

Package leaflet: Information for the user
Cyclo-Progynova® 2 mg
Estradiol valerate and norgestrel

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Cyclo-Progynova 2 mg will be called Cyclo-Progynova.

What is in this leaflet

1. What Cyclo-Progynova is and what it is used for
2. What you need to know before you take Cyclo-Progynova
3. How to take Cyclo-Progynova
4. Possible side effects
5. How to store Cyclo-Progynova
6. Contents of the pack and other information

1. What Cyclo-Progynova is and what it is used for

Cyclo-Progynova belongs to a group of medicines called hormone replacement therapy (HRT). Cyclo-Progynova contains two hormones called estradiol (an oestrogen) and norgestrel (a progestogen). These act in different ways in your body. Cyclo-Progynova is used in postmenopausal women with at least 6 months since their last natural period and in peri-menopausal women.

Cyclo-Progynova works by replacing the oestrogen you lose during the menopause and therefore improves the unpleasant symptoms you may get. Oestrogen can also make the lining of your womb grow more than usual, which may lead to cancer developing there. The other hormone in Cyclo-Progynova called a progestogen reduces the chance of getting cancer of the womb.

Cyclo-Progynova is used for:

Relief of symptoms occurring after menopause

During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Cyclo-Progynova alleviates these symptoms after menopause. You will only be prescribed Cyclo-Progynova if your symptoms seriously hinder your daily life.

Prevention of osteoporosis

After the menopause some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor.

If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Cyclo-Progynova to prevent osteoporosis after menopause.

There are some small risks with taking HRT and you should discuss this with your doctor before you start taking Cyclo-Progynova (also see Section 2).

2. What you need to know before you take Cyclo-Progynova

Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on Cyclo-Progynova you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Cyclo-Progynova.

Go for regular breast screening, as recommended by your doctor.

Do not take Cyclo-Progynova if any of the following applies to you. If you are not sure about any of the point below, **talk to your doctor** before taking Cyclo-Progynova.

Do not take Cyclo-Progynova:

- If you are **allergic** (hypersensitive) to **estradiol valerate, norgestrel** or any of the other ingredients of Cyclo-Progynova (listed in section 6 Further information)
- If you have or have ever had **breast cancer**, or if you are suspected of having it
- If you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have any **unexplained vaginal bleeding**
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal
- If you have a rare blood problem called “porphyria” which is passed down in families (inherited).

If any of the above conditions appear for the first time while taking Cyclo-Progynova, stop taking it at once and consult your doctor immediately.

Warnings and precautions

Tell your doctor before taking Cyclo-Progynova if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Cyclo-Progynova. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots (see “Blood clots in a vein (thrombosis)”)
- increased risk of getting an oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems
- premature menopause
- hereditary and acquired angioedema (see section 4).

Stop taking Cyclo-Progynova and see a doctor immediately

- If you notice any of the following when taking HRT: any of the conditions mentioned in the ‘DO NOT take Cyclo-Progynova’ section;
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- swollen face, tongue and / or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as
 - painful swelling and redness of the legs
 - sudden chest pain
 - difficulty in breathing.

For more information, see ‘Blood clots in a vein (thrombosis)’

Note: Cyclo-Progynova is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

The progestogen in Cyclo-Progynova protects you from this extra risk.

Irregular bleeding

You may have irregular bleeding or drops of blood (spotting) during the first 3-6 months of taking Cyclo-Progynova. However, if the irregular bleeding:

- carries on for more than the first 6 months
- starts after you have been taking Cyclo-Progynova for more than 6 months
- carries on after you have stopped taking Cyclo-Progynova

see your doctor as soon as possible.

Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking Cyclo-Progynova. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:

- carries on for more than the first 6 months
- starts after you have been taking Cyclo-Progynova more than 6 months
- carries on after you have stopped taking Cyclo-Progynova

see your doctor as soon as possible.

Breast cancer

Evidence shows that taking combined oestrogen-progestogen or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT, the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Compare

Women aged 50 to 54 who are not taking HRT, on average, 13 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period.

For women aged 50 who start taking oestrogen-only HRT for 5 years, there will be 16-17 cases in 1000 users (i.e. an extra 0 to 3 cases).

For women aged 50 who start taking oestrogen-progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases).

Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period.

For women aged 50 who start taking oestrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases).

For women aged 50 who start taking oestrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. 21 extra cases).

- **Regularly check your breasts. See your doctor if you notice any changes such as:**
 - dimpling of the skin
 - changes in the nipple
 - any lumps you can see or feel.

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer

Ovarian cancer is rare - much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

Effects of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m²)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer.

For signs of a blood clot, see “Stop taking Cyclo-Progynova and see a doctor immediately”.

Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

For women in their 50s who have had their womb removed and have been taking oestrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1000 users (i.e. 1 extra case).

Heart disease (heart attack)

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Other conditions

- HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Other medicines and Cyclo-Progynova

Some medicines may interfere with the effect of Cyclo-Progynova . This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine)
- Medicines for **tuberculosis** such as rifampicin or rifabutin (to treat infections)
- Herbal medicines containing the herb **St. John's Wort** (*Hypericum perforatum*)
- Medicines to treat **diabetes** (such as Insulin)
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir).

HRT can affect the way some other medicines work:

- A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures
- Medicines for Hepatitis C virus (HCV) (such as combination regimens ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Cyclo-Progynova contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Cyclo-Progynova with this HCV combination regimen.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription herbal medicines or other natural products. Your doctor will advise you.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking Cyclo-Progynova, because this medicine can affect the results of some tests.

Pregnancy and breast-feeding

Cyclo-Progynova is for use in perimenopausal and postmenopausal women only. If you become pregnant, stop taking Cyclo-Progynova and contact your doctor.

Driving and using machines

Whilst taking Cyclo-Progynova you may feel dizzy. If this happens, do not drive or operate machinery.

Cyclo-Progynova contains Lactose and Sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Cyclo-Progynova

Always take Cyclo-Progynova exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

When to start taking your medicine for the first time

Depending on your situation you should start to take this medicine at the following times of the month:

- If you are having regular periods, start taking the medicine on the fifth day of your period
- If you are not having regular periods, you can start at any time
- If you are changing from another HRT medicine that gives you a period complete the treatment course of the other medicine. Then on the next day start to take this medicine
- If you are changing from another HRT medicine that does not give you a period, you can start at any time.

How to use the medicine

- Your pack contains 1 foil memo-strip and 7 blue stickers showing days of the week. Each blue sticker starts with a different day of the week
- Peel off a strip that starts with your starting day. Stick this sticker along the top of the foil memostrip where it states 'fix the blue sticker here' so that the first day is above the pill marked 'start'
- You can now see on which days you have to take each tablet. Take one tablet each day, following the direction of the arrows, until you have finished all 21 tablets
- Swallow the tablets whole with water. Do not chew the tablets
- Take the tablets at the same time every day
- After day 21 you will have a 7 day tablet free break. During this week, bleeding similar to a period may occur. This is normal
- Start the next strip immediately after the 7 day break. You will start your new strip of tablets on the same day of each month. Take the tablets even if your bleeding has not finished
- If you are not sure how to use the sticker and the memo-pack then please ask your pharmacist for advice.

Medical check-ups

Once you are taking this medicine:

- Regularly check your breasts for any changes. **If you notice dimpling of the skin, changes in the nipple, or any lumps you must see your doctor as soon as possible**
- Go for regular breast screening
- Go for regular cervical smear tests.

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 HRT.

What bleeding pattern to expect with Cyclo-Progynova

As with normal periods, the amount of blood loss will vary from woman to woman.

Your bleeding pattern may change when you are taking this medicine. You may have:

- Bleeding in the first three weeks of starting the tablets. If so, ask your doctor for advice
- Heavier bleeding. You may notice this more if your periods have become short or lighter before you started treatment. This is normal
- Bleeding in the break where you take no tablets. This is normal.

If after several months you are still getting spotting or breakthrough bleeding, or you are worried about your bleeding you must see your doctor.

If you take more Cyclo-Progynova than you should

If you or somebody else takes too many Cyclo-Progynova tablets, they are unlikely to come to any harm. Overdose may cause nausea and vomiting and irregular bleeding.

No specific treatment is necessary, but you should consult your doctor if you are concerned.

If you forget to take Cyclo-Progynova

- If your tablet is less than 12 hours late, take the tablet as soon as possible, then take your next tablet at the normal time
- If your tablet is more than 12 hours late, leave the forgotten tablet in the pack, and take your next tablet at the normal time
- You may get some vaginal bleeding (breakthrough bleeding) if you have missed a tablet. This is normal.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking Cyclo-Progynova . You may need to stop taking Cyclo-Progynova about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start taking Cyclo-Progynova again.

4. Possible side effects

Like all medicines, Cyclo-Progynova can cause side effects, although not everybody gets them.

If you have any of the following symptoms:

- **Chest pain that spreads to your arm or neck**
- **Sudden numbness or confusion**
- **Difficulty breathing**
- **Severe rash that might blister**
- **Sudden pain and swelling in your leg**
- **You notice yellowing of your skin or eyes**
- **Severe or prolonged headache, possibly with disturbed vision for the first time.**

Seek immediate medical help and stop taking Cyclo-Progynova.

If you get any of the following symptoms:

- **If you notice any changes in your breast such as a lump, dimpling in the skin or the nipple changing**
- **If bleeding or spotting carries on for more than the first few months, or starts after you have been taking the tablets for a while**
- **If bleeding or spotting carries on even after you've stopped taking HRT.**

See your doctor as soon as possible.

Important: All the symptoms in the boxes above are signs that you may be developing a serious problem. If you ignore these symptoms, they may become worse.

The following diseases are reported more often in women using HRT medicines which circulate in the blood compared to women not using HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65.

For more information about these side effects, see Section 2.

Other possible side effects

The following symptoms, which may or may not have been caused by hormone replacement therapy, and which in some cases were probably symptoms of the climacteric, have been reported in users of different oral hormone replacement therapy preparations:

Common undesirable effects (between 1 and 10 in every 100 users may be affected)

- weight loss or gain
- headache
- stomach pain, nausea
- rash, itching
- vaginal bleeding including Spotting (bleeding irregularities usually subside during continued treatment)

Uncommon undesirable effects (between 1 and 10 persons in every 1,000 users may be affected)

- allergies (hypersensitivity reaction)
- depressed mood
- dizziness
- visual disturbances
- palpitations (irregular, rapid beating or pulsation of the heart)
- dyspepsia (indigestion)
- erythema nodosum (reddish painful nodules),
- urticaria (hives)
- breast pain, breast tenderness

Rare undesirable effects (between 1 and 10 in every 10,000 users may be affected)

- anxiety, libido decreased, or libido increased (an increase or a decreased interest in sex)

- migraine
- contact lens intolerance
- bloating, vomiting
- hirsutism (excessive hair growth), acne
- muscle cramps
- dysmenorrhoea (painful period), vaginal discharge, Pre-menstrual-like syndrome, swollen breast
- fatigue

The following side effects have been reported with other HRTs:

- gall bladder disease
- various skin disorders:
 - discoloration of the skin especially of the face or neck known as “pregnancy patches” (chloasma);
 - rash with target-shaped reddening or sores (erythema multiforme).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cyclo-Progynova

Keep out of the sight and reach of children.

Do not use Cyclo-Progynova after the expiry date on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cyclo-Progynova contains

- There are two active substances in this medicine. The white tablets contain 2mg of estradiol valerate. The pale-brown tablets contain 2 mg of estradiol valerate and 0.5 mg of norgestrel
- The other ingredients are lactose (see section 2 “Cyclo-Progynova contains Lactose and Sucrose”), maize starch, povidone, talc, magnesium stearate (E572), sucrose (see section 2 “Cyclo-Progynova contains Lactose and Sucrose”), calcium carbonate (E170), polyethylene glycol 6000.

The white tablets also contain titanium dioxide (E171), yellow ferric oxide (E172) and red brown ferric oxide (E172)

The pale-brown tablets also contain glycerin and montan glycol wax.

What Cyclo-Progynova looks like and contents of the pack

Cyclo-Progynova is made up of white and pale brown tablets.

Each carton contains 1 or 3 memo-packs. Each memo-pack contains 21 tablets, which include 11 white tablets and 10 pale brown tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viartis Products Ltd.,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer

Bayer Weimar GmbH und Co KG, Weimar, Dobereinerstrasse 20D-99427, Germany and
Bayer Pharma AG, Berlin, Germany

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Viartis Products Ltd., Station Close, Potters Bar, EN6 1TL, U.K.