

Getting started with NEXTSTELLIS®

How is NEXTSTELLIS different?

NEXTSTELLIS is a combined oral contraceptive using estrogen that ...

- ✓ Works **differently** from other estrogens in birth control pills
- ✓ Is found **naturally** in the body
- ✓ Is produced from a **plant source**

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT NEXTSTELLIS?

WARNING TO FEMALES WHO SMOKE

Do not use NEXTSTELLIS if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots, or stroke. This risk increases with age and the number of cigarettes you smoke.

Please see the enclosed full Prescribing Information, including Boxed Warning, and Patient Information.

 **nextstellis**[®]
(drospirenone and
estetrol tablets)
3 mg/14.2 mg

For the last 50 years,
estrogens in birth control
pills have been the same ...

Until now.

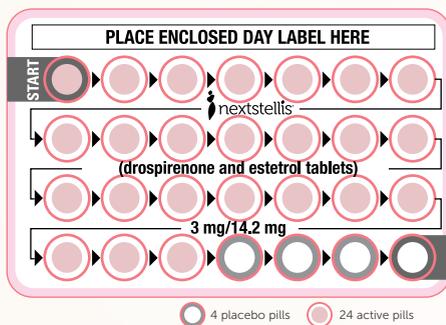
FAQs about NEXTSTELLIS®

How should I take NEXTSTELLIS?

Adding NEXTSTELLIS to your daily routine is easy.

- 1 If you start taking NEXTSTELLIS on any day other than the first day of your natural menstrual period, use a back-up non-hormonal birth control method (such as condoms or spermicide) until you have taken 1 active (pink) pill every day for 7 days.
- 2 Take your first pink pill on the first day of your next period.
- 3 Continue taking the pills in order every day, including the white pills at the end of your pack.

Pro Tip: Take your pills at the same time every day. Set an alarm on your phone to help you remember.



Important Safety Information

What is NEXTSTELLIS?

NEXTSTELLIS is a prescription combination oral birth control pill used for the prevention of pregnancy. NEXTSTELLIS does not protect against HIV infections (AIDS) and other sexually transmitted diseases. NEXTSTELLIS may be less effective if you have a body mass index (BMI) of 30 or higher.

Please see the enclosed full Prescribing Information, including Boxed Warning, and Patient Information.

How does NEXTSTELLIS work?

NEXTSTELLIS combines 2 hormones—a type of estrogen called estroretol, and a progestin called drospirenone.

estrogen + progestin = 
[estroretol] [drospirenone] [NEXTSTELLIS]

Typically, levels of these hormones rise and fall during the menstrual cycle. NEXTSTELLIS keeps the levels of these hormones constant, which blocks the hormonal changes that signal the body to release an egg (ovulate). Without ovulation, it is not possible to get pregnant.

NEXTSTELLIS is **98% effective** at preventing pregnancy when taken every day as prescribed.

What makes NEXTSTELLIS different from other birth control pills?

NEXTSTELLIS is the only birth control pill made with a type of estrogen called estroretol

- **Estroretol is unique because it is found naturally in the body**
- 99% of birth control pills that contain estrogen use a synthetic, modified form of estrogen called ethinyl estradiol
- The estroretol in NEXTSTELLIS is **produced from a plant source**

Important Safety Information

What is NEXTSTELLIS? (cont)

It is not known if NEXTSTELLIS is safe and effective in females with a body mass index (BMI) of 35 or higher. If you are moderately obese, discuss with your healthcare provider whether NEXTSTELLIS is appropriate for you.

 **nextstellis**
(drospirenone and estroretol tablets)
3 mg/14.2 mg

FAQs about NEXTSTELLIS®

What will happen to my period?

Like a natural period, most NEXTSTELLIS users had predictable monthly bleeding (called withdrawal bleeding) in clinical trials

- Most NEXTSTELLIS users experienced very little unscheduled bleeding or spotting. For those who did, the majority were spotting only*
- Unscheduled bleeding is most common in the first month and becomes less common after month 4
- Understand it may take a few months for your body to adjust. This is normal

On average,
unscheduled bleeding
or spotting lasted
LESS THAN 1 DAY

*Spotting is any light bleeding that does not require the use of sanitary protection, including pantyliners.

Important Safety Information

Who should not take NEXTSTELLIS?

Do not use NEXTSTELLIS if you smoke and are 35 years of age or older. Do not use NEXTSTELLIS if you have or have had blood clots, history of heart attack, stroke or certain heart valve problems, high blood pressure that medicine cannot control, diabetes for more than 20 years, severe migraine headaches with aura, breast cancer or any cancer that is sensitive to female hormones, liver disease or liver tumors, unexplained bleeding from the vagina, have kidney disease or kidney failure, have reduced adrenal gland function, or if you take Hepatitis C drugs containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, as this may increase levels of liver enzymes in the blood.

Please see the enclosed full Prescribing Information, including Boxed Warning, and Patient Information.

What about side effects?

NEXTSTELLIS users reported low rates of side effects



After 6 months on NEXTSTELLIS, the average weight increase was less than **1.1 lb**



Low rates of acne (4%) and lowered sex drive (2%)



The rate of blood clots—one of the most serious side effects of combined hormonal birth control pills—was **3.66 per 10,000 women-years**. In non-pregnant, non-combined pill users, the rate ranges from 1 to 5 per 10,000 women-years

In clinical trials, NEXTSTELLIS also had a low impact on:



CHOLESTEROL



TRIGLYCERIDES



GLUCOSE

The trial did not include women with complications from diabetes, women with diabetes diagnosed ≥ 20 years ago, or women taking lipid-lowering medications.

Important Safety Information

What else should I know about taking NEXTSTELLIS?

Before taking NEXTSTELLIS, tell your healthcare provider about all of your medical conditions, including if you:

- are scheduled for surgery. NEXTSTELLIS may increase your risks of blood clots after surgery. Talk to your healthcare provider about taking NEXTSTELLIS before and after your surgery or if you are going to be unable to walk for an extended period of time.
- are depressed now or have been depressed in the past.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT NEXTSTELLIS?

What else should I know about taking NEXTSTELLIS? (cont)

- had yellowing of your skin or eyes caused by pregnancy.
- are pregnant or think you may be pregnant.
- are breastfeeding or plan to breastfeed. NEXTSTELLIS may decrease the amount of breast milk you make. NEXTSTELLIS may pass into your breastmilk. Talk to your healthcare provider about the best birth control method for you while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. NEXTSTELLIS may affect the way other medicines work, and other medicines may affect how well NEXTSTELLIS works.

What are the most serious risks of taking NEXTSTELLIS?

NEXTSTELLIS may cause serious side effects that may lead to death including blood clots in your lungs, heart attack, or a stroke. Some other examples of serious blood clots include blood clots in the legs or eyes. Other serious risks include high potassium levels in your blood, high blood pressure, new or worsening headaches including migraine headaches, possible cancer that is sensitive to female hormones, liver problems, changes in the sugar and fat blood levels, gallbladder problems, irregular or unusual vaginal bleeding, spotting, or absence of menstrual periods, depression,

What are the most serious risks of taking NEXTSTELLIS? (cont)

possible cancer of the cervix, swelling of the skin especially around the mouth, eyes, and in the throat, and dark patches of skin around your forehead, nose, cheeks, and around your mouth, especially during pregnancy.

What are the possible side effects of NEXTSTELLIS?

The most common side effects reported by females taking NEXTSTELLIS in a study were spotting or bleeding between menstrual periods, mood changes, headache, breast tenderness, pain and discomfort, painful periods, acne, weight gain, and decreased sex drive.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the enclosed [full Prescribing Information, including Boxed Warning, and Patient Information.](#)