%); vulvovaginal mycotic infection/vaginal candidiasis (14.5%); abdominal pain/lower/upper (13.3%); dysmenorrhea (12.5%); vaginal discharge (11.8%); UTI/cystitis/pyelonephritis/genitourinary tract infection (10.0%); breast pain/tenderness/discomfort (9.5%); metrorrhagia/menstrual disorder (7.5%); diarrhea (7.2%); and genital pruritus (5.5%).

Adverse Reactions Leading to Discontinuation

Among subjects using ANNOVERA for contraception, 12% discontinued from the clinical trials due to an adverse reaction. Adverse reactions leading to discontinuation by ≥1% of ANNOVERA-treated subjects, include: metrorrhagia/menorrhagia (1.7%); headache, including migraine (1.3%), vaginal discharge/vulvovaginal mycotic infections (1.3%); nausea/vomiting (1.2%). In addition, 1.4% of subjects discontinued ANNOVERA use due to vaginal system expulsions.

Serious Adverse Reactions

Serious adverse reactions occurring in ≥2 subjects were: VTEs (deep venous thrombosis, cerebral vein thrombosis, pulmonary embolism); psychiatric events; drug hypersensitivity reactions; and spontaneous abortions.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a backup or alternative method of contraception when enzyme inducers are used with ANNOVERA. Do not co-administer ANNOVERA with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations.

USE IN SPECIFIC POPULATIONS

Pregnancy

Discontinue ANNOVERA if pregnancy occurs.

Lactation

Not recommended for nursing mothers; can decrease milk production.

Pediatric Use

Safety and efficacy of ANNOVERA have been established in women of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 as for users 18 years and older. Use of ANNOVERA before menarche is not indicated.

Geriatric Use

ANNOVERA has not been studied in females who have reached menopause and is not indicated in this population.

Hepatic Impairment

No studies have been conducted to evaluate the effect of hepatic impairment on the disposition of ANNOVERA. Acute or chronic disturbances of liver function may necessitate the discontinuation of CHC use until markers of liver function return to normal and CHC causation has been excluded.

Renal Impairment

No studies were conducted in subjects with renal impairment; ANNOVERA is not recommended in patients with renal impairment.

Body Mass Index (BMI)/Body Weight

The safety and efficacy of ANNOVERA in females with a BMI >29 kg/m^2 have not been adequately evaluated because this subpopulation was excluded from the clinical trials after 2 VTEs occurred in females with a BMI > 29 kg/m^2. Higher body weight is associated with lower systemic exposure of SA and EE.

Manufactured for: TherapeuticsMD, Inc.
Boca Raton, FL 33431
Based on ANVA-LAB-20001.2 01/2020

TherapeuticsMD®

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