



(drospirenone and estetrol tablets)
3 mg/14.2 mg

FULL PRESCRIBING INFORMATION

HEALTHCARE PROFESSIONAL SITE

INDICATION

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. 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.

IMPORTANT SAFETY INFORMATION

**WARNING:
CIGARETTE
SMOKING**

A NATURAL CHOICE FOR TODAY'S WOMAN

YOU CAN SAVE ON YOUR PRESCRIPTION OF NEXTSTELLIS

Covered, eligible patients may pay as little as \$0 for each 1-month or 3-month prescription fill*

Most uncovered, eligible patients may pay as little as \$25 for each 1-month prescription fill or \$50 for each 3-month prescription fill*

By selecting the button below, you acknowledge that your information will be shared with Mayne Pharma and agree to receive future communications from Mayne Pharma. Please see our Privacy Policy for more information.

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AND
SERIOUS
CARDIOVASCULAR
EVENTS

Cigarette
smoking
increases
the risk of
serious
cardiovascular
events
from
combined
oral
contraceptive (COC) use.
This risk
increases
with age,
particularly
in females
over 35
years of age,
and with
the number
of cigarettes
smoked. For
this reason,
COCs,
including
NEXTSTELLIS
, are
contraindicated in
females
who are
over 35
years of age
and smoke.
[See
Contraindications (4)
and
Warnings
and

*Depending on insurance coverage, eligible patients may pay as little as \$0 for up to 12 one-month NEXTSTELLIS prescription fills OR each of up to 4 three-month NEXTSTELLIS prescription fills. Check with Pharmacist for copay.

discount. Maximum savings limits apply; patient out-of-pocket expense will vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Please see Program Terms, Conditions, and Eligibility Criteria here.

**Precautions
(5.1)]**

DESIGNED FOR SATISFACTION. POWERED BY TRUST

**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.

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.

[PRIVACY POLICY](#) [TERMS & CONDITIONS](#)

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- are depressed now or have been depressed in the past.
- 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, 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 [full Prescribing Information](#), including Boxed Warning, and [Patient Information](#).

