

Consumer Medicine Information

Warning

The Women's Health Initiative (WHI) trial examined the health benefits and risks of combined estrogen plus progestogen therapy (n=16,608) and estrogen-alone therapy (n=10,739) in postmenopausal women aged 50 to 79 years.

The estrogen plus progestogen arm of the WHI trial indicated an increased risk of myocardial infarction (MI), stroke, invasive breast cancer, pulmonary embolism and deep vein thrombosis in postmenopausal women receiving treatment with combined conjugated equine estrogens (CEE, 0.625 mg/day) and medroxyprogesterone acetate (MPA, 2.5 mg/day) for 5.2 years compared to those receiving placebo.

The estrogen-alone arm of the WHI trial indicated an increased risk of stroke and deep vein thrombosis in hysterectomised women treated with CEE-alone (0.625 mg/day) for 6.8 years compared to those receiving placebo. Other doses of oral conjugated estrogens with medroxyprogesterone acetate, and other combinations and dosage forms of estrogens and progestogens were not studied in the WHI clinical trials and, in the absence of comparable data, these risks should be assumed to be similar.

Therefore, the following should be given serious consideration at the time of prescribing:

- Estrogens with or without progestogens should not be prescribed for primary or secondary prevention of cardiovascular diseases.
- Estrogens with or without progestogens should be prescribed at the lowest effective dose for the approved indication.
- Estrogens with or without progestogens should be prescribed for the shortest period possible for the approved indication.
- For the prevention of osteoporosis, estrogen treatment should be considered in light of other available therapies.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Climara. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT CLIMARA IS USED FOR

Climara is used for the treatment of menopausal symptoms due to estrogen deficiency during menopause or after a surgical procedure, where estrogen production is decreased. Climara is only intended for short term use.

Climara is an adhesive patch, which delivers estradiol through the skin and into the blood stream. Climara releases estradiol 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 of estrogen than would be needed in a tablet. The estradiol in Climara can replace the estrogen in the body.

During menopause, the estradiol production of the ovaries declines. Although menopause is natural, it often causes distressing symptoms, which are connected with the gradual loss of the hormones produced by the ovaries.

Climara provides estrogen, which the body is no longer making, to prevent or relieve menopausal symptoms such as hot flushes (night sweats), sleep disturbances, vaginal dryness, depression, nervousness, irritability, headache, dizziness.

Climara can also be used to prevent bone mineral density loss (where the bones become weaker, more brittle and likely to break) during menopause.

Calcium, vitamin D and regular exercise are some other factors that may help to prevent thinning of the bones. You should include foods that are good sources of calcium and vitamin D in your daily diet and exercise regularly. Your doctor can advise you on which foods and types of exercise are best for you.

Climara is not a contraceptive. It will not prevent you from falling pregnant.

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 reason.

BEFORE YOU USE CLIMARA

When you must not use it

Do not use Climara if you have an allergy to:

- estradiol, the active ingredient in Climara
- any of the ingredients listed at the end of this leaflet.

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.

Do not use Climara if you have:

- severe uncontrolled high blood pressure
- severe liver disease such as jaundice (signs of liver problems such as yellowing of skin and/or eyes) or persistent itching during a previous pregnancy
- a history of or existing liver tumours
- suspected or existing tumours in the uterus, ovaries or breast
- known or suspected tumours influenced by sex hormones
- endometriosis (the presence of tissue of the lining of the womb in places in the body where it is not usually found)
- a history of or existing blood clot in the blood vessels (such as blood clots in the legs)
- if you recently had a heart attack and/or stroke
- if you have a high risk of venous or arterial thrombosis (blood clot)
- severe diabetes
- sickle-cell anaemia (inherited disorder which causes the red blood cells to change shape)
- disturbances of fat metabolism
- a history of herpes during pregnancy

- hearing loss (otosclerosis) that worsens during pregnancy
- undiagnosed abnormal vaginal bleeding

If you have not had your uterus (womb) removed (hysterectomy), do not use Climara unless your doctor has prescribed another hormone progestogen to take with Climara.

The use of estrogens alone and over a prolonged period can lead to excessive development of the lining of the womb and this can increase the incidence of cancer of the womb. This risk can be avoided by the additional administration of a progestogen. The general result of this is regular shedding of the lining of the womb and, therefore, menstruation-like bleeding. If you have not had a hysterectomy (your uterus/womb removed) your doctor should prescribe a progestogen for you to take and you should discuss this with your doctor before using Climara.

If you have not told your doctor about any of the above, tell them before you start using Climara.

Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breast-feed if you are using this medicine.

The active ingredient in Climara passes into breast milk and there is a possibility that your baby may be affected.

Do not use this medicine after the expiry date printed on the pack and pouch.

The expiry date is printed on the carton and on each pouch after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you are overweight
- you smoke

- you or anyone in your immediate family has had blood clots (thrombosis)
- systemic lupus erythematosus (SLE, a chronic inflammatory disease)
- you have any planned hospitalisation, surgery or prolonged immobilisation

Studies have suggested that HRT may be associated with an increased risk of developing blood clots. You have an increased risk of a blood clot if you have any of the above risk factors. In addition to these, there may be other risk factors. In the case of a combination of factors, the risk may be higher than simply adding two individual risks.

Talk to your doctor if you have any concerns. Using Climara may also increase your risk of coronary heart disease. Tell your doctor if you experience chest pain or discomfort.

Using Climara may increase your risk of gall bladder disease. This is because estrogen stimulates the liver to remove more cholesterol from blood and divert it to the gallbladder.

Before being prescribed Climara, your doctor should perform a thorough medical and gynaecological examination (including the breasts and a pap smear). Your doctor will also note your family medical history and exclude pregnancy.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes
- high blood pressure
- varicose veins
- otosclerosis (a type of hearing loss)
- endometriosis (the presence of tissue of the lining of the womb in places in the body where it is not normally found)
- multiple sclerosis
- epilepsy
- porphyria (inherited or acquired disorder of certain enzymes)
- tetany (mineral imbalance in the body that results in severe muscle spasms)
- chorea minor (disorder characterised by irregular and involuntary muscles)
- kidney or heart disease
- tumours in the pituitary gland
- yellowing of the skin and/or eyes (cholestatic jaundice) with previous estrogen use or during pregnancy
- migraine
- a high level of triglycerides (fats) in the blood
- high or low calcium levels in the blood
- an underactive thyroid gland (hypothyroidism)
- an abnormal build-up of blood vessels in the liver (hepatic haemangioma)
- chloasma (yellowish brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- asthma
- systemic lupus erythematosus (SLE; a disease affecting the skin all over the body)
- tumours in the womb or liver

- hereditary angioedema, an inherited disorder where repeated episodes of severe swelling occur

Tell your doctor if you are 65 years or older when HRT is initiated. The reason is that there is limited evidence from clinical studies that hormonal treatment may increase the risk of significant loss of intellectual abilities such as memory capacity (dementia).

If Climara is used in the presence of any of the conditions listed above you will need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use Climara.

HRT and cancer

Endometrial cancer

The risk of cancer of the lining of the womb (endometrial cancer) increases when estrogens are used alone for prolonged periods. Taking a progestogen in addition to the estrogen lowers this risk.

Please inform your doctor if you frequently have bleeding irregularities or persistent bleeding during the treatment with Climara.

Breast cancer

Tell your doctor if you have suffered from fibrocystic disease of the breasts (lumps in the breast) or if you have first degree relatives (mother, sisters, daughters) who have had breast cancer.

Breast cancer has been diagnosed slightly more often in women who use hormone replacement therapy (HRT) than in women of the same age who do not use HRT. If you are concerned about this information you should discuss this with your doctor. It is recommended that yearly breast examinations are conducted and regular breast self examination (monthly) should be carried out.

HRT has been reported to result in an increased number of abnormal mammograms requiring further evaluation.

Ovarian cancer

Some observational studies show a slightly increased overall risk of developing ovarian cancer in women who have used HRT compared to women who have never used HRT. In women currently using HRT, this risk was further increased. These associations have not been shown in all studies. There is no consistent evidence that the risk of developing ovarian cancer is related to the duration of use of HRT. However, the risk may be more relevant with long-term use (for several years).

Liver tumour

During or after the use of hormones such as those that are contained in Climara, benign liver tumours have rarely occurred, and malignant liver tumours even more rarely. In isolated cases, bleeding has occurred from such tumours into the abdominal cavity. Although such events are rare, you should inform your doctor about any pain in your upper abdomen that does not disappear within a short time.

Taking other medicines

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

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

- medicines to treat high blood pressure, chest pain and/or irregular heart beat such as ACE inhibitors, verapamil, diltiazem
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- medication used to treat epilepsy, such as hydantoins, barbituates, primidone, carbamazepine
- rifampicin for the treatment of tuberculosis
- herbal medicines containing St John's Wort
- medicines used to treat HIV such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole, fluconazole
- grapefruit juice
- medicines used to treat diabetes, such as insulin or anti-diabetic medications

These medicines may be affected by Climara or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

HOW TO USE CLIMARA

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

They may differ from the information contained in this leaflet.

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

How much to use

The amount of estrogen you need will depend upon your body's requirements. Your doctor may adjust this amount by changing the size of the patch you use.

How to use it

The best place to apply Climara patches is on your lower abdomen or buttocks. **NEVER put Climara patches on your breasts.** Do not put the patch on your waistline where tight clothes may rub it. Avoid putting the patch on areas where the skin is hairy or folded.

Before applying a Climara patch, make sure your skin is clean and dry. Do not apply the patch to oily, broken or irritated skin.

1. Remove Climara from the pouch

The Climara patch is packed in a protective pouch. Tear open the pouch at the notched corner and remove the patch. Do not use scissors as you may accidentally cut the patch. Do not peel the square silver sticker inside the pouch as this contains the desiccant. **This is not the Climara patch.** Dispose of the pouch once the Climara patch has been applied.

2. Take the backing off the patch

A clear plastic protective backing which is slightly larger than the patch itself covers the sticky side of the patch. The

backing must be removed before you apply the patch to your skin. Remove the backing by holding the edge of the patch in one hand and peeling the backing off with the other hand from the crease line. Half of the backing will come off, exposing part of the patch. As you apply the patch to your skin, peel off the rest of the backing. Do not touch the sticky side of the patch. Apply the patch immediately after opening the pouch and removing the backing. Throw away the backing.

3. Apply the patch to your skin

Place the sticky side of the patch on a clean, dry area of skin. Press the patch firmly in place for about 10 seconds. Make sure the patch sticks well, especially around the edges.

4. Changing Climara patches

Change the patch once every week (every 7 days). Remove the old patch and discard it, out of the way of children. Apply your new patch to a **different** area of clean, dry skin. **Do not put the patch on the same area of skin each week.**

5. What to do if your patch comes off

Climara patches are unlikely to fall off. But if the patch does fall off put a new patch on for the rest of the seven days.

When to use it

Climara patches are usually worn continuously, and replaced every 7 days. You should only wear one patch at a time, unless your doctor tells you otherwise.

Your doctor will explain when to start using the patch and if you should use it any other way (for example, for 3 weeks out of 4).

How long to use it

Your doctor will advise you on how long to use Climara. Your doctor should discuss with you the risks and benefits with extended use of this product and your treatment with hormone therapy should also be re-evaluated at regular intervals.

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

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

If you forget to use it

If you forget to change the Climara patch, change it as soon as you remember. One patch only works for 7 days.

If you lose a patch or forget to replace it for several days, irregular bleeding may occur.

If you use too much (overdose)

Estrogen overdose is unlikely with this type of application. In the event of accidental overdose, remove the patch.

If you are worried, telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or

anyone else may have used too much Climara.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, breast discomfort, breakthrough bleeding, fluid retention and bloating.

WHILE YOU ARE USING CLIMARA

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Tell your doctor immediately if you become pregnant while using Climara. The use of Climara should be stopped immediately.

If you are still able to fall pregnant, barrier methods of contraception should be practised (such as condoms or a diaphragm). If there is a chance that pregnancy has occurred, stop using the patch until it has been ruled out.

If you are going to have surgery, tell the surgeon or anaesthetist well in advance that you are using this medicine.

Climara should not be used at least four to six weeks before surgery.

If irregular menstrual bleeding occurs repeatedly during the use of Climara or if the bleeding in the treatment-free weeks is unusually heavy, tell your doctor.

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, and monitor your blood pressure

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.

Stop using it immediately if

You should stop treatment at once and consult your doctor if you have any of the following conditions:

- your very first attack of migraine (typically a throbbing headache and nausea preceded by visual disturbances)
- worsening of pre-existing migraine, any unusually frequent or unusually severe headaches
- sudden disturbances of vision or hearing
- swollen veins (thrombophlebitis),
- itching of the whole body
- unusual upper abdominal pains that do not disappear within a short period of time
- planned operations/surgery or immobilisation
- seizures
- increase in blood pressure

If you get a blood clot while you are using Climara or there is a suspicion of this you should stop using it immediately and contact

your doctor. Warning signs to look out for are:

- coughing blood
- unusual pains or swelling of your arms or legs
- sudden shortness of breath, pain or tightness in the chest
- fainting

Climara must also be stopped at once if you develop jaundice (yellowing of the skin and/or eyes). Tell your doctor immediately if either occurs.

Things you must not do

Do not use Climara to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

What to be careful of

Excess intake of alcohol during use of HRT has an influence on the treatment. Your doctor will advise you.

Other things to know

- You can bathe, shower or swim when wearing a Climara patch. The patch might, however, become detached from the skin in very hot water or in the sauna.
- You can still drive safely when you are using Climara patches.
- If there are, repeatedly, persistent skin irritations (e.g. persistent reddening or itching at the application site) even if the application site is changed according to the directions given, you should consider stopping treatment.

SIDE EFFECTS

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

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- redness, rash, itching, stinging and blisters on the skin after the patch has been removed
- tender or painful breasts, breast enlargement
- irregular menstrual bleeding
- fluid retention (bloating or swelling in the arms, ankles or feet)
- rash or itching
- nausea
- headache
- nervousness or depressive moods
- dizziness

- unusual tiredness
- changes in body weight
- pain (including back and pelvic pain)
- increased sweating
- leg cramps
- stomach pain, cramps or wind
- acne
- vaginal itching, burning or discharge

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, or other parts of the body, shortness of breath, wheezing, or trouble breathing
- yellowing of the skin and/or eyes (cholestatic jaundice)
- coughing blood, unusual pains or swelling of your arms or legs, sudden shortness of breath, fainting

If you have these side effects, you may need urgent medical attention.

Skin disorders have been reported in women receiving HRT. Tell your doctor if you notice itchy, reddish, painful lumps (erythema nodosum, erythema multiforme, haemorrhagic dermatitis) or yellowish brown pigmentation on the skin (chloasma).

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

Other side effects not listed above may also occur in some people.

Also tell your doctor if you have any of the symptoms listed under “*While you are taking Climara - stop taking it immediately*”.

AFTER USING CLIMARA

Storage

Keep your patches in the pack until it is time to use them.

Do not remove the patch from the protective pouch until you are ready to apply it.

Keep your patches in a cool dry place below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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

When disposing of patches, make sure children cannot reach them.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

A Climara patch is a clear oval thin film with an adhesive side (sticky side) attached to a clear plastic protective backing. Each pack of

Climara contains 4 pouches each containing a patch.

Climara is available in 4 strengths:

- Climara 25
- Climara 50
- Climara 75
- Climara 100

The suffixes ‘25’, ‘50’, ‘75’ and ‘100’ refer to the daily amount of estradiol transferred via the skin to your body from the respective Climara patch.

Not all strengths may be marketed.

Ingredients

Active ingredient per patch:

- Climara 25 - 2 mg of estradiol
- Climara 50 - 3.8 mg of estradiol
- Climara 75 - 5.7 mg of estradiol
- Climara 100 - 7.6 mg of estradiol

Inactive ingredients:

- polymer 55236
- ethyl oleate
- polyethylene backing
- acrylate copolymer adhesive
- glycerol laurate
- isopropyl myristate

Supplier

Made in USA for:

Bayer Australia Ltd
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 875 Pacific Highway
 Pymble NSW 2073
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Australian Registration Number

Climara 25 - AUST R 73962

Climara 50 - AUST R 56197

Climara 75 - AUST R 73963

Climara 100 - AUST R 56198

Date of preparation

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See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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