



Read all of this leaflet carefully before you start using this medicine.

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.*
- *If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

The name of your medicine is Climanor 5mg Film-Coated Tablets. In the rest of this leaflet it is called Climanor Tablets.

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1. WHAT CLIMANOR IS AND WHAT IT IS USED FOR

The active ingredient in Climanor Tablets is medroxy progesterone acetate (MPA) a type of progesterone. Climanor Tablets are used for irregular or absent periods, endometriosis (see definition below) and for hormone replacement therapy.

Hormone Replacement Therapy (HRT)

Climanor Tablets can also be used along with an oestrogen product for hormone replacement therapy in women who have not had their womb removed (hysterectomy). Levels of the female hormone oestrogen fall during and after the menopause and this fall causes symptoms such as hot flushes, sweats and vaginal dryness. Oestrogen products relieve these symptoms, but they stimulate the lining of the womb and if given alone there is an increased risk of the number of cells in the lining of the womb increasing and cancer of the womb occurring. Taking Climanor Tablets as well as an oestrogen product reduces this risk.

Climanor is used for:

Irregular or absent periods

There are lots of reasons for your period pattern to change, for example losing weight or getting stressed. Your doctor will try to find out the reason why your periods have become absent or irregular. It may be that something has disrupted your hormone rhythm causing your progesterone levels to be lower than normal. Normally, a week before your period your progesterone levels will increase. Climanor Tablets copy this rise in progesterone levels and after two to three months of taking Climanor Tablets your progesterone levels may even out, allowing you to have regular periods.

Endometriosis

Endometriosis is a condition in which small pieces of lining from the womb spread to other parts of the abdomen (ovaries, womb and bladder). Usually these pieces are cleared away, but sometimes they will grow into patches. These patches will thicken, break down and bleed every month just like the real womb lining. In some cases endometriosis may cause pain and can also cause problems with the bladder and bowels. Climanor Tablets will stop these patches from thickening and bleeding. After taking Climanor Tablets these patches will become smaller and maybe disappear altogether.

2. BEFORE YOU TAKE CLIMANOR

Medical history and regular check-ups Regular check-ups

Once you've started on Climanor Tablets, you should see your doctor for regular check-ups (at least once a year). At these check-ups, your doctor will discuss with you the benefits and risks of continuing to take Climanor Tablets. As well as benefits, HRT has some risks which you need to consider when you are deciding whether to take it, or whether to carry on taking it.

Before you start taking Climamor Tablets

Before you start taking Climamor Tablets, your doctor should ask about your own and your family's medical history. Your doctor may decide to examine your breasts and/or abdomen, and may do an internal examination -but only if these examinations are necessary for you, or if you have any special concerns.

Be sure to:

- go for regular breast screening and cervical smear tests
- regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

Do not take Climamor

- are allergic to medroxyprogesterone acetate or any of the other ingredients contained in Climamor Tablets (see list under heading 'What Climamor Tablets contain 'in.
- Currently have or have previously had breast cancer
- Currently have or have previously suffered from dots forming in the veins or travelling to other parts of the body, such as the lungs
- have an abnormality of your clotting system that makes you more prone to develop blood dots.
- have porphyry (an inherited blood disorder)
- have angina or have recently had a heart attack (myocardial infarction)
- have acute liver disease or a history of liver disease which is not completely resolved
- are pregnant or think you might be pregnant (you should use extra non-hormone contraceptive precautions whilst taking Climamor Tablets)
- are breast-feeding

Do not take Climamor Tablets with an oestrogen product for HRT if you:

- have cancer which is dependent on oestrogen e.g. endometrial cancer (cancer of the lining of the womb)
- have abnormal vaginal bleeding which has not been diagnosed
- have endometrial hyperplasia (an increase in the number of cells in the lining of the womb) which has not been treated

If any of the above statements apply to you, you should not take Climamor Tablets

When to take special care with Climamor

Speak to your doctor before taking Climamor Tablets if you are suffering from any of the following conditions, or have suffered from any of these conditions in the past, as these conditions may come back or get worse with Climamor Tablets and so your doctor may wish to see you more often:

- epilepsy
- migraine or severe headaches
- asthma
- high blood pressure
- A risk of cancer which is dependent on oestrogen e.g. a family history of breast or endometrial cancer (cancer of the lining of the womb).
- fibroids (growths in the womb)
- endometriosis (the growth of tissue from the womb outside the womb)
- a history of endometrial hyperplasia (an increase in the number of cells in the lining of the womb)
- gall stones
- diabetes
- deafness caused by a condition of the middle ear (otosclerosis)
- Systemic Lupus Erythematosus (SLE) (a disease where the body's immune system attacks the body's cells and tissues)
- any condition which makes you at risk of blood clots.
- liver problems

Stop taking Climamor and see a doctor immediately

- jaundice (yellowing of the skin or eyes) or other liver problems
- significantly increased blood pressure
- pregnancy
- new or unusual migraine-type headaches, with or without disturbed vision
- if you start to have any of the conditions listed earlier in 'Some women should not take Climamor Tablets:

Speak to your doctor immediately and stop taking Climamor Tablets.

HRT and cancer

For women who have not had their womb removed, 10mg should be taken every day for the last 14days of each 28day cycle.

Your doctor will aim to give you the lowest dose of HRT for the shortest time needed to help your symptoms.

Irregular bleeding If you get breakthrough bleeding or spotting, it is usually nothing to worry about, especially during the first few months of taking Climanor Tablets. However, you should speak to your doctor if your vaginal bleeding carries on for more than the first few months, starts after you have been on Climanor Tablets for awhile or carries on even after you have stopped taking Climanor Tablets,

Endometrial cancer (cancer of the lining of the womb)

Taking oestrogen-only HRT for a long time can increase the risk of cancer of the lining of the womb (the endometrial).

Taking a progesterone (such as Climanor Tablets) as well as the oestrogen helps to lower the extra risk.

If you still have your womb, your doctor will therefore usually prescribe a progesterone as well as oestrogen.

If you have had your womb removed (a hysterectomy), your doctor will discuss with you whether you can safely take oestrogen without a progesterone. Climanor Tablets are not recommended for patients who have had their womb removed.

If you get breakthrough bleeding or spotting, it is usually nothing to worry about, especially during the first few months of taking Climanor Tablets. Speak to your doctor if the bleeding or spotting:

- carries on for more than the first few months
- starts after you have been on Climanor Tablets for awhile
- carries on even after you have stopped taking Climanor Tablets.

The above may be a sign that your endometrium has become thicker or you have endometrial cancer.

How likely is Endometrial cancer?

*Looking at women who still have a uterus and who **are not** taking HRT -on average **5 in 1,000** will be diagnosed with endometrial cancer.*

*For women who take oestrogen-only HRT, the number will be **2-12 times higher**, depending on the dose and how long they take it. Even after they stop taking oestrogen-only HRT, they will be at higher risk for at least 10years*

The addition of progesterone to oestrogen-only HRT, for at least 12 days per month (such as Climanor Tablets), prevents the extra risk of endometrial cancer seen with oestrogen-only HRT.

Breast cancer

Women who have or are suspected of having breast cancer, or have had breast cancer in the past, should not take HRT. Taking HRT increases the risk of breast cancer.

The risk for a woman who is taking oestrogen plus progesterone HRT is higher than for oestrogen-only HRT (but oestrogen plus progesterone HRT is beneficial for the endometrium, see 'Endometrial cancer' above).

For all kinds of HRT, the extra risk of breast cancer goes up the longer you take HRT, but it returns to normal within about five years after stopping HRT.

Your risk of breast cancer is also higher if you:

- have a close relative (mother, sister or grandmother) who has had breast cancer
- are seriously overweight.

Speak to your doctor immediately and stop taking Climanor Tablets if you notice any changes in your breast such as:

- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel.

How likely is breast cancer?

Looking at women between the ages of 50 and 65 who are not taking HRT -around 9-12 in 1,000 will be diagnosed with breast cancer over a 5year period'.

*For women who start taking **oestrogen plus progesterone HRT** and take it for **5 years**, there will be around an extra **6 cases per 1,000**.*

*If they take **oestrogen plus progesterone HRT** for more than **5 years**, the risk of breast cancer is doubled.*

Ovarian cancer

Some studies have indicated that taking oestrogen plus progesterone HRT for more than 5 years may slightly increase the risk of ovarian cancer by 1 extra case per 2,500 women.

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

HRT may increase the risk of blood clots in the veins (also called deep vein thrombosis, or DVT), by up to 3 times, especially during the first year of taking it. These blood clots are not always serious, but if one travels up to the lungs it can cause chest pain, breathlessness, collapse or even death. This condition is called pulmonary embolism or PE. DVT and PE are examples of a condition called venous thromboembolism or VTE.

The risk of a blood clot increases with age. In addition you are more likely to get a blood clot if:

- you are seriously overweight
- you have had a blood clot before
- any of your close family have had blood clots
- you are pregnant or just recently had a baby
- you have had one or more miscarriages
- you have any blood clotting problem that needs treatment with a medicine such as warfarin
- you are off your feet for a long time because of major surgery, injury or illness
- you have a rare condition called SLE
- you have cancer.

If any of the above statements apply to you; speak to your doctor to see if you should take Climamor Tablets.

Speak to your doctor immediately and stop taking HRT if you get any of the following as these may be signs of blood clot:

- painful swelling in your leg
- sudden chest pain
- difficulty breathing.

How likely is a blood clot?

*Looking at women in their 50s who **are not** taking HRT -on average, over a 5 year period; **4 in 1,000** would be expected to get a blood clot.*

*For women in their 50s who **are** taking oestrogen plus progesterone HRT, the figure would be around **9 in 1,000 (i.e an extra 5 cases)**.*

Heart disease (heart attack)

HRT is **not recommended** for women who have heart disease, or have recently had heart disease. If you have ever had heart disease, speak to your doctor to see if you should be taking Climamor Tablets.

Climamor Tablets will not help to prevent heart disease.

Studies have shown that women over the age of 60 taking oestrogen plus progesterone HRT may be slightly more likely to get heart disease.

Speak to your doctor immediately and stop taking HRT if you get a pain in your chest that spreads across your arm or neck as this pain could be a sign of heart disease.

Stroke

New or unusual migraine-type headaches, with or without disturbed vision, could be an early warning of a stroke.

Speak to your doctor immediately and stop taking HRT if you experience this.

The risk of having a stroke is up to 1.5 times higher with oestrogen plus progesterone HRT.. Other things that can increase the risk of stroke include:

- getting older
- family history of stroke
- high blood pressure
- smoking
- high cholesterol
- being overweight or obese
- drinking too much alcohol
- an irregular heartbeat

If you are worried about any of the above or if you have had a stroke in the past, speak to your doctor to see if you should take Climamor Tablets.

How likely is a Stroke?

Looking at women in their 50s who **are not** taking HRT -on average, over a 5 year period; 8 in 1,000 would be expected to have a stroke.

For women in their 50s who **are** taking HRT, the figure would be around 11 in 1,000 (i.e. an extra 3 cases).

3. HOW TO TAKE & USE Climanor

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely and also follow any special instructions or warnings which appear on the label which the pharmacist has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist. Climanor Tablets should be swallowed with a glass of water. 5-10mg per day should be taken for 5-10 days starting on the 16th to 20th day of your menstrual cycle, for two consecutive cycles. If you are also prescribed an oestrogen product you may be asked to take Climanor Tablets for 12 days. 5-10mg per day should be taken for 5-10 days starting on the 16th to 20th day of your menstrual cycle, for three consecutive cycles. If you are also prescribed an oestrogen product you may be asked to take Climanor Tablets for 12 days. 10mg should be taken three times a day for 90 consecutive days beginning on the first day of the menstrual cycle. Breakthrough bleeding may occur.

If you need to have surgery

If you are going to have surgery make sure your doctor knows about it. You may need to stop taking Climanor Tablets about four to six weeks before the operation to reduce the risk of a blood clot. Your doctor will tell you when to start taking Climanor Tablets again.

4. POSSIBLE SIDE EFFECTS

Like many medicines Climanor Tablets may cause side effects in some patients, although not everybody gets them. Tell your doctor or pharmacist if you are worried about any side effects which you think may be due to Climanor Tablets.

Serious side effects - see your doctor immediately

You should speak to your doctor immediately and stop taking Climanor Tablets if you experience any of the following:

- jaundice (yellowing of the skin or eyes) or other liver problems
- significantly increased blood pressure
- pregnancy
- signs of a blood clot in your leg or lungs e.g. painful swelling in your leg, sudden chest pain or difficulty breathing
- signs of heart disease e.g. pain in your chest that spreads to your arm or neck which may be a heart attack
- new or unusual migraine-type headaches, with or without disturbed vision
- stroke
- serious allergic reaction e.g. rash, itching, swelling of face, throat or tongue, wheezing, difficulty breathing, unconsciousness
- any changes in your breast such as dimpling of the skin, changes in the nipple or any lumps you can see or feel
- breast cancer
- endometrial cancer (cancer of the lining of the womb).

Other side effects

In the reproductive and urinary system

- spotting | bleeding from the vagina.

In the breasts

- tenderness
- secretion of milk.

In the stomach

- feeling sick
- indigestion
- gall bladder disease.

In the skin

- itching
- rash
- acne
- loss of scalp hair
- excessive growth of body hair.

In the nervous system and brain

- nervousness
- unable to sleep
- feeling tired

- dizziness
- mental depression
- headache
- dementia over the age of 65.

In other parts of the body

- increase in weight

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist immediately.

5. HOW TO STORE CLIMANOR TABLETS

Keep out of the reach and sight of children.

Do not take this medicine if the expiry date on the pack has passed. The expiry date refers to the last day of that month.

Climanor Tablets should not be taken if they show signs of deterioration such as discoloration.

Do not store above 25 °C.

Store in the original container or package in order to protect from light and moisture. Do not transfer the tablets to another container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Climanor Tablets contain**

The active ingredient in Climanor Tablets is medroxyprogesterone acetate (MPA).

Other ingredients are lactose, crospovidone, povidone, talc, magnesium stearate, Opradry white Y-1-7000, methocel E5 premium, titanium dioxide E171 and polyethylene glycol.

What Climanor Tablets look like and contents of the pack

Climanor Tablets are round, white, biconvex (curved on both sides) film coated tablets, 6mm in diameter. They are available in pack sizes of 10, 14 and 28 tablets.

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