

Patient Information
ANNOVERA® (ann-o-VER-ah)
(segesterone acetate and ethinyl estradiol vaginal system)

Read this Patient Information carefully before you decide if ANNOVERA is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about ANNOVERA, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

What is the most important information I should know about ANNOVERA?

- **Do not use ANNOVERA 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 (STIs).

What is ANNOVERA?

ANNOVERA is a hormone-releasing system used by females who are able to become pregnant to prevent pregnancy. You insert ANNOVERA into your vagina. ANNOVERA is in the shape of a ring that is reusable for 1 year. The vaginal system is made of silicone and contains two female hormones that are slowly released into your vagina and then enter your blood. One hormone is an estrogen called ethinyl estradiol. The other hormone is a progestin called segesterone acetate.

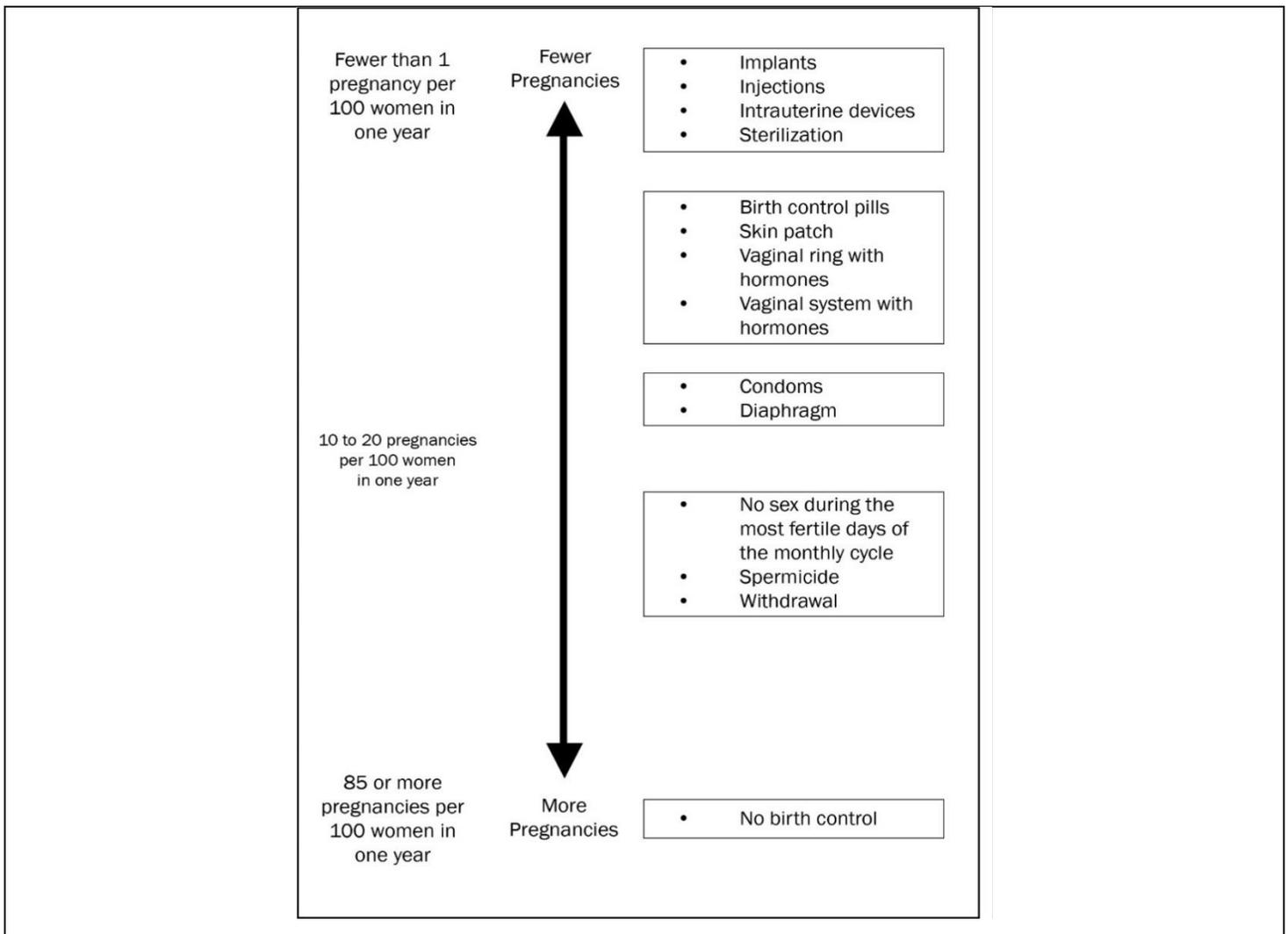
How well does ANNOVERA work for contraception?

Your chance of getting pregnant depends on how well you follow the directions for using the vaginal system. The more carefully you follow the directions, the less chance you have of getting pregnant.

Based on the results of two clinical studies that lasted 12 months, about 2 to 4 women out of 100 women may get pregnant during the first year they use ANNOVERA. ANNOVERA was designed to be reused for 1 year. Replace ANNOVERA at the end of 1 year if you choose to continue using ANNOVERA. There is not enough hormone left in the vaginal system to provide you effective birth control after 1 year of use.

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in how well they work to prevent pregnancy. The most effective methods are at the top of the chart. The box at the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

ANNOVERA, a vaginal system with hormones, is in the second box from the top of the chart.



Who should not use ANNOVERA?

Do not use ANNOVERA if you:

- smoke and are over 35 years old.
- 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. See the end of this leaflet for a complete list of ingredients in ANNOVERA.
- take any Hepatitis C drug combination medicine containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme alanine aminotransferase (ALT) in the blood.

What should I tell my healthcare provider before using ANNOVERA?

Before you use ANNOVERA tell your healthcare provider if you:

- have any of the conditions listed above.
- smoke.
- are pregnant or think you are pregnant.
- recently had a baby, miscarriage, or abortion.
- have breast problems such as an abnormal mammogram or breast x-ray, breast nodules, fibrocystic breast disease, or a family history of breast cancer.
- have any medical condition, especially migraine headaches, depression, seizures, diabetes, high blood pressure, high cholesterol or triglycerides, gallbladder disease, liver disease, heart disease, or kidney disease.
- have a family history of blood clots or stroke.
- have yellowing of the skin or eyes (jaundice).
- have a condition that makes your vagina become irritated easily.
- have a history of toxic shock syndrome.
- had gallbladder problems when you were pregnant.
- are scheduled for surgery. The hormones in ANNOVERA may increase your risk of blood clots after surgery. You should stop using ANNOVERA at least 4 weeks before you have surgery and not restart until at least 2 weeks after your surgery.
- are scheduled for any laboratory tests. Certain blood tests may be affected by hormonal birth control methods.
- are breastfeeding or plan to breastfeed. You should not use ANNOVERA if you are breastfeeding. The hormones in ANNOVERA may decrease your milk production. The hormones in ANNOVERA pass into your breast milk. Talk with your healthcare provider about the best birth control method for you while breastfeeding.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines, vitamins, and herbal supplements make hormonal contraception less effective, such as:

- anti-seizure medicines
- medicine used to treat fungal infections
- combinations of HIV medicines
- Hepatitis C (HCV) medicines
- non-nucleoside reverse transcriptase inhibitors
- medicine to treat tuberculosis
- medicine to treat high blood pressure in the vessels of the lung
- medicine to treat chemotherapy-induced nausea and vomiting
- St. John's wort

Talk to your healthcare provider if you take any of the medicines listed above to see if the specific medicine you take may make hormonal contraceptives less effective. Use a back-up or another birth control method when you take medicine that may make hormonal contraceptives less effective and for 28 days after stopping the medicine.

Do not use any vaginal products such as oil-based suppositories, oil-based creams, or oil-based gels while the vaginal system is in your vagina. **Do not** use any vaginal lubricants that have silicone or oil in them. Water-based lubricants are ok to use. **Be sure to read the ingredients on the label carefully before you buy a vaginal lubricant.**

Some medicines and grapefruit juice may increase the level of ethinyl estradiol in your blood if used together, including:

- the pain reliever acetaminophen
- ascorbic acid (vitamin C)
- types of medicines used to treat fungal infections
- HIV medicines
- non-nucleoside reverse transcriptase inhibitors
- medicines to lower cholesterol

ANNOVERA may affect the way that lamotrigine (a medicine used to treat seizures) works and may increase the risk of seizures. Your healthcare provider may need to adjust your dose of lamotrigine.

Females who take thyroid hormone replacement medicine or corticosteroid replacement medicine may need increased doses of their thyroid hormone or cortisol medicines.

Ask your healthcare provider if you are not sure if you take any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Talk to your healthcare provider before you start taking a new medicine.

How should I use ANNOVERA?

- Read the **Instructions for Use** at the end of this Patient Information that comes with ANNOVERA for information about the right way to insert, remove, clean, store, and dispose of (throw away) ANNOVERA.
- Use ANNOVERA exactly as your healthcare provider tells you to use it.

ANNOVERA is a hormonal birth control method that is used for 3 out of 4 weeks every month. The same vaginal system is reusable for up to 1 full year (1 year includes 13 cycles; each cycle is 28 days).

After you insert ANNOVERA for the first time, you will remove it at the end of week 3 and leave it out for 7 days. You will reinsert ANNOVERA at the end of week 4 of each 4-week cycle. You will repeat this pattern with ANNOVERA for up to 13 cycles. Scheduled insertions and removals of ANNOVERA should be at about the same time of the day and the same day of the week for each monthly cycle.

- The **day** of the week when you first insert ANNOVERA (referred to as “Day 1”) is your vaginal system change day.
- For each cycle, you put the vaginal system into your vagina and let it stay there 3 weeks (21 full days). **Remember to keep the vaginal system in for the whole 3 weeks (21 full days).**
- You take the vaginal system out on your vaginal system change day (Day 22) and **let it stay out for 1 week (7 full days)**. Note that your vaginal system should be cleaned with warm water and mild soap, dried with a clean cloth towel or paper towel, and stored in the case provided, away from children, pets, and extreme temperatures. (See the Instructions for Use.)
- Then you start over again for another 4 weeks. You may not be bleeding when you put the vaginal system in.
- Always put the vaginal system in or take it out on your vaginal system change day at about the same time of day. For example, if you put your vaginal system in on Monday at 9:00 in the morning, always take it out or put it back in on Monday at about 9:00 in the morning.
- You do not have to take the vaginal system out when you have sex. If you decide to remove it, remember to reinsert it within 2 hours after removing it or you may not be protected from pregnancy. **However, if ANNOVERA is out of your vagina for more than 2 hours at one time or if ANNOVERA is out of your vagina at different times that add up to more than a total of 2 hours over the first 21 days of your cycle, you will need to use another method of birth control** (such as male condoms or spermicide) until ANNOVERA has been in your vagina for 7 days in a row.

The diagram shows the timing for putting the vaginal system in and taking it out for 2 cycles.

Schedule			
Cycle 1	Put vaginal system in → (vaginal system change day)	Day 1	Weeks 1, 2, and 3 Days 1-21
	Take vaginal system out → (vaginal system change day)	Day 22	Week 4 Days 22-28
Cycle 2 (repeat for Cycles 3-13)	Put vaginal system in → (vaginal system change day)	Day 1	Weeks 1, 2, and 3 Days 1-21
	Take vaginal system out → (vaginal system change day)	Day 22	Week 4 Days 22-28

- Repeat the 4-week cycle for all 13 cycles of the use of the vaginal system.
- Do not use the vaginal system for more than 13 cycles (1 year). At the end of the 13 cycles, take the vaginal system out of your vagina. Place the used vaginal system in the case that comes with ANNOVERA and dispose of it (throw away) at a drug take-back location, if available. If a drug take-back location is not available, dispose of it in the trash out of reach of children and pets. **Do not** flush ANNOVERA down the toilet.
 - If you want to continue using ANNOVERA after 13 cycles, you will need to receive a new prescription from your healthcare provider for a new vaginal system.
- If you start using ANNOVERA 4 or more weeks after having a baby and you have not had a menstrual period yet, you should use another method of birth control until you have used ANNOVERA for 7 days in a row.

What happens if I am off schedule using the vaginal system?

It is very important to follow the schedule every cycle and remove and insert ANNOVERA on your vaginal system-in and vaginal system-out days at about the same time. If you take the vaginal system out too soon or put it back in too late, your chance of getting pregnant is higher.

If you are more than 1 or 2 days off schedule for vaginal system insertion you will need to use new vaginal system-in and vaginal system-out days for the remaining cycles of use. You will also need to use back-up contraception, such as condoms or spermicide, for the first 7 days of the new schedule if you have sexual intercourse.

If you put the vaginal system back in:	Then:
Too early , after it had been out for only 5 or 6 days.	Keep the vaginal system in for at least 3 weeks (21 days) . You may keep it in up to your normal vaginal system-out day .
Too late , after it had been out for more than 7 days.	Put the vaginal system back in right away. You will now have a new vaginal system-in day . You must use condoms or spermicide as back-up contraception for the next 7 days when you have sexual intercourse.
If you took the vaginal system out:	Then:
Too early , after it had been in for only 19 or 20 days.	Leave the vaginal system out for 1 week. Put it back in after the week is over, as you would normally do. You may then keep it in up to your normal vaginal system-out day , 22 or 23 days after you put the vaginal system in.
Too late , after it had been in for 22 or 23 days.	Remove the vaginal system as soon as you realize this. Then reinsert the vaginal system 7 days later.

During the 21 days of continuous use, if ANNOVERA is out of the vagina for more than 2 continuous hours or more than 2 cumulative hours (multiple inadvertent removals or expulsions adding up to 2 hours), 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.

What if I miss my menstrual period or if I think I am pregnant?

It is possible that you are pregnant if you miss your scheduled period (no bleeding on the 7 days that the vaginal system is out). Tell your healthcare provider right away that you have missed your period. Also, tell your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. It is important that your healthcare provider check you to find out if you are pregnant. You may need a pregnancy test to determine if you are pregnant. Do not remove the vaginal system until you are certain you are pregnant. Stop using ANNOVERA if your healthcare provider tells you that you are pregnant.

What are the possible side effects of ANNOVERA?

ANNOVERA can cause serious side effects, including:

See: "What is the most important information I should know about ANNOVERA?"

- **blood clots.** Like pregnancy, hormonal contraceptives increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age greater than 35. This increased risk is highest when you first start taking hormonal contraceptives and when you restart the same or different hormonal contraceptive after not using it for 4 weeks or more.

It is possible to die or be permanently disabled from a problem caused by a blood clot, such as a heart attack or a stroke. Some examples of serious blood clots are blood clots in the:

- legs (deep vein thrombosis)
- lungs (pulmonary embolus)
- eyes (loss of eyesight)
- heart (heart attack)
- brain (stroke)

Call your healthcare provider or get emergency medical care right away if you have:

- leg pain that does not go away
- sudden shortness of breath
- sudden changes in vision or blindness

- severe pain or pressure in your chest
- a sudden, severe headache unlike your usual headaches
- weakness or numbness in an arm or leg
- trouble speaking

• **toxic shock syndrome (TSS).** Some symptoms of TSS are the same as flu symptoms, but they can become serious very quickly. Call your healthcare provider or get emergency medical care right away if you have the following symptoms:

- | | |
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| ○ sudden high fever | ○ a sunburn-like rash |
| ○ vomiting | ○ muscle aches |
| ○ diarrhea | ○ dizziness |
| ○ fainting or feeling faint when standing up | |

• **liver problems, including liver tumors.** Tell your healthcare provider right away if you have yellowing of your skin or eyes (jaundice).

• **high blood pressure.**

• **gallbladder problems** or worsening of a gallbladder problem you already have. You may have an increased risk of gallbladder problems with the use of ANNOVERA if you had gallbladder problems when you were pregnant.

• **changes in the sugar and fat (cholesterol and triglycerides) levels in your blood.**

• **headache.** Tell your healthcare provider if you have new headaches that keep coming back, that do not go away, or are severe. Also tell your healthcare provider if your migraine headaches happen more often or are more severe than normal.

• **irregular or unusual vaginal bleeding and spotting between your menstrual periods,** especially during the first month of using ANNOVERA, or the absence of menstrual periods (amenorrhea).

• **depression.**

• **possible cancer in your cervix.**

• **swelling of your skin especially around your mouth, eyes, and in your throat (angioedema).** Call your healthcare provider or get emergency medical care right away if you have a swollen face, lips, mouth, tongue, or throat as this may lead to difficulty swallowing or breathing. Your risk of having angioedema is higher if you have a history of angioedema.

• **dark patches of skin on your forehead, cheeks, upper lip, and chin (chloasma).** Your risk of getting chloasma with the use of ANNOVERA is higher if you had chloasma during pregnancy. Women who tend to get chloasma should avoid spending a long time in sunlight, tanning booths, and under sunlamps while using ANNOVERA. Use sunscreen if you have to be in the sunlight.

The most common side effects of ANNOVERA include:

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

This is not a complete list of possible side effects. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to TherapeuticsMD® at 1-888-228-0150.

No serious problems have been reported from a hormonal contraceptive overdose.

Does hormonal birth control cause cancer?

It is not known if hormonal birth control causes breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control because some breast cancers are sensitive to hormones.

Women who use hormonal contraceptives may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

What should I know about my period when taking ANNOVERA?

When you take ANNOVERA you should expect to have regular 28-day cycles. Each period is likely to last about 5 days. You may have bleeding or spotting between your scheduled periods especially during the first cycle. This bleeding or spotting tends to decrease after the first cycle. Do not stop taking ANNOVERA because of this bleeding or spotting. If the spotting continues for more than 7 consecutive days or if the bleeding is unusually heavy, call your healthcare provider. Tell your healthcare provider if you do not have your period.

What if I want to become pregnant?

You may stop using ANNOVERA whenever you wish. Consider a visit with your healthcare provider for a pre-pregnancy checkup before you stop taking ANNOVERA.

General information about the safe and effective use of ANNOVERA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ANNOVERA for a condition for which it was not prescribed. Do not give ANNOVERA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about ANNOVERA that is written for health professionals.

What if I have other questions?

If you have concerns or questions, ask your healthcare provider.

What are the ingredients in ANNOVERA?

Active ingredients: segesterone acetate and ethinyl estradiol.

Inactive ingredients: dibutyltin dilaurate, silicone elastomers, silicone medical adhesive, and titanium dioxide.

Instructions for Use
ANNOVERA® (ann-o-VER-ah)
(segesterone acetate and ethinyl estradiol vaginal system)

Read this Instructions for Use carefully before you decide if ANNOVERA is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about ANNOVERA, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

How should I start using ANNOVERA?

If you are not currently using hormonal birth control, start using ANNOVERA between Days 2 and 5 of your menstrual period.

- If your menstrual periods are not regular or if you start using ANNOVERA more than 5 days from when you started your menstrual period, you should use a barrier method of birth control, such as a male condom or spermicide during sexual intercourse for the first 7 days you use ANNOVERA.

If you are changing from a birth control pill or patch or monthly disposable contraceptive vaginal ring to ANNOVERA:

- If you have been using your birth control method correctly and are certain that you are not pregnant, you can change to ANNOVERA any day of your birth control cycle. Do not start ANNOVERA any later than the day you would start your next birth control pill, apply your next patch or insert your next monthly disposable contraceptive vaginal ring.

If you are changing from a progestin-only birth control method, such as a minipill, injection, implant or intrauterine system (IUS):

- You may switch from a minipill on any day. Start using ANNOVERA on the day that you would have taken your next minipill.
- You should switch from an injectable and start using ANNOVERA on the day when your next injection would be due.
- You should switch from an implant or the IUS and start using ANNOVERA at the time the implant or IUS is removed.

If you are changing from a minipill, injection, implant, or an intrauterine system to ANNOVERA, you should use a barrier method of birth control, such as a male condom or spermicide, during sexual intercourse for the first 7 days you use ANNOVERA.

If you start using ANNOVERA after an abortion or miscarriage:

- **Following a first trimester abortion or miscarriage:** You may start ANNOVERA within 5 days following a first trimester abortion or miscarriage (the first 12 weeks of pregnancy). You do not need to use an additional birth control method.
 - If you do not start ANNOVERA within 5 days after a first trimester abortion or miscarriage, use a non-hormonal birth control method, such as male condoms or spermicide, while you wait for your menstrual period to start. **Start using ANNOVERA between days 2 and 5 of your menstrual period.**
 - If you start using ANNOVERA more than 5 days from when you started your menstrual period, you should use a barrier method of birth control, such as a male condom or spermicide during

sexual intercourse for the first 7 days you use ANNOVERA.

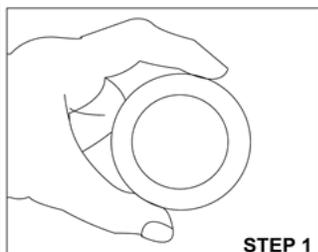
- **Following a second trimester abortion or miscarriage:** You may start using ANNOVERA no sooner than 4 weeks (28 days) after a second trimester abortion (after the first 12 weeks of pregnancy).

If you are starting ANNOVERA after childbirth:

- You may start using ANNOVERA no sooner than 4 weeks (28 days) after having a baby if you are not breastfeeding.
- If you have not gotten your menstrual period after childbirth, you should talk to your healthcare provider. You may need a pregnancy test to make sure you are not pregnant before you start using ANNOVERA.
- Use another birth control method, such as a male condom or spermicide, during sexual intercourse for the first 7 days you use ANNOVERA if you have not yet had a period.

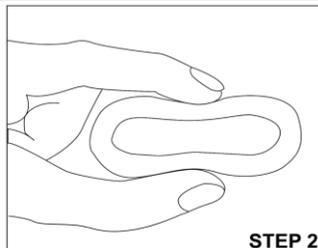
If you are breastfeeding, you should not use ANNOVERA. Use other birth control methods until you are no longer breastfeeding.

How do I use ANNOVERA?



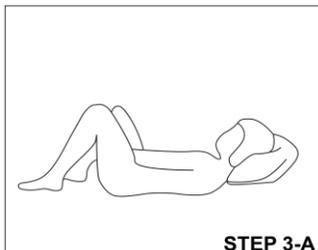
Step 1. Open the package and remove ANNOVERA.

- Wash your hands with mild soap and water. Dry them well.
- Take ANNOVERA out of its package (See Figure, Step 1).
- Wash ANNOVERA with mild soap and water, rinse and pat dry with a clean cloth towel or paper towel.



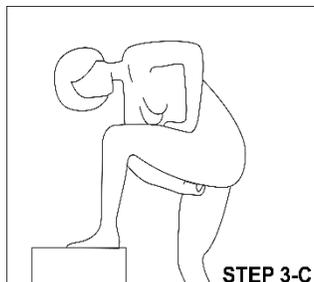
Step 2. Prepare to insert ANNOVERA.

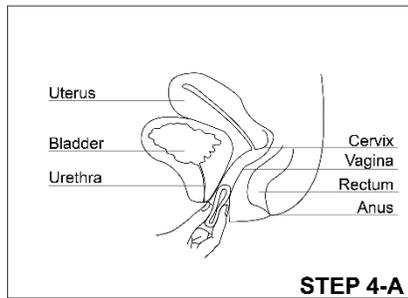
- Hold ANNOVERA between your thumb and first (index) finger.
- Press the sides of ANNOVERA together to make it narrow (See Figure, Step 2).



Step 3. Choose a position for insertion of ANNOVERA.

- Choose the position that is comfortable for you. For example, lying down, squatting, or standing with 1 leg up (See Figures, Steps 3-A, 3-B, 3-C).



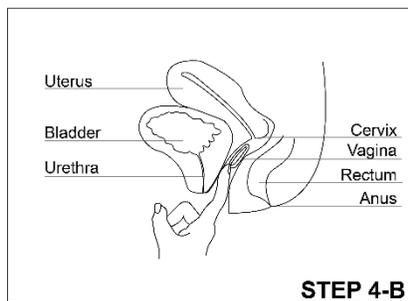


Step 4. Insert ANNOVERA into your vagina.

- Gently insert the folded ANNOVERA into your vagina (See Figure, Step 4-A).
- Push ANNOVERA further up into your vagina using your index finger.
- Push it in as far as you can. It sometimes helps to push down with the muscles in your vagina while you are inserting ANNOVERA.
- When you insert ANNOVERA, it may be in different positions in your vagina, but ANNOVERA does not have to be in an exact position for it to work.
- Mark your vaginal system “in day” on your calendar.

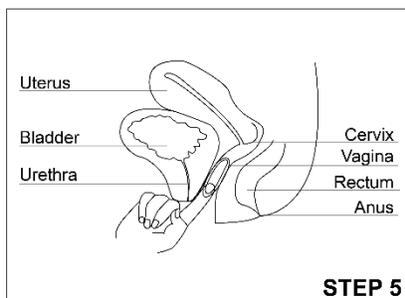
Note:

- If you feel the ANNOVERA in your vagina or if it feels uncomfortable, you may not have pushed the ANNOVERA into your vagina far enough. Use your index finger to gently push ANNOVERA as far as you can into your vagina (See Figure, Step 4-B). There is no danger of ANNOVERA being pushed too far up in the vagina or getting lost.
 - You should not feel ANNOVERA after you have placed it into your vagina.
- Some women and their partners may be aware of ANNOVERA in the vagina during sexual intercourse.



Step 5. How do I remove ANNOVERA?

- Wash and dry your hands.
- Choose the position that is most comfortable for you (See Step 3).
- Put your index finger into your vagina and hook it through ANNOVERA. Gently pull downward and forward to remove ANNOVERA and pull it out (See Figure, Step 5). It sometimes helps to push down with the muscles in your vagina while you are removing ANNOVERA.
- Wash the ANNOVERA vaginal system with mild soap and lukewarm water, pat it dry, and store in the case provided.
- Mark your vaginal system “out day” on your calendar.



What else should I know about ANNOVERA?

- The day of the week when you first insert ANNOVERA (called “Day 1”) is your vaginal system change day. This is described further in the Patient Information section entitled “How should I use ANNOVERA?”
- For each cycle, you put the vaginal system into your vagina and let it stay there 3 weeks (21 full days). **Remember** to keep the vaginal system in for the whole 3 weeks (21 full days).
- You take the vaginal system out on your vaginal system change day (Day 22) and let it stay out for 1 week (7 full days). Note that your vaginal system should be stored in the case provided, away from children, pets, and extreme temperatures.

- Then you start over again for another 4 weeks. You may not be bleeding when you put the vaginal system in.
- Always put the vaginal system in or take it out on your vaginal system change day at about the same time of day. For example, if you put your vaginal system in on Monday at 9:00 in the morning, always take it out or put it back in on Monday at about 9:00 in the morning.
- You do not have to take the vaginal system out when you have sex. If you decide to remove it, remember to reinsert it within 2 hours after removing it or you may not be protected from pregnancy. **However, if ANNOVERA is out of your vagina for more than 2 hours at one time or if ANNOVERA is out of your vagina at different times that add up to more than a total of 2 hours over the first 21 days of your cycle, you will need to use another method of birth control** until ANNOVERA has been in your vagina for 7 days in a row, such as male condoms or spermicides.
- Repeat the 4-week cycle for all 13 cycles of the use of the vaginal system.
- Do not use the vaginal system for more than 13 cycles (1 year). When you take the vaginal system out of your vagina at the end of the 13 cycles, dispose of it. See “How should I dispose of (throw away) ANNOVERA?” below.
- If you want to continue using ANNOVERA after 13 cycles, you will need to get a new prescription from your healthcare provider to obtain a new vaginal system.
- Do not use any vaginal products such as oil-based suppositories, oil-based creams, or oil-based gels while the vaginal system is in your vagina. Do not use any vaginal lubricants that have silicone or oil in them. Water-based lubricants are ok to use. Be sure to read the ingredients on the labels carefully before you buy a vaginal lubricant.
- Do not take any medicines unless your healthcare provider says it is ok to take them. Tell your healthcare provider when you start a new medicine.

How do I clean ANNOVERA?

- After removing ANNOVERA from your vagina, wash it with mild soap and warm water, rinse, and pat it dry with a clean cloth towel or paper towel before you store it. Only use mild soap and warm water to clean.
- Wash ANNOVERA with mild soap and warm water and pat it dry before you put it back into your vagina.
- Store ANNOVERA in the case provided.

How should I store ANNOVERA?

- Store ANNOVERA in the supplied case at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect ANNOVERA from direct sunlight.
- Do not refrigerate or freeze ANNOVERA.
- Avoid storing ANNOVERA in extreme heat.
- **Keep ANNOVERA and all medicines out of the reach of children and pets.**

How should I dispose of (throw away) ANNOVERA?

- After 13 cycles of use, place ANNOVERA in the case that comes with it.
- Dispose of ANNOVERA at a drug take-back location, if available. If a drug take-back location is not available, dispose of ANNOVERA in the trash, out of the reach of children and pets.
- Do not throw away ANNOVERA in the toilet.
- See www.fda.gov/drugdisposal for more information about disposal of medicines.

When does ANNOVERA become effective?

ANNOVERA becomes effective on the day it is inserted (Day 1), if it is inserted between Days 2 and 5 of your menstrual period. If ANNOVERA is inserted more than 5 days from when you start your menstrual period, you should use a barrier method of birth control, such as a male condom or spermicide, during sexual intercourse for the first 7 days you use ANNOVERA.

Will ANNOVERA interfere during sexual intercourse?

- If ANNOVERA is placed as high as possible in your vagina, it will not interfere with sexual intercourse.

Can I take ANNOVERA out during the first 3 weeks of my cycle?

- You should leave ANNOVERA in the entire 21 days (3 weeks).
 - If ANNOVERA comes out or if you remove it, put it back in as soon as possible. If you put ANNOVERA back into your vagina before 2 hours has passed, you do not need to use another method of birth control. **However, if ANNOVERA is out of your vagina for more than 2 hours at one time or if ANNOVERA is out of your vagina at different times that add up to more than a total of 2 hours over the first 21 days of your cycle, you will need to use another method of birth control** until ANNOVERA has been in your vagina for 7 days in a row, such as male condoms or spermicides.

What should I do if ANNOVERA comes out of my vagina?

ANNOVERA can slip or accidentally come out of your vagina (expelled), for example, during sexual intercourse, bowel movements, or use of tampons.

- If ANNOVERA slips out of your vagina, wash ANNOVERA with mild soap and warm water, rinse and pat dry with a clean cloth towel or paper towel and put it back in your vagina right away or within 2 hours. See “Can I take ANNOVERA out during the first 3 weeks of my cycle?” in the section above.
- ANNOVERA can move around and become visible at the opening of your vagina. If this happens follow “Step 4” above for directions on how to push ANNOVERA back to its right position.

What if I lose ANNOVERA?

- Call your healthcare provider right away if you lose ANNOVERA. You should use a back-up method of birth control such as a male condom or spermicide for preventing pregnancy until you get a new ANNOVERA.

If you have other questions call your healthcare provider.

For information, go to www.TherapeuticsMD.com or call TherapeuticsMD, Inc. at 1-877-833-0176

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