

NEXTSTELLIS®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using NEXTSTELLIS?

NEXTSTELLIS is a birth control tablet (oral contraceptive) used by women to prevent pregnancy. NEXTSTELLIS contains the active ingredients estetrol (as estetrol monohydrate) and drospirenone. The estetrol (also called E4) in NEXTSTELLIS is made from a plant source to match the naturally occurring estrogen in the body and has selective activity.

For more information, see Section [1. Why am I using NEXTSTELLIS?](#) in the full CMI.

2. What should I know before I use NEXTSTELLIS?

Do not use if you have ever had an allergic reaction to E4, drospirenone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NEXTSTELLIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEXTSTELLIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NEXTSTELLIS?

Take one tablet every day at the same time. Take the tablets in the order directed on the blister pack. Both the pink tablets and white tablets should be swallowed whole.

More instructions can be found in Section [4. How do I use NEXTSTELLIS?](#) in the full CMI.

5. What should I know while using NEXTSTELLIS?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using NEXTSTELLIS.

	<ul style="list-style-type: none"> • Tell your doctor, dentist or pharmacist about all of your medical conditions. • Tell your doctor, dentist or pharmacist about all the medicines you take.
Things you should not do	<ul style="list-style-type: none"> • Do not use NEXTSTELLIS for a condition for which it was not prescribed. • Do not give NEXTSTELLIS to anyone else. • Do not skip your tablets, even if you do not have sex often.
Driving or using machines	<ul style="list-style-type: none"> • NEXTSTELLIS has no influence on ability to drive or use machines.
Drinking alcohol	<ul style="list-style-type: none"> • Drinking alcohol has no effect on NEXTSTELLIS.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 30°C. • Keep NEXTSTELLIS and all medicines out of the reach of children.

For more information, see Section [5. What should I know while using NEXTSTELLIS?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects of NEXTSTELLIS may include: acne, headache, irregular vaginal bleeding (including absence of period), pain with your periods, weight gain, breast tenderness, pain and discomfort, decreased sex drive, nausea and mood changes. Serious side effects may include: blood clots in your lungs, heart attack, or a stroke that may lead to death. Other examples of serious blood clots include blood clots in the legs or eyes. An Information Card for women is available on nextstellis.com.au. Combined oral contraceptives are associated with other serious side effects which are listed in Section [6. Are there any side effects?](#) For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

NEXTSTELLIS®

Active ingredients: *estetrol (as estetrol monohydrate) and drospirenone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NEXTSTELLIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NEXTSTELLIS.**

Where to find information in this leaflet:

- [1. Why am I using NEXTSTELLIS?](#)
- [2. What should I know before I use NEXTSTELLIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NEXTSTELLIS?](#)
- [5. What should I know while using NEXTSTELLIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NEXTSTELLIS?

NEXTSTELLIS is a birth control tablet (oral contraceptive) used by women to prevent pregnancy.

NEXTSTELLIS contains the active ingredients estetrol (as estetrol monohydrate) and drospirenone.

The estetrol (also called E4) in NEXTSTELLIS is made from a plant source to match the naturally occurring estrogen in the body. E4 has highly selective action on estrogen receptors. Drospirenone is a synthetic version of another naturally occurring female reproductive hormone.

2. What should I know before I use NEXTSTELLIS?

Warnings

Do not use NEXTSTELLIS if:

- You are allergic to E4 or drospirenone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have or have had blood clots in your arms, legs, lungs, or eyes.

- You have a problem with your blood that makes it clot more than normal.
- You have certain heart valve problems or irregular heartbeat that increases your risk of having blood clots.
- You had a stroke.
- You had a heart attack.
- You have high blood pressure that cannot be controlled by medicine.
- You have diabetes with kidney, eye, nerve, or blood vessel damage.
- You have certain kinds of severe migraine headaches with aura or numbness, weakness or changes in vision.
- You have liver problems, including liver tumours.
- You have a problem with your adrenal glands where they do not produce enough hormones.
- You have any unexplained vaginal bleeding.
- You are pregnant.
- You have or have had breast cancer or any cancer that is sensitive to female hormones.
- You have kidney disease or kidney failure.
- You have or have had a blood clot in:
 - The blood vessels of the legs (deep vein thrombosis - DVT).
 - The lungs (pulmonary embolism - PE).
 - The heart (heart attack).
 - The brain (stroke).
 - Other parts of the body.

- You have or are concerned about an increased risk of blood clots. Blood clots are rare. Very occasionally blood clots may cause serious permanent disabilities or may even be fatal. You are more at risk of having a blood clot when you take the Pill. But the risk of having a blood clot when taking the Pill is less than the risk during pregnancy.
- You are concerned about an increased risk of blood clots because of multiple risk factors such as a family history of blood clots in a sibling or parent, age or smoking. The risk of having a heart attack or stroke increases as you get older (above 35 years). It also increases if you smoke heavily (around 15 or more cigarettes per day). You should stop smoking when taking the Pill.
- You have, or have had:
 - Any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions.
 - A confirmed blood test showing:
 - Increased levels of homocysteine.
 - Antiphospholipid antibodies e.g. anticardiolipin-antibodies and lupus anticoagulant. These may

increase your risk for blood clots or pregnancy losses (miscarriage).

- Major surgery after which you have not been able to move around for a period of time.
- Angina (chest pain).
- A mini stroke (also known as TIA or transient ischaemic attack).
- Severe kidney insufficiency or an acute failure of your kidney.
- A migraine, where you have also had problems with seeing, speaking or had weakness or numbness in any part of your body.
- A high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood.
- Pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- Severe liver disease and your liver function has not returned to normal.
- Cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- A benign or malignant liver tumour.
- Unexplained vaginal bleeding.

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

Symptoms of blood clots:

Stroke (blood clot in the brain)

- Sudden weakness or numbness of the face, arm or leg, especially on one side of the body.
- Sudden confusion, trouble speaking or understanding.
- Sudden trouble seeing in one or both eyes.
- Sudden trouble walking, dizziness, loss of balance or coordination.
- Sudden, severe or prolonged headache with no known cause.
- Loss of consciousness or fainting with or without seizure.

Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.

Heart attack

- Chest pain, discomfort, pressure, heaviness.
- Sensation of squeezing or fullness in the chest, arm or below the breastbone.
- Fullness, indigestion or choking feeling.
- Upper body discomfort radiating to the back, jaw, throat, arm and stomach.
- Sweating, nausea, vomiting or dizziness.
- Extreme weakness, anxiety, or shortness of breath.
- Rapid or irregular heartbeats.

DVT (blood clot in the legs)

- Swelling of one leg or along a vein in the leg or foot.
- Pain or tenderness in the leg which may be felt only when standing or walking.

- Increased warmth in the affected leg.
- Change in colour of the skin on the leg e.g. turning pale, red or blue.

PE (blood clot in the lungs)

- Sudden unexplained breathlessness or rapid breathing.
- Sudden cough without an obvious cause, which may bring up blood.
- Sharp chest pain which may increase with deep breathing.
- Severe light headedness or dizziness.
- Rapid or irregular heartbeat.

If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').

Retinal vein thrombosis (blood clot in the eye)

- Immediate loss of vision.
- Painless blurring of vision which can progress to loss of vision.

Symptoms most commonly occur in one eye.

Blood clots blocking other blood vessels

- Sudden pain, swelling and slight blue discolouration of an extremity.

An Information Card for women is available on nextstellis.com.au.

Check with your doctor if you:

- Have any other medical conditions.
- Take any medicines for any other condition.
- Are scheduled for surgery. NEXTSTELLIS may increase your risk of blood clots after surgery. You should stop using NEXTSTELLIS at least four weeks before you have surgery and not restart it until at least two weeks after your surgery.
- Think you may be pregnant.
- Are depressed now or have been depressed in the past. Depression can be serious and is a well-known risk factor for suicidal behaviour. Contact your doctor if you experience any mood changes or depressive symptoms after starting the treatment.
- Have yellowing of your skin or eyes (jaundice) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows).
- Have gall bladder disease.
- Have an inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
- Are breastfeeding or plan to breastfeed. NEXTSTELLIS may decrease the amount of breastmilk you make. A small amount of the hormones in NEXTSTELLIS may pass into your breastmilk. Talk to your doctor about the best birth control method for you while breastfeeding.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

If you are currently on daily, long-term treatment for a chronic condition with any of the following medications, you should consult with your doctor or pharmacist before taking NEXTSTELLIS:

- CYP inducers (aprepitant, barbituates, bosentan, carbamazepine, efavirenz, felbamate, griseofluvin, oxycarbazepine, phenytoin, rifampin, ribatin, topiramate, products containing St. John's wort, and others).
- Atorvastatin or rosuvastatin.
- CYP inhibitors (azoles such as fluconazole and others).

- HIV/hepatitis C virus protease inhibitors and non-nucleoside reverse transcriptase inhibitors (nelfinavir, ritonavir, boceprevir, telaprevir, indinavir, nevirapine, etravirine and others).
- Any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" in the blood.
- Lamotrigine.
- ACE inhibitors (captopril, enalapril, lisinopril, and others).
- Angiotensin-II receptor antagonists (Cozaar, Diovan, Avapro, and others).
- Potassium-sparing diuretics (spironolactone and others).
- Potassium supplementation.
- Heparin.
- NSAIDS (ibuprofen, naproxen, and others).

Some medicines may interfere with NEXTSTELLIS and affect how it works.

NEXTSTELLIS may affect the way other medicines work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEXTSTELLIS.

4. How do I use NEXTSTELLIS?

How much to take

- Take one tablet every day at the same time. Take the tablets in the order directed on your blister pack. Both the pink tablets and white tablets should be swallowed whole.
- Do not skip your tablets, even if you do not have sex often. If you miss tablets (including starting the pack late) you could get pregnant. The more tablets you miss, the more likely you are to get pregnant.
- If you have trouble remembering to take NEXTSTELLIS, talk to your doctor or pharmacist.
- When you first start taking NEXTSTELLIS, spotting or light bleeding in between your periods may occur. Contact your doctor if this does not go away after a few months.
- Some women miss periods on hormonal birth control, even when they are not pregnant. However, if you miss a period and have not taken NEXTSTELLIS according to directions, or miss two periods in a row, or feel like you may be pregnant, call your doctor. If you have a positive pregnancy test, you should stop taking NEXTSTELLIS.
- If you have vomiting or diarrhea (within three to four hours after you take your tablet), follow the instructions for "If you forget to use NEXTSTELLIS". If you have diarrhea or if you take certain medicines, including some antibiotics and some herbal products such as St. John's Wort, your tablets may not work as well.

- Stop taking NEXTSTELLIS at least four weeks before you have major surgery and do not restart it until at least two weeks after your surgery. Be sure to use other forms of contraception (like condoms) during this time period.
- Follow the instructions provided and use NEXTSTELLIS until your doctor tells you to stop.
- If you want to become pregnant, you may stop taking the tablet whenever you wish. Consider a visit with your doctor for a pre-pregnancy check-up before you stop taking the tablet.

Before you start taking NEXTSTELLIS

- Decide what time of day you want to take your tablet. It is important to take it at the same time every day and in the order as directed on the blister pack.
- Have backup contraception (condoms) available and an extra full pack of tablets as needed.

When to take / use NEXTSTELLIS

If you start taking NEXTSTELLIS and you have not used a hormonal birth control method before:

Your doctor should tell you when to start taking your birth control tablet.

Tablet-taking should start on the first day of your period. If not starting on the first day of your period for any reason, use a non-hormonal contraceptive (condoms) as back-up until tablets have been taken for 7 days in a row.

1. Take the first tablet from the purple area on the blister pack corresponding to the day of the week.
2. Follow the direction of the arrows on the blister pack until all the tablets have been taken.
3. A period should begin 2-3 days after starting to take the white inactive tablets and may not have finished before the next pack is started.
4. Always start a new blister pack on the same day of the week as the previous pack.

If you start taking NEXTSTELLIS and you are switching from another birth control tablet:

- Start your new NEXTSTELLIS pack on the day after the last active tablet of your previous birth control tablet.

If you start taking NEXTSTELLIS and previously used a vaginal ring or transdermal patch:

- Start using NEXTSTELLIS on the day you remove the vaginal ring
- Start using NEXTSTELLIS on the day you would have applied a new patch.

If you start taking NEXTSTELLIS and you are switching from a progestin-only method such as an implant or injection:

- Start taking NEXTSTELLIS on the day of removal of your implant or on the day when you would have had your next injection.

If you start taking NEXTSTELLIS and you are switching from an intrauterine device or system (IUD or IUS):

- Start taking NEXTSTELLIS on the day of removal of your IUD or IUS.
- You do not need back-up contraception if your IUD or IUS is removed on the first day of your period. If your IUD or IUS is removed on any other day, use non-hormonal back-up contraception such as condoms for the first seven days that you take NEXTSTELLIS.

Keep a calendar to track your period.

If you forget to use NEXTSTELLIS

NEXTSTELLIS should be taken regularly at the same time each day.

If you miss one pink active tablet in Weeks 1, 2 or 3, follow these steps:

- Take it as soon as you remember. Take the next tablet at your regular time. This means you may take two tablets in one day.
- Then continue taking one tablet every day until you finish the pack.
- You do not need to use a back-up birth control method if you have sex.

If you miss two or more pink active tablets in week 1 or week 2, follow these steps:

- Take one missed tablet as soon as possible and the tablet scheduled for the current day (which means you will take two tablets in the one day).
- Discard the other missed tablet(s).
- Then continue one tablet a day until the pack is finished.

- Use a non-hormonal birth control method (such as a condom) as a back-up if you have sex during the first seven days after missing your tablets.

If you miss two or more pink active tablets in week 3, follow these steps:

- Take one missed tablet as soon as possible and the tablet scheduled for the current day (which means you will take two tablets in the one day).
- Discard the other missed tablet(s).
- Finish the pink active tablets until you reach the white inactive tablets, then start a new pack the next day.
- Having skipped the white inactive tablets, you may not have your period this month, which is expected. However, if you miss your period two months in a row, call your doctor because you might be pregnant.
- You could become pregnant if you have sex during the first seven days after you restart your tablets. If you have sex within 7 days after missing tablets, non-hormonal contraception (such as condoms) should be used as back-up until pink tablets have been taken for 7 days in a row.

If you take too much NEXTSTELLIS

If you think that you have used too much NEXTSTELLIS, you may need urgent medical attention.

If you take too much NEXTSTELLIS you should immediately:

- Phone the Poisons Information Centre (by calling **13 11 26**), or

- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NEXTSTELLIS?

Things you should do

- Tell your doctor, dentist or pharmacist about all of your medical conditions.
- Tell your doctor, dentist or pharmacist about all the medicines you take.
- Tell your doctor you are taking NEXTSTELLIS if you are scheduled for any lab tests. Certain blood tests may be affected by NEXTSTELLIS.
- Tell your doctor you are taking NEXTSTELLIS if you are scheduled to have a surgical procedure that would require a significant period of immobilisation. The risk of having blood clots is temporarily increased in this situation. In women who take combined oral contraceptives, the risk may be higher.
- Talk to your doctor if you will be immobilised for an extended period of time. Risk factors for blood clotting includes prolonged or temporary immobilisation (e.g. from travel), particularly in women with other risk factors. Consult your doctor if you plan to travel for greater than 4 hours.

Call your doctor straight away if you:

- Miss a period and have not taken NEXTSTELLIS according to directions, or miss two periods in a row, or feel like you may be pregnant, or
- Experience any side effects.

Remind any doctor, dentist or pharmacist you visit that you are using NEXTSTELLIS.

Things you should not do

- Do not use NEXTSTELLIS for a condition for which it was not prescribed.
- Do not give NEXTSTELLIS to anyone else.
- Do not skip your tablets, even if you do not have sex often.

Driving or using machines

NEXTSTELLIS has no influence on ability to drive or use machines.

Looking after your medicine

- Store below 30°C.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Acne.• Headache.• Irregular vaginal bleeding (including absence of period).• Pain with your periods.• Weight gain.• Breast tenderness, pain and discomfort.• Decreased sex drive.• Nausea.• Mood changes.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Blood clots:</p> <ul style="list-style-type: none">● Blood clots in your lungs, heart attack, or a stroke that may lead to death.● Blood clots in the legs or eyes.● Serious blood clots can happen especially if you smoke or are obese. Serious blood clots are more likely to happen when you:<ul style="list-style-type: none">○ First start taking birth control tablets.○ Restart the same or different birth control tablets after not using them for a month or more.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Symptoms include: <ul style="list-style-type: none"> ○ Leg pain that will not go away. ○ Sudden severe shortness of breath. ○ Sudden change in vision or blindness. ○ Chest pain. ○ Sudden, severe headache unlike your usual headaches. ○ Weakness or numbness in your arm or leg. <p>Liver problems:</p> <ul style="list-style-type: none"> ● Rare liver tumours. ● Jaundice (cholestasis), (yellowing of your skin or eyes). <p>High blood pressure:</p> <ul style="list-style-type: none"> ● You should see your doctor to check your blood pressure regularly. <p>Changes in the sugar and fat (cholesterol and triglycerides) levels in your blood</p>	

Serious side effects	What to do
<p data-bbox="204 286 683 452">New or worsening headaches including migraine headaches</p> <p data-bbox="204 510 466 564">Depression</p> <p data-bbox="204 622 746 721">Possible cancer in your breast and cervix</p>	

Serious side effects	What to do
<p data-bbox="204 945 778 1160">Swelling of your skin especially around your mouth, eyes, and in your throat (angioedema):</p> <ul data-bbox="204 1196 778 1653" style="list-style-type: none"> <li data-bbox="204 1196 778 1653">● Swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing. Your chance of having angioedema is higher if you have a history of angioedema. <p data-bbox="204 1697 721 1906">Dark patches of skin around your forehead, nose, cheeks and around your mouth,</p>	<p data-bbox="817 945 1375 1326">Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>especially during pregnancy (chloasma):</p> <ul style="list-style-type: none"> • Women who tend to get chloasma should avoid spending a long time in sunlight, tanning booths, or under sun lamps while taking NEXTSTELLIS. Use sunscreen if you have to be in the sunlight. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NEXTSTELLIS contains

Active ingredient (main ingredients)	Active Tablet: estetrol 14.2 mg (as estetrol monohydrate) and drospirenone 3 mg
Other ingredients (inactive ingredients)	Active Tablet: lactose monohydrate, sodium starch glycollate type A, maize starch, povidone and magnesium stearate Film-coating on active tablet: AquaPolish Pink 044.08 MS (hypromellose, hypromellose, purified talc, hydrogenated cottonseed oil, titanium dioxide and iron oxide red) Inactive Tablet:

	<p>StarLac (lactose monohydrate and maize starch) and magnesium stearate</p> <p>Film-coating on inactive tablet:</p> <p>AquaPolish White 014.17 MS (hypromellose, hypromellose, purified talc, hydrogenated cottonseed oil and titanium dioxide)</p>
Potential allergens	Lactose

Do not take this medicine if you are allergic to any of these ingredients.

What NEXTSTELLIS looks like

NEXTSTELLIS is supplied in plastic blister packs, each containing 24 pink (active) tablets and 4 white (inactive) tablets. Both the pink and white tablets have a drop-shaped logo on one side.

NEXTSTELLIS is supplied in cardboard cartons containing 1, 3 or 6 blister packs.

Aust R 341876.

Who distributes NEXTSTELLIS?

Mayne Pharma International Pty Ltd

1538 Main North Road
Salisbury South, SA 5106

This leaflet was prepared in March 2022.

For the most up to date version of this leaflet, go to
nextstellis.com.au.