

CONSUMER MEDICINE INFORMATION

CLIMARA Oestradiol Transdermal Delivery System

Warning

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

The *oestrogen plus progestogen* arm of the WHI trial indicated an increased risk of *myocardial infarction (MI), stroke, invasive breast cancer, pulmonary emboli 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 *oestrogen-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 oestrogens with medroxyprogesterone acetate, and other combinations and dosage forms of oestrogens 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:

- Oestrogens with or without progestogens should not be prescribed for primary or secondary prevention of cardiovascular diseases.
- Oestrogens with or without progestogens should be prescribed at the lowest effective dose for the approved indication.
- Oestrogens with or without progestogens should be prescribed for the shortest period possible for the approved indication.
- For the prevention of osteoporosis, oestrogen 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 a patch used to replace the oestrogen that the body stops producing around the time of the menopause.

Menopause ("change of life") is the cessation of menstruation, ie the time a woman has her last menstrual period; but the term menopause is used to define the years around that event when the body begins to produce less oestrogen.

This dropping level of oestrogen may cause symptoms in some women.

Climara can also be used in women who have had an operation to remove their ovaries as this causes instant menopause.

The symptoms of menopause are caused by a lack of oestrogen. These symptoms include:

- hot flushes (night sweats)
- sleep disturbances
- vaginal dryness
- depression
- nervousness
- irritability
- headache
- dizziness
- thinning of the bones (this can cause fractures)

Calcium, vitamin D and regular exercise 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 an adhesive patch, which delivers oestradiol through the skin and into the blood stream.

The oestradiol in Climara can replace the oestrogen, which the body is no longer making.

Climara releases oestradiol 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 oestrogen than would be needed in a tablet.

The use of oestrogens 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 for you a progestogen to take and you should discuss this with your doctor before using Climara.

Climara is not a contraceptive.

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

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

Hormone replacement therapy should not be prescribed to prevent heart disease or for general well being.

If there is a suspicion of an adenoma (a type of non-cancerous tumour) of the anterior lobe of the pituitary gland, this should be ruled out by your doctor before starting treatment.

When you must not use it
Do not use Climara if you have an allergy to:

- oestradiol, 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 this medicine if you are pregnant.

It may affect your developing baby if you take 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.

Climara should not be used if any of the following conditions exist:

- severe uncontrolled high blood pressure
- severe disturbances of liver function
- jaundice or persistent itching during a previous pregnancy
- previous or existing liver tumours
- tumours of the womb, ovaries or breast or a suspicion or a history of such tumours
- endometriosis
- existing or previous thromboembolic processes, (such as blood clots in the legs, stroke, heart attack)
- severe diabetes mellitus with changes to your blood vessels
- sickle-cell anaemia
- disturbances of fat metabolism
- a history of herpes of pregnancy
- otosclerosis (a form of hearing loss) with deterioration during pregnancy

- undiagnosed abnormal vaginal bleeding.

If you think any of these conditions apply to you, you should discuss this with your doctor.

Do not use Climara or other oestrogens, with or without a progestogen to prevent heart attack, stroke or dementia.

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 09 refers to November 2009). 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 taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes. You should be aware of the following before using Climara:

- Climara is not a contraceptive
- if you are still able to fall pregnant, contraception should be practised with non-hormonal methods (with the exception of the rhythm and temperature methods). If there is a

chance that pregnancy has occurred, patch use must be interrupted until it has been ruled out

- if you become pregnant Climara should be immediately discontinued.

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)
- 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 (neurological disorder characterised by irregular and involuntary muscles)
- heart failure
- disturbances of kidney or liver function
- migraine
- gall bladder disease
- a high level of triglycerides in the blood
- unusually high or low calcium level in the blood
- low levels of thyroid hormone requiring supplementation
- there is a family history of breast cancer, blood clots or cancer of the womb
- you have or have had chloasma (yellow brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- you suffer from asthma
- you have systemic lupus erythematosus (SLE; a

disease affecting the skin all over the body)

- you suffer from episodes of swelling in body parts such as hands, feet, face, airway passages that are caused by a defect in the gene that controls a blood protein called C1-inhibitor (hereditary angioedema). The hormone oestradiol in Climara may induce or exacerbate symptoms of hereditary angioedema
- 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).

Please also inform your doctor if you have suffered from fibrocystic disease of the breasts 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. Hormone replacement therapy has been reported to result in an increased number of abnormal mammograms requiring further evaluation.

Also inform your doctor if you have suffered from benign tumours of the uterine smooth muscles, since the size of such

tumours can increase under oestrogen therapy. In all these cases, and also where there is a history of swelling or unusual pains in the legs, strict medical supervision is necessary.

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:

- birth control pills
- sleeping tablets
- arthritis medicine
- antibiotics
- medications for tuberculosis
- medication for epilepsy
- medicines containing St John's Wort.

The requirement for oral antidiabetic medication and insulin can change.

Excess intake of alcohol during use of hormone replacement therapy can have an influence on the treatment. Your doctor will advise you.

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.

The requirement for oral antidiabetic medication and insulin can change.

Your doctor and pharmacist have more information on

medicines to be careful with or avoid while taking 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 oestrogen 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.

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 take 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)

Oestrogen 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

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 taking Climara.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Do not use Climara patches if you are having an operation. Stop Climara at least four to six weeks before any planned operations.

If you have an accident or you have to stay in bed for several weeks, stop using Climara patches.

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

Contact your doctor as soon as possible if you feel a lump in your breast.

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 taking it suddenly, your condition may worsen or you may have unwanted side effects.

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 you should consider stopping transdermal treatment.
- In rare cases benign and in even rarer cases malignant liver tumours leading in

isolated cases to life-threatening intra-abdominal haemorrhage have been observed after the use of hormonal substances such as the one contained in Climara. The doctor must therefore be informed of the occurrence of unusual upper abdominal complaints which do not disappear spontaneously within a short time.

Studies have suggested that HRT may be associated with an increased risk of developing blood clots in the deep veins of the legs which may break away and block the arteries of the lungs. Possible signs of these include an unusual cough, coughing of blood, severe pain in the chest, breathlessness, severe pain or swelling in either of your legs, fainting. If any of these develop you should stop using Climara and contact your doctor immediately.

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 lists of side effects. You may not experience any of them.

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

The most common side effects of Climara include:

- itching under the patch
- reddening of the skin after the patch has been removed. This usually disappears within a few days
- tender or painful breasts
- breakthrough bleeding ("spotting") between periods
- fluid retention (bloating or oedema)
- rash or itching
- nausea
- headache
- change in menstrual flow
- itching of the vagina
- nervousness or depressive moods
- dizziness
- unusual tiredness
- alterations in body weight
- pain (including back and pelvic pain)
- increased sweating
- leg cramps
- stomach pain or wind
- acne
- changes in vaginal secretion.

The less common side effects of Climara include:

Check with your doctor as soon as possible if the following side effects occur, since they may need medical attention:

- vomiting or abdominal cramps
- abnormal heartbeat
- frequent headaches or worsening of migraines
- yellow colour of the skin or eyes
- dark coloured urine
- change in sex drive
- darkened patches on the skin, particularly on the face
- worsening of the inherited disease called porphyria

- increase in size of fibroids of the womb
- changes in vaginal secretion

Stop using Climara immediately and contact your doctor if you notice any of the following:

- pain or swelling of the legs
- stabbing pain on breathing or coughing for no apparent reason
- breathlessness
- a feeling of pain or tightness in the chest
- onset of jaundice
- onset of hepatitis
- itching of the whole body
- increase in epileptic seizures
- significant rise in blood pressure
- pregnancy
- 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
- inflamed veins (phlebitis).

In women with episodes of swelling of body parts such as hands, feet, face, airway passages that are caused by a defect in the gene that controls a blood protein called C-inhibitor (hereditary angioedema) the hormone oestradiol in Climara may induce or exacerbate symptoms of hereditary angioedema.

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.

AFTER USING CLIMARA

Storage

Keep your patches in the cardboard carton 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 cardboard carton 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 damp 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 taking 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 oestradiol transferred via the skin to your body from the respective Climara patch.

Ingredients

Active ingredients per patch:

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

Inactive ingredients:

- polymer 55236
- ethyl oleate
- polyethylene backing
- glycerol laurate
- isopropyl myristate

Supplier

Made in USA for:

Bayer Australia Limited
 ABN 22 000 138 714
 875 Pacific Highway
 Pymble NSW 2073
 Australia

Bayer New Zealand Limited
 3 Argus Place
 Hillcrest, North Shore
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 New Zealand

Australian registration number

Climara 25 AUST R 73962
Climara 50 AUST R 56197
Climara 75 AUST R 73963
Climara 100 AUST R 56198.

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September 2011

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

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