

# Estalis<sup>®</sup> Continuous

## 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.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using Estalis Continuous?

Estalis Continuous contains the active ingredients estradiol and norethisterone acetate (NETA). Estalis Continuous is used for the short-term relief of symptoms of the menopause.

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

### 2. What should I know before I use Estalis Continuous?

Do not use if you have ever had an allergic reaction to Estalis Continuous 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 Estalis Continuous?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Estalis Continuous 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 Estalis Continuous?

- You will have a patch on all the time. You will apply a new patch twice weekly (every 3 or 4 days). There are 8 patches in the carton, enough for a 4-week cycle.

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

### 5. What should I know while using Estalis Continuous?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Estalis Continuous.</li><li>If you become pregnant while using Estalis Continuous, tell your doctor immediately.</li><li>See your doctor at least once a year for a check-up. Some women will need to go more often.</li><li>Check your breasts each month and report any changes promptly to your doctor.</li><li>Tell your doctor that you are using Estalis Continuous well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using it.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not use this medicine to treat any other complaints unless your doctor tells you to.</li><li>Do not give it to anyone else, even if their symptoms seem similar to yours.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your medicine in the original container until it is time to use it.</li><li>Store it in a cool dry place.</li></ul>

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

### 6. Are there any side effects?

Common side effects: irregular vaginal bleeding or spotting, tender, painful or swollen breasts, period-like pain, redness, irritation or itching under the patch, skin rash, vaginal itching, inflammation or fluid discharge, swelling of the lower legs, ankles, fingers or abdomen due to fluid retention, nausea, abdominal cramps, vomiting, heartburn, wind, diarrhoea, headache, migraine, rise in blood pressure, weakness or dizziness, depression, nervousness, rapid changes in mood, difficulty sleeping, back pain, change in sex drive, weight gain, acne, itchy or dry skin, skin discolouration, tingling or numbness, gallbladder disorder, fibroids, breast cancer, darkening of the skin particularly on the face or abdomen, abnormal tumour growth related to estrogens, hair loss, inflammatory bowel disease.

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.

**WARNING: Do not use Estalis Continuous or other estrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.**

A study called the Women's Health Initiative indicated increased risk of heart attack, stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated estrogens 0.625 mg and the progestogen medroxyprogesterone acetate (MPA). The researchers stopped the study after 5 years when it was determined the risks were greater than the benefits in this group. The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged 65-79 years taking conjugated estrogens and MPA. There are no comparable data currently available for other doses of conjugated estrogens and MPA or other combinations of estrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing estrogen and progestogen combinations.

Talk regularly with your doctor about whether you still need treatment with Estalis Continuous.

Treatment with estrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.

# Estalis<sup>®</sup> Continuous

**Active ingredient(s):** *estradiol, norethisterone acetate (NETA)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Estalis Continuous. **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 Estalis Continuous.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Estalis Continuous?

Estalis Continuous contains the active ingredients **estradiol and norethisterone acetate (NETA)**. Estalis Continuous is type of treatment called hormone replacement therapy (HRT). It is a stick-on patch that contains the hormones, estradiol and norethisterone acetate (NETA).

**Estalis Continuous is used for the short-term relief of symptoms of the menopause.**

**It can also be used to prevent thinning of the bones in women with a high risk of fractures due to osteoporosis who cannot use other treatments.**

**Estalis Continuous is used only for women who still have a uterus (womb).**

HRT should not be used for the long-term maintenance of general health or to prevent heart disease or dementia.

Estalis Continuous is not suitable for birth control and it will not restore fertility.

## How it works

Estradiol is a natural female sex hormone called an estrogen. It is the same hormone that your ovaries were producing before the menopause. NETA is a hormone called a progestogen. It has effects similar to the female hormone, progesterone, which your ovaries also produced before the menopause.

The menopause occurs naturally in the course of a woman's life, usually between the ages of 45 and 55. After menopause, your body produces much less estrogen than it did before. This can cause unpleasant symptoms such as a feeling of warmth in the face, neck and chest, "hot flushes" (sudden, intense feelings of heat and sweating throughout the body), sleep problems, irritability and depression. Some women also have problems with dryness of the vagina causing discomfort during or after sex. Estrogens can be given to reduce or eliminate these symptoms.

After the age of 40, and especially after the menopause, some women develop osteoporosis. This is a thinning of the bones that makes them weaker and more likely to break, especially the bones of the spine, hip and wrist. Exercise, calcium and vitamin D can help reduce the risk of osteoporosis.

Women who still have a uterus must take both estrogen and progestogen as part of HRT. This is because estrogen stimulates the growth of the lining of the uterus (called the endometrium). Before menopause this lining is removed during your period through the action of a natural progestogen. After menopause, taking estrogen on its own as HRT may lead to irregular bleeding and to a disorder called endometrial hyperplasia. Progestogens such as NETA help to protect the lining of the uterus from developing this disorder.

Estalis Continuous patches release estradiol and NETA in a continuous and controlled way just as your ovaries were doing before. Because the medicine does not have to pass through your stomach and liver, it allows you to take a

much lower dose than would be needed in a tablet and helps to avoid some unpleasant side effects.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another purpose.

## 2. What should I know before I use Estalis Continuous?

**Do not use Estalis Continuous if you are allergic to:**

- estradiol or NETA, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- any other medicine containing estrogen or progestogen, including the birth control pill.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you had a severe skin reaction in the past, you could have a very serious reaction if you use any type of estrogen or progestogen (patch, tablet, cream, etc.) again in the future.

**Do not use Estalis Continuous if you have:**

- cancer of the breast or uterus (womb) or any other estrogen dependent cancer, or you have had this condition in the past
- blood clots in your blood vessels, now or in the past. You may have had painful inflammation of the veins or blockage of a blood vessel in the legs, lungs, brain or heart
- a condition that increases the tendency for you to get blood clots
- endometriosis (a disorder of the uterus that may cause painful periods and abnormal bleeding)
- abnormal vaginal bleeding that has not been investigated
- severe liver problems
- a condition called porphyria
- a tumour of the pituitary gland or hypothalamus
- a disease of the connective tissue
- hearing loss due to a problem with the bones in the ear called otosclerosis

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

**Check with your doctor if you have:**

- a family history of breast cancer
- nodules, lumps or cysts in your breasts or any other benign breast condition (not cancer)
- fibroids or other benign tumours of the uterus (not cancer)

- had one or more pregnancies where you lost the baby before birth
- high blood pressure
- heart disease
- kidney or liver problems
- diabetes
- epilepsy
- migraine or other severe headaches
- gall bladder disease
- asthma
- a high level of triglycerides in the blood
- a disorder called systemic lupus erythematosus (SLE)
- a condition called hypothyroidism (your thyroid gland fails to produce enough thyroid hormone)
- low levels of thyroid hormone
- a bone disease causing high calcium levels in the blood
- very low calcium levels in the blood
- had a problem in the past with jaundice (a liver problem) or itching skin when you took an estrogen (e.g. the birth control pill or HRT)
- a skin condition that could be made worse by applying a patch
- severe allergic reactions
- a condition called hereditary angioedema or if you have had episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract
- contact lens discomfort

**Tell your doctor if you are likely to have an increased risk of developing blood clots in your blood vessels. The risk increases as you get older and it may also be increased if:**

- anyone in your immediate family has ever had blood clots in the blood vessels of the legs or lungs
- you are overweight
- you have varicose veins
- you have a disorder called systemic lupus erythematosus (SLE)

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

**Do not use Estalis Continuous if you are pregnant or breast-feeding.**

It may affect your baby.

## 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.

**Tell your doctor if you are taking birth control pills.**

Estalis Continuous is not a contraceptive. Since pregnancy may be possible early in the menopause while you are still having menstrual periods, you should ask your doctor to suggest another (non-hormonal) method of birth control.

### **Some medicines may interfere with Estalis Continuous and affect how it works.**

- herbal medicines containing St. John's wort
- some medicines to help you sleep, including barbiturates and meprobamate
- some medicines for epilepsy, including phenytoin and carbamazepine
- phenylbutazone, a medicine for pain and inflammation
- some antibiotics and other anti-infective medicines, including rifampicin, ketoconazole, erythromycin, rifabutin, nevirapine, efavirenz, ritonavir and nelfinavir

You may need to take different amounts of your medicines or to take different medicines while you are using Estalis Continuous. Your doctor and pharmacist have more information.

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

## **4. How do I use Estalis Continuous?**

### **How much to use**

- The patches come in two strengths. You will usually start with the Estalis Continuous 50/250 patch. Your doctor will check your progress and may change to the lower strength 50/140 patch.

### **When to use Estalis Continuous**

- If you are not already using HRT, you can start Estalis Continuous at a convenient time for you. If you are already using a different type of HRT, your doctor can advise you when to switch to Estalis Continuous.

### **How to use Estalis Continuous**

- A leaflet in the carton contains pictures and information on how to apply the patch properly.
- You will have a patch on all the time. You will apply a new patch twice weekly (every 3 or 4 days). There are 8 patches in the carton, enough for a 4-week cycle.
- You will probably have some bleeding or spotting at odd times during the first few months. This can be a nuisance but is quite normal and not a cause for concern. The bleeding usually becomes lighter and less frequent over time and eventually stops. If you have heavy bleeding, tell your doctor.

### **How long to use Estalis Continuous**

**If you want to continue using HRT for longer than a few months, discuss the possible risks and benefits with your doctor.**

You may have an increased risk of developing breast cancer, heart disease, stroke, blood clots on the lungs and dementia. On the other hand, the risk of hip fractures and bowel cancer may be reduced. Women taking estrogens, alone or in combination with progestogens, may have a higher risk of ovarian cancer that may appear within 5 years of use and slowly diminishes over time after

discontinuation. Your doctor can discuss these risks and benefits with you, taking into account your particular circumstances.

### **If you forget to use Estalis Continuous**

Apply a new patch as soon as you remember, and then go back to your usual schedule.

If you have trouble remembering when to replace your patches, ask your pharmacist for some hints.

### **If you use too much Estalis Continuous**

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

#### **You should immediately:**

- phone the Australian 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.**

Because of the way this medicine is used, an intentional overdose is unlikely. Swallowing a patch may cause nausea and vomiting.

## **5. What should I know while using Estalis Continuous?**

### **Things you should do**

**If you become pregnant while using Estalis Continuous, tell your doctor immediately.**

It should not be used while you are pregnant or if you want to become pregnant.

**See your doctor at least once a year for a check-up. Some women will need to go more often. Your doctor will:**

- check your breasts and order a mammogram at regular intervals
- check your uterus and cervix and do a pap smear at regular intervals
- check your blood pressure and cholesterol level

**Check your breasts each month and report any changes promptly to your doctor.**

Your doctor or nurse can show you how to check your breasts properly.

**Tell your doctor that you are using Estalis Continuous well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using it.**

The risk of developing blood clots in your blood vessels may be temporarily increased as a result of an operation, serious injury or having to stay in bed for a prolonged period. If possible, this medicine should be stopped at least 4 weeks before surgery and it should not be restarted until you are fully mobile.

**Tell your doctor that you are on treatment with Estalis Sequi if you are going to have laboratory tests.**

Some laboratory tests, such as tests for glucose tolerance or thyroid function, may be affected by Estalis Sequi therapy.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Estalis Continuous.**

**Tell any other doctor, dentist or pharmacist who treats you that you are using Estalis Continuous.**

### Things you should not do

**Do not use this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give it to anyone else, even if their symptoms seem similar to yours.**

### Looking after your medicine

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### When to discard your medicine

**Fold used patches in half with the sticky side inwards. Dispose of them where children cannot reach them.**

Used patches still contain some estradiol and NETA which could harm a child.

### Getting rid of any unwanted medicine

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any patches that are left over.

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"> <li>• irregular vaginal bleeding or spotting (if bleeding is heavy,</li> </ul>	<b>Speak to your doctor if you</b>

<p>check with your doctor as soon as possible)</p> <ul style="list-style-type: none"> <li>• tender, painful or swollen breasts</li> <li>• period-like pain</li> <li>• redness, irritation or itching under the patch (signs of application site reaction includes bleeding, bruising, burning, discomfort, dryness, skin boils, oedema, erythema, inflammation, irritation, pain, tiny solid skin bumps, rash, skin discolouration, skin pigmentation, swelling, hives and blisters)</li> <li>• skin rash</li> <li>• vaginal itching, inflammation or fluid discharge</li> <li>• swelling of the lower legs, ankles, fingers or abdomen due to fluid retention</li> <li>• nausea (feeling sick), abdominal cramps, vomiting, heartburn, wind, diarrhoea</li> <li>• headache, migraine</li> <li>• rise in blood pressure</li> <li>• weakness or dizziness</li> <li>• depression, nervousness, rapid changes in mood, difficulty sleeping</li> <li>• back pain</li> <li>• change in sex drive</li> <li>• weight gain</li> <li>• acne, itchy or dry skin, skin discolouration</li> <li>• tingling or numbness</li> <li>• gallbladder disorder (tendency to form gallstones)</li> <li>• fibroids (benign growths in the uterus)</li> <li>• breast cancer</li> <li>• darkening of the skin particularly on the face or abdomen (chloasma)</li> <li>• abnormal tumour growth related to estrogens, e.g. cancer of the lining of the womb (endometrial cancer)</li> <li>• hair loss</li> <li>• inflammatory bowel disease</li> </ul>	<b>have any of these less serious side effects and they worry you.</b>
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue, the area around the eyes or other part of the body; rash,</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency</b>

<p>itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening</p> <ul style="list-style-type: none"> <li>• signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood</li> <li>• pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting</li> <li>• a yellow colour to the skin or eyes, itching, dark coloured urine or light coloured bowel motions.</li> </ul>	<p><b>Department at your nearest hospital if you notice any of these serious side effects.</b></p>
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**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. Some side effects can only be found when laboratory tests are done.

### 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](http://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 Estalis Continuous contains

Estalis Continuous patches release approximately 50 micrograms of estradiol and 140 or 250 micrograms of NETA in 24 hours.

<b>Active ingredient (main ingredient)</b>	estradiol norethisterone acetate (NETA)
<b>Other ingredients (inactive ingredients)</b>	silicone and acrylic adhesives to make the patch stick povidone oleic acid dipropylene glycol

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

### What Estalis Continuous looks like

Estalis Continuous patches come in two strengths:

Estalis Continuous 50/140 – clear round patches sealed in individual pouches. Each carton contains 8 patches (enough for 4 weeks of treatment) (AUST R 70813, 479505).

Estalis Continuous 50/250 – clear round patches sealed in individual pouches. Each carton contains 8 patches (enough for 4 weeks of treatment) (AUST R 70817, 479506).

The patch is made up of three layers:

- a waterproof backing
- a sticky layer containing the active ingredients
- a protective liner (to be removed before use)

### Who distributes Estalis Continuous

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia

Tel 1800 726 369

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