CLIMARA®

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 CLIMARA®?

CLIMARA® contains the active ingredient estradiol. 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.

For more information, see Section 1. Why am I using CLIMARA®? in the full CMI.

2. What should I know before I use CLIMARA®?

Do not use if you have ever had an allergic reaction to estradiol 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 CLIMARA®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLIMARA® 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 CLIMARA®?

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.
The best place to apply CLIMARA® patches is on your lower abdomen or buttocks. Never put CLIMARA® patches on your breasts.

More instructions can be found in Section 4. How do I use CLIMARA®? in the full CMI.

5. What should I know while using CLIMARA®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CLIMARA®. • If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	• Do not take 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.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how CLIMARA® affects you. • CLIMARA® may cause dizziness in some people.
Drinking alcohol	• Tell your doctor if you drink alcohol. • Excess intake of alcohol during use of HRT has an influence on the treatment.
Looking after your medicine	• 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.

For more information, see Section 5. What should I know while using CLIMARA®? in the full CMI.

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. Ask your doctor or pharmacist if you have any further questions about side effects.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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.

CLIMARA® (Clim·AR·rah)

Active ingredient(s): *estradiol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CLIMARA®. **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 CLIMARA®.**

Where to find information in this leaflet:

1. Why am I using CLIMARA®?

CLIMARA® contains the active ingredient estradiol. CLIMARA® is an adhesive patch, which delivers estradiol through the skin and into the blood stream.

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® 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.

2. What should I know before I use CLIMARA®?

Warnings

Do not use CLIMARA® if you have:

- an allergy to estradiol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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

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 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®.

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.
- smoke.
- or anyone in your immediate family has had blood clots (thrombosis).
- have systemic lupus erythematosus (SLE, a chronic inflammatory disease).
- 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 gall bladder.

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®.

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 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.

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.

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.

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

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

4. How do I use CLIMARA®?

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.

- Follow the instructions provided and use CLIMARA® until your doctor tells you to stop.

When to use CLIMARA®

- 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 to use CLIMARA®

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.

How long to use CLIMARA®

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 CLIMARA®

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 CLIMARA®

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

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. Symptoms of an overdose may include nausea, vomiting, breast discomfort, breakthrough bleeding, fluid retention and bloating.

5. What should I know while using CLIMARA®?

Things you should 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.

Call your doctor straight away

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 CLIMARA® 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 should 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.

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.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CLIMARA® affects you.

CLIMARA® may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

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

- 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.

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 windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

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

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.

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).

Less serious side effects

Less serious side effects	What to do
General disorders and application site conditions: • redness, rash, itching, stinging and blisters on the skin after the patch has been removed • fluid retention (bloating or swelling in the arms, ankles or feet) • unusual tiredness • pain (including back and pelvic pain) **Reproductive:** • tender or painful breasts, breast enlargement • irregular menstrual bleeding • vaginal itching, burning or discharge **Central and peripheral nervous system:** • headache • dizziness • leg cramps **Autonomic nervous system:** • increased sweating **Gastrointestinal system:** • nausea • stomach pain, cramps or wind **Metabolic and nutritional:** • changes in body weight **Psychiatric:** • nervousness or depressive moods **Skin and appendages:** • rash or itching • acne	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Immune system disorders: • 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 **Gastrointestinal system:** • yellowing of the skin and/or eyes (cholestatic jaundice) **General disorders:** • coughing blood, unusual pains or swelling of your arms or legs, sudden shortness of breath, fainting	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

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

Reporting side effects

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

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

7. Product details

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

What CLIMARA® contains

Active ingredient (main ingredient)	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
Other ingredients (inactive ingredients)	• polymer 55236 • ethyl oleate • polyethylene backing • acrylate copolymer adhesive • glycerol laurate • isopropyl myristate

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

What CLIMARA® 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 (Aust R 73962)
- CLIMARA® 50 (Aust R 56197)
- CLIMARA® 75 (Aust R 73963)
- CLIMARA® 100 (Aust R 56198)

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.

Who distributes CLIMARA®

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

www.bayer.com.au

This leaflet was prepared in December 2021.

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

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