

# PROGYNOVA

## CONSUMER MEDICINE INFORMATION

### Warning

The Women's Health Initiative (WHI) trial examined the health benefits and risks of combined *oestrogen plus progestogen* therapy (n=16,608) and *oestrogen-alone* therapy (n=10,739) in postmenopausal women aged 50 to 79 years.

The *oestrogen plus progestogen* arm of the WHI trial indicated an increased risk of *myocardial infarction (MI), stroke, invasive breast cancer, pulmonary emboli and deep vein thrombosis* in postmenopausal women receiving treatment with combined conjugated equine oestrogens (CEE, 0.625 mg/day) and medroxyprogesterone acetate (MPA, 2.5 mg/day) for 5.2 years compared to those receiving placebo.

The *oestrogen-alone* arm of the WHI trial indicated an increased risk of *stroke and deep vein thrombosis* in hysterectomized women treated with CEE-alone (0.625 mg/day) for 6.8 years compared to those receiving placebo.

Other doses of oral conjugated oestrogens with medroxyprogesterone acetate, and other combinations and dosage forms of oestrogens 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:

- Oestrogens with or without progestogens should not be prescribed for primary or secondary prevention of cardiovascular diseases.
- Oestrogens with or without progestogens should be prescribed at the lowest effective dose for the approved indication.
- Oestrogens with or without progestogens should be prescribed for the shortest period possible for the approved indication.
- For the prevention of osteoporosis, oestrogen treatment should be considered in light of other available therapies.

# PROGYNOVA<sup>®</sup> (PRO-guy-no-va)

*oestradiol valerate*

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## Consumer Medicine Information

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### WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about Progynova tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Progynova against the benefits they expect it will provide.

**If you have any concerns about using Progynova, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### WHAT PROGYNOVA IS USED FOR

Progynova provides hormone replacement therapy (HRT) for the treatment of climacteric complaints after the cessation of monthly bleeding or after removal of the ovaries (ovariectomy). Progynova is only intended for short term use.

Progynova contains oestradiol valerate, a prodrug of the natural human oestradiol. During the climacteric ('the change of life') the oestradiol production of the ovaries declines. Although the change of life is natural, it often causes distressing symptoms, which are

connected with the gradual loss of the hormones produced by the ovaries.

Progynova replaces the hormone oestradiol that the body no longer makes. The oestradiol prevents or relieves troublesome symptoms (climacteric complaints) such as hot flushes, sweats, sleep disturbances, nervousness, irritability, dizziness, headaches as well as vaginal dryness and burning.

If you still have a womb (you have not had a hysterectomy) your doctor will prescribe another hormone progestogen to take with Progynova.

Progynova is not a contraceptive. It will not prevent you from falling pregnant.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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### BEFORE YOU TAKE PROGYNOVA

**When you must not take it**

**Do not take Progynova if you have an allergy to:**

- oestradiol valerate, the active ingredient in Progynova
- any of the ingredients listed at the end of this leaflet.

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.

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breast-feed if you are taking this medicine.**

The active ingredient in Progynova passes into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to a child.**

**Do not take Progynova if:**

- you have undiagnosed vaginal bleeding
- you have or if there is a suspicion of cancer of the breast
- you have or if there is a suspicion of other malignancies influenced by sex hormones
- you have or have had liver tumours (benign or malignant)
- you have severe liver disease
- you recently had a heart attack and/or stroke
- you have, or have had, or are at a high risk of a thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- you have severely elevated blood levels of triglycerides (special type of blood lipids)

- you have had jaundice or persistent itching during a previous pregnancy or with prior use of hormonal products (oral contraceptives or hormone therapy)
- you have had otosclerosis (a form of hearing loss) with deterioration during pregnancy
- you have severe diabetes mellitus with changes to your blood vessels.

**Do not take this medicine after the expiry date printed on the pack and blister.**

The expiry date is printed on the carton and on each blister after “EXP” (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

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

If the packaging is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

**Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if:**

- you smoke
- you are overweight
- you or anyone in your immediate family has had blood clots in the legs (thrombosis), a heart attack, a stroke, breast cancer or high cholesterol.

Before starting Progynova, your doctor should conduct a thorough general medical and gynaecological examination (including the breasts) and pregnancy must be ruled out.

**Tell your doctor if you have or have had any of the following:**

- varicose veins
- fibroids of the womb
- endometriosis (the presence of tissue of the lining of the womb in places in the body where it is not normally found)
- liver or gallbladder disease
- jaundice during pregnancy or previous use of sex steroids
- you suffer from diabetes
- you have elevated levels of triglycerides (a special type of blood lipids)
- high blood pressure
- unusually high or low calcium levels in the blood
- low levels of thyroid hormone requiring supplementation
- chloasma (yellow brown patches on the skin); if so, avoid too much exposure to the sun or ultraviolet radiation
- epilepsy
- lumpy or painful breasts (benign breast disease)
- you suffer from migraine
- porphyria (inherited or acquired disorder of certain enzymes)
- inherited deafness (otosclerosis)
- systemic lupus erythematosus (SLE; a chronic inflammatory disease)
- chorea minor (illness with unusual movements).

If HRT 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 take Progynova.

**Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from**

**your pharmacy, supermarket or health food shop.**

Some medicines and Progynova may interfere with each other.

These include:

- medicines used to treat epilepsy (e.g. hydantoins, barbiturates, primidone, carbamazepine)
- medicines used to treat tuberculosis (e.g. rifampicin)
- antibiotics (e.g. penicillins and tetracyclines)
- herbal medicines containing St John’s Wort.

These medicines may be affected by Progynova or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are diabetic, your doctor may alter the dose of the diabetes medication.

Excess of alcohol during use of hormone replacement therapy has an influence on the treatment. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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**HOW TO TAKE PROGYNOVA**

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**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet.

**If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.**

**How to take it**

Take one tablet at the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

When you have finished each blister foil start the next one on the following day. Never leave a break between blister foils unless your doctor has advised you to. Tablet taking should be continuous.

**Swallow the tablets whole with a glass of water.**

### ***How long to take it***

Progynova is only intended for short term use. Your doctor will discuss the risks of long term treatment with HRT with you. Some recent studies have shown that women using HRT have a small increase in breast cancer risk. The risk increases with the length of HRT use.

Recent studies with other HRT preparations have shown that HRT is associated with a small increase in the risk of heart attacks, strokes and blood clots, including clots in the lungs. On the other hand the risk of hip fractures and bowel cancer may be reduced. Another study has shown that in women older than 65 years, a different oestrogen taken with a progestogen is associated with a small increase in risk of dementia. The risk may be decreased in younger women and it is not known whether these findings also apply to other HRT products such as Progynova.

### ***If you forget to take it***

If you are less than 24 hours late take your tablet as soon as possible, and take the next one at the normal time. If you miss tablets for several days, irregular bleeding may occur.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Progynova.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## **WHILE YOU ARE TAKING PROGYNOVA**

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Progynova.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

### ***Stop taking it 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
- inflamed veins (phlebitis)
- itching of the whole body
- unusual upper abdominal complaints if these don't disappear within a short period of time.

If you get a blood clot while you are taking Progynova or there is a suspicion of this you should stop taking 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
- fainting.

Progynova must also be stopped at once if you become pregnant or if you develop jaundice. Tell your doctor immediately if either occur.

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

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## **SIDE EFFECTS**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Progynova.

This medicine helps most women, although a few may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

During the first few months of treatment you may experience some breast tenderness or enlargement. These symptoms are usually

temporary and normally disappear with continued treatment. If they do not, contact your doctor.

The following symptoms have been reported in users of various oral HRT preparations:

- changes in vaginal bleeding pattern and abnormal bleeding or flow
- breakthrough bleeding
- spotting (bleeding irregularities usually subside during continued treatment)
- dysmenorrhoea
- changes of vaginal secretion
- premenstrual-like syndrome
- breast pain, tenderness or enlargement
- dyspepsia
- bloating
- nausea
- vomiting
- abdominal pain
- rashes
- various skin disorders (including pruritus, eczema, urticaria, acne, hirsutism, hair loss, *erythema nodosum*)
- headache
- migraine
- dizziness
- anxiety/depressive symptoms
- fatigue
- palpitations
- oedema
- muscle cramps
- changes in body weight
- increased appetite
- changes in libido
- visual disturbances
- intolerance to contact lenses

Other side effects not listed above may occur in some patients.

### **HRT and cancer**

#### *Endometrial cancer*

The risk of cancer of the lining of the womb (endometrial cancer) increases when oestrogens are used

alone for prolonged periods. Taking a progestogen in addition to the oestrogen lowers the increased risk.

Please inform your doctor if you frequently have bleeding irregularities or persistent bleeding during the treatment with Progynova.

#### *Breast cancer*

Please inform your doctor if you have suffered from fibrocystic disease of the breasts 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 have used hormone replacement therapy (HRT) than in women of the same age who have never used 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 self examination (monthly) should be carried out.

HRT increases the density of mammographic images. This may complicate the mammographic detection of breast cancer in some cases. Therefore your doctor may choose to use other breast cancer screening techniques as well.

#### *Ovarian cancer*

In one study, ovarian cancer was reported to occur slightly more often in women who had been on oestrogen therapy for longer than 10 years. A survey of 15 other studies did not find an increased risk for women on oestrogen therapy. Currently the influence of this replacement therapy on ovarian cancer is not clear.

#### *Liver tumour*

During or after the use of hormones such as those that are contained in Progynova, benign liver tumours have rarely occurred, and malignant liver tumours even more rarely. In isolated cases, bleeding from such tumours into the abdominal cavity has endangered life. Although such events are extremely improbable you should inform your doctor about any unusual feelings in your upper abdomen that do not disappear within a short time.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## **AFTER TAKING PROGYNOVA**

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### **Storage**

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep it where children cannot reach it.** A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

### **Disposal**

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your**

pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

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## PRODUCT DESCRIPTION

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### *What it looks like*

Progynova (1 mg) are small round beige sugar coated tablets packaged in calendar blister strips containing 28 tablets.

Progynova (2 mg) are small round blue sugar coated tablets packaged in calendar blister strips containing 28 tablets. Each pack contains 2 blister strips.

### *Ingredients*

Active ingredients per tablet

- Progynova 1 – 1 mg oestradiol valerate
- Progynova 2 – 2 mg oestradiol valerate

Inactive ingredients per 1 mg tablet:

- lactose
- maize starch
- povidone
- purified talc
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- glycerol
- glycol montanate
- titanium dioxide
- iron oxide yellow

Inactive ingredients per 2 mg tablet:

- lactose
- maize starch
- povidone
- purified talc
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- glycerol

- glycol montanate
- titanium dioxide
- indigo carmine

### *Suppliers*

Made in France for:

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

Bayer New Zealand Limited  
3 Argus Place, Hillcrest,  
North Shore  
Auckland 0627

### *Australian Registration Numbers:*

Progynova (1mg) - AUST R 10708  
Progynova (2mg) - AUST R 10709

### *Date of preparation:*

October 2011

See TGA website ([www.tga.gov.au](http://www.tga.gov.au)) for latest Australian Consumer Medicine Information.

See MEDSAFE website ([www.medsafe.govt.nz](http://www.medsafe.govt.nz)) for latest New Zealand Consumer Medicine Information.

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