Package leaflet: Information for the user

Progynova 1 mg Tablets
Estradiol valerate

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.

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
- hereditary and acquired angioedema

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
- swollen face, tongue and/or throat 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: 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

In 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 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.

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 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. an extra 21 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/m^2)
- 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 have 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.

Stroke

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

Other things that can increase the risk of stroke include:

- high blood pressure
- smoking
- drinking too much alcohol
- an irregular heartbeat

If you are worried about any of these things, or **if you have had a stroke in the past**, talk to your doctor to see if you should take HRT.

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.
- If you have **heart** or **kidney problems,** your doctor should examine you carefully as **oestrogens** may cause fluid retention resulting in swelling
- If you have pre-existing **elevated triglycerides** (a type of blood fat) your doctor should monitor you closely during oestrogen replacement therapy or HRT. Rare cases of large increases of plasma triglycerides (hypertriglyceridemia) leading to inflammation of the pancreas (pancreatitis) have been reported with oestrogen replacement therapy
- If you have a tendency to develop **blotchy brown patches** (chloasma) on the face you should avoid exposure to the sun or ultraviolet light whilst using Progynova
- Your doctor will monitor you carefully if you have **terminal kidney insufficiency** as the blood levels of the active substances in Progynova will probably increase

Other medicines and Progynova

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

- Medicines for **epilepsy** (such as barbiturates, phenytoin, primidone, carbamazepine and possibly oxcarbazepine, topiramate and felbamate)
- Medicines for **tuberculosis** (such as rifampicin, rifabutin)
- Medicines for **HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Herbal remedies containing **St. John's wort** (*Hypericum perforatum*)
- Medicines for **treatment of fungal infections** (such as griseofulvin, fluconazole, itraconazole, ketoconazole and voriconazole)
- Medicines for **treatment of bacterial infections** (such as clarithromycin and erythromycin)
- Medicines for **treatment of certain heart diseases, high blood pressure** (such as verapamil and diltiazem)
- **Grapefruit juice**

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 combinations 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 (combined hormonal contraceptives) containing ethinylestradiol. Progynova contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Progynova with this HCV combination regimen.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.Your doctor will advise you.

Laboratory tests

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

Pregnancy and breast-feeding

Progynova is for use in post-menopausal women only. Do not take if you are pregnant or breast-feeding.

If you become pregnant, stop taking Progynova immediately and contact your doctor.

Driving and using machines

No effects on ability to drive and use machines have been observed in users of Progynova.

Progynova contains lactose monohydrate and sucrose

Progynova contains lactose and sucrose (types of sugar). If you have been told by your doctor that you have an **intolerance to some sugars,** contact your doctor before taking this medicinal product.

3. HOW TO TAKE PROGYNOVA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet of Progynova 1 mg to be taken daily.

Use in children and adolescents

Progynova is **not** for use in adolescents or children.

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.

Patients with hepatic impairment

Do not take Progynova if you have or have had liver tumors. Do not take Progynova if you have severe liver disease (see “Do not take Progynova”).

About the pack

This pack is designed to help you remember to take your medicine. Each tablet is placed in a section marked with the day of the week on which it should be taken. The arrows between tablets show the order in which they must be taken. Your doctor may tell you when to start (see "when to start" for further information).

On the day you start, take your first tablet from the top row of tablets marked with the correct day. For instance, if you start on a Tuesday, press out the tablet from the blister marked 'TUE'.

Take one tablet each day, following the directions of the arrows, until you have finished all 28 tablets in the memo strip. When you have finished each memo strip, start the next memo strip on the following day. Do not leave a break between memo strips. It is best to take your tablet at the same time each day. You can take Progynova with or without food. The tablet should be swallowed whole with a glass of water or milk.

Your doctor may prescribe the hormone progestogen in addition to Progynova for at least 12-14 days each month:

- if you still have your womb
- if you have a history of endometriosis

When to start

If you have been taking other HRT preparations: carry on until you have finished your current pack and have taken all the tablets for that month. Take your first Progynova tablet the next day. Do not leave a break between your old tablets and the Progynova tablets.

If this is your first HRT treatment and you are still having regular periods: start your Progynova tablets on the first day of bleeding

If this is your first HRT treatment and your periods have become very infrequent or have stopped completely: you can start your Progynova tablets at any time if you are sure you are not pregnant.

If you take more Progynova than you should

Overdose may cause nausea and vomiting and irregular bleeding. No specific treatment is necessary but you should consult your doctor or pharmacist if you are concerned.

If you forget to take Progynova

If you forget to take a tablet at your usual time and you are less than 12 hours late, take it as soon as possible. Take the next tablet at the usual time.

If you are more than 12 hours late, leave the forgotten tablet in the pack. Continue to take the rest of the tablets at the usual time every day. You may experience breakthrough bleeding.

If you stop taking Progynova

You may begin to feel the usual symptoms of menopause again, which may include hot flushes, trouble sleeping, nervousness, dizziness or vaginal dryness. Consult your doctor or pharmacist if you want to stop taking Progynova tablets.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking Progynova. You may need to stop taking 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 (thrombosis)"). Ask your doctor when you can start taking Progynova again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:

Serious side effects

- 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 side effects that have been linked to the use of Progynova and other oral hormone replacement therapies:

- During the first few months of treatment you may experience some vaginal bleeding at unexpected times (breakthrough bleeding and spotting). These symptoms normally lessen with continued treatment. If they don't, contact your doctor (see section 2 'HRT and cancer/Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)' for more information)
- breast pain, tenderness or enlargement, breast discharge
- painful periods, changes in vaginal secretions, pre-menstrual symptoms, increased size of fibroids in the womb, thrush, changes to the neck of the womb
- indigestion, a feeling of being bloated, passing wind, feeling or being sick, abdominal pain, gall bladder disease
- skin rashes or discolouration, itching, eczema, acne, unusual hair loss or hair growth, increased skin pigment especially on the face (chloasma – see section 2 'other conditions' for more information), some rare skin problems
- headache, migraine, dizziness, anxiety or depressive symptoms, fatigue
- fast or irregular heartbeat (palpitations), high blood pressure, inflammation of veins usually in the legs
- fluid retention leading to swelling of parts of the body
- changes in body weight and sex drive, increased appetite
- muscle cramps, leg pains
- nose bleeds, visual disturbances (such as blurred vision), discomfort with contact lenses, allergic-type reactions, a worsening of glucose tolerance, bladder inflammation, rare disorders (porphyria, chorea).

The following side effects have been reported with other HRTs:

- various skin disorders:
  - painful reddish skin nodules (erythema nodosum)
  - rash with target-shaped reddening or sores (erythema multiforme)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PROGYNOVA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. 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 Progynova contains

The **active substance** is estradiol valerate.

The **other ingredients** are lactose monohydrate, maize starch, povidone 25,000, talc, magnesium stearate (E572), sucrose, povidone 700,000, macrogol 6,000, calcium carbonate (E170), titanium dioxide (E171), glycerol 85% (E422), montan glycol wax, ferric oxide pigment (E172) and purified water.

What Progynova looks like and contents of the pack

Progynova 1 mg tablets are beige sugar-coated tablets.
They are supplied in a blister pack (memo strip) containing 28 tablets with the days of the week printed on the blister.

Boxes containing three blister packs are available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Bayer plc
400 South Oak Way
Reading, RG2 6AD

Manufacturer

Progynova 1 mg is made by Bayer Weimar GmbH und Co. KG, 99427 Weimar, Germany or Bayer AG, 13353 Berlin, Germany.

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