

Progynova® 2mg Tablets

(estradiol valerate)

Your medicine is available as the above name, but will be referred to as Progynova throughout this:

Patient Information Leaflet

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.

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1) What Progynova is and what it is used for

What Progynova is

Progynova is a Hormone Replacement Therapy (HRT). It contains the female hormone, oestrogen. Your ovaries gradually make less of this hormone as you get older and will no longer produce it after you have been through the menopause. Progynova can be used in peri- and postmenopausal women.

What 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"). Progynova alleviates these symptoms after menopause. You will only be prescribed 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 Progynova to prevent osteoporosis after menopause.

2) What you need to know before you take 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 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 to take Progynova.

Be sure to:

- **go for regular breast screening and cervical smear tests, as recommended by your doctor.**
- **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 Progynova:

If any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before taking Progynova,

Do not take Progynova

- ▶ 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 vein 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 you are **allergic** to estradiol valerate or any of the other ingredients of this medicine (listed in section 6)
- ▶ If you have been told to **avoid lactose**, that you have a rare hereditary condition called **Lapp lactase deficiency** or **glucose-galactose malabsorption**
- ▶ If you have any reason to believe that you either are, or may be, **pregnant**, or if you are **producing milk** (lactating) and **breast-feeding**. (See also the 'Pregnancy and breast-feeding' section of this leaflet)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Progynova

Tell your doctor 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 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 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

Stop taking 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 Progynova' section
- ▶ yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- ▶ 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: 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).

Taking a progestogen in addition to the oestrogen for at least 12 days of each 28 day cycle protects you from this extra risk.

If you still have your womb, your doctor will prescribe a progestogen separately.

If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen.

If you've had your womb removed because of endometriosis, any endometrium left in your body may be at risk. So your doctor may prescribe HRT that includes a progestogen as well as an oestrogen.

Compare

Women who still have a womb and who are not taking HRT, on average, 5 in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women, aged 50 to 65, who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and how long it is taken.

Breast cancer

Evidence suggests that taking combined oestrogen-progestogen and possibly also oestrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.

For women who have had their womb removed and who are using oestrogen-only HRT for 5 years, little or no increase in breast cancer risk is shown.

Your risk of breast cancer is also higher:

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

Compare

Women aged 50 to 79 who are not taking HRT, on average, 9 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking oestrogen-progestogen HRT over 5 years, there will be 13 to 23 cases in 1000 users (i.e. an extra 4 to 6 cases).

Regularly check your breasts. See your doctor 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

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 (cancer of the ovaries) is rare - much rarer than breast cancer. It can be difficult to diagnose because there are often no obvious signs of the disease. The use of oestrogen-only or combined oestrogen-progestogen 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 or circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** (also called **deep vein thrombosis**, or **DVT**) is about 1.3 to 3-times higher in HRT users than 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. This condition is called **pulmonary embolism**, or **PE**.

DVT and PE are examples of a condition called **venous thromboembolism**, or **VTE**.

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 apply 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
- ▶ any of your close relatives has ever had a blood clot in the leg, lung or any other organ
- ▶ you have had one or more miscarriages
- ▶ you have systemic lupus erythematosus (SLE)
- ▶ you have cancer

For signs of a blood clot, see "Stop taking 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 are taking oestrogen-progestogen HRT, for over 5 years, there will be 9 – 12 cases in 1000 (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.

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

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.

For women who had their womb removed and are taking oestrogen-only therapy there is no increased risk of developing a heart disease.

If you get:

- ▶ a pain in your chest that spreads to your arm or neck
- **See a doctor as soon as possible and do not take any more HRT** until your doctor says you can. This pain could be a sign of heart disease.

