

Estalis[®] Sequi

estradiol / norethisterone acetate (NETA)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about the menopause (the "change of life"), hormone replacement therapy and Estalis Sequi.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

When you must not use Estalis Sequi

Do not use Estalis Sequi 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 Sequi.

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

What Estalis Sequi is used for

Estalis Sequi is a type of treatment called hormone replacement therapy (HRT). It is a combination pack consisting of stick-on patches that contain hormones. Estalis Sequi

Weeks 1 and 2 patches contain estradiol. Estalis Sequi Weeks 3 and 4 patches contain estradiol plus norethisterone acetate (NETA).

Estalis Sequi is used for the short-term relief of symptoms of the menopause. This medicine 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 Sequi 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 need to 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 Sequi 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.

This medicine is available only with a doctor's prescription. It is not habit-forming.

Before you use Estalis Sequi

When you must not use it

Do not use Estalis Sequi if you have an allergy to:

- estradiol or NETA, the active ingredients, or to any of the other ingredients listed at the end of this leaflet

- 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 Sequi 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 Estalis Sequi if you are pregnant or breast-feeding.

It may affect your baby.

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.

Before you start to use it

Tell 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)
- 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

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)

Taking other medicines

Tell your doctor if you are taking birth control pills.

Estalis Sequi 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.

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

Some medicines and Estalis Sequi may interfere with each other. These include:

- 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 Sequi. Your doctor and pharmacist have more information.

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 have not told your doctor about any of these things, tell him/her before you start using this medicine.

How to use Estalis Sequi

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

When to start it

If you are not already using HRT, you can start Estalis Sequi 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 Sequi.

How much to use

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

How to use it

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.

The patches for Weeks 1 and 2 contain estradiol and the patches for Weeks 3 and 4 contain estradiol plus NETA. It is important to use the patches in the correct order (i.e. Weeks 1 & 2 before Weeks 3 & 4).

Most women will have a period at the end of each 4-week cycle. This is quite normal. Regardless of whether or not you have a period, you should start the next pack of Estalis Sequi as soon as you have finished the previous one. If you have irregular or heavy bleeding, tell your doctor.

How long to use it

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 it

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 (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that an overdose has happened. Keep

the telephone numbers for these places handy.

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

While you are using Estalis Sequi

Things you must do

If you become pregnant while using Estalis Sequi, 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 Sequi 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.

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are using Estalis Sequi.

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

Things you must 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Estalis Sequi.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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, 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.
- 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

- pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting
- a yellow colour to the skin or eyes, itching, dark coloured urine or light coloured bowel motions.

Tell your doctor if you notice any of the following and they worry you:

- irregular vaginal bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible)
- tender, painful or swollen breasts
- period-like pain
- 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)
- skin rash
- vaginal itching, inflammation or fluid discharge
- swelling of the lower legs, ankles, fingers or abdomen due to fluid retention
- nausea (feeling sick), 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 (tendency to form gallstones)
- fibroids (benign growths in the uterus)
- breast cancer
- darkening of the skin particularly on the face or abdomen (chloasma)
- abnormal tumour growth related to estrogens, e.g. cancer of the lining of the womb (endometrial cancer)
- contact lens discomfort
- hair loss
- inflammatory bowel disease

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects can only be found when laboratory tests are done.

After using Estalis Sequi

Storage

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place.
- Do not store Estalis Sequi or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the patches where young children cannot reach them.

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

Disposal

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.

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.

Product description

What it looks like

Estalis Sequi patches come in two strengths: 50/140 and 50/250. They are clear patches sealed in individual pouches. Each carton contains eight patches (four patches for Weeks 1 and 2 and four patches for Weeks 3 and 4).

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)

Ingredients

Estalis Sequi Weeks 1 and 2 patches release approximately 50 micrograms of estradiol in 24 hours. The following inactive ingredients are also used to make the patch:

- silicone and acrylic based synthetic adhesives to make the patch stick
- dipropylene glycol
- oleyl alcohol
- povidone
- Dow BLF 2550 non-removable backing layer
- Scotchpak 1022 removable release liner

Estalis Sequi Weeks 3 and 4 patches release approximately 50 micrograms of estradiol and 140 or 250 micrograms of NETA in 24 hours.

The following inactive ingredients are also used to make the patch:

- silicone and acrylic adhesives to make the patch stick
- povidone
- oleic acid
- dipropylene glycol

Sponsor

Estalis Sequi is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

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This leaflet was prepared in October 2020.

Australian Registration Number.

Estalis Sequi 50/140 AUST R 338041

Estalis Sequi 50/250 AUST R 338042

(elq091020c.doc) based on PI (elq091020i.doc)