PROGYNOVA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using PROGYNOVA®?

PROGYNOVA® contains the active ingredient estradiol valerate. PROGYNOVA® provides hormone replacement therapy (HRT) for the treatment of menopausal complaints after the cessation of monthly bleeding, after surgical removal of the ovaries (oophorectomy) or due to radiotherapy.

For more information, see Section 1. Why am I using PROGYNOVA®? in the full CMI.

2. What should I know before I use PROGYNOVA®?

Do not use if you have ever had an allergic reaction to estradiol valerate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use PROGYNOVA®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PROGYNOVA® and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use PROGYNOVA®?

Take one tablet at the same time each day. Swallow the tablets whole with a glass of water.

More instructions can be found in Section 4. How do I use PROGYNOVA®? in the full CMI.

5. What should I know while using PROGYNOVA®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using PROGYNOVA®. • If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	• Do not take PROGYNOVA® to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how PROGYNOVA® affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. • Excess intake of alcohol during use of HRT has an influence on the treatment.
Looking after your medicine	• PROGYNOVA® 1 mg: Store below 30°C; PROGYNOVA® 2 mg: Store below 25°C. • Store it in a cool dry place away from moisture, heat or sunlight. Keep out of reach of children.

For more information, see Section 5. What should I know while using PROGYNOVA®? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any further questions about side effects.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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

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

The estrogen-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 estrogens with medroxyprogesterone acetate, and other combinations and dosage forms of estrogens 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:

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

PROGYNOVA®

(PRO.guy.no.va)

Active ingredient(s): *estradiol valerate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PROGYNOVA®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PROGYNOVA®.**

Where to find information in this leaflet:

1. Why am I using PROGYNOVA®?

PROGYNOVA® provides hormone replacement therapy (HRT) for the treatment of menopausal complaints after the cessation of monthly bleeding, after surgical removal of the ovaries (oophorectomy) or due to radiotherapy. PROGYNOVA® is only intended for short term use.

PROGYNOVA® contains the active ingredient estradiol valerate, a precursor of the hormone estradiol. During menopause, the estradiol production of the ovaries declines. Although menopause 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 estradiol that the body no longer makes and prevents or relieves symptoms such as hot flushes, sweats, sleep disturbances, depressive moods, irritability, dizziness, headaches as well as vaginal dryness and burning.

If you have not had your uterus removed (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.

2. What should I know before I use PROGYNOVA®?

Warnings

Do not use PROGYNOVA® if:

- you are allergic to estradiol valerate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- undiagnosed vaginal bleeding
- breast cancer or a suspicion of breast cancer
- other tumours (including liver tumours) or a suspicion of other tumours
- severe liver disease including jaundice (yellowing of the skin and/or eyes)
- had a heart attack and/or stroke

- a history of or are at a high risk of a blood clot in the blood vessels of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- high levels of fat in the blood (triglycerides)
- hearing loss caused by an abnormal bone growth in the ear (otosclerosis), which worsens during pregnancy
- severe diabetes

Do not take this medicine if you are under 18 years old.

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 (thrombosis)
- you have any hospitalisation, surgery or prolonged immobilization

You have an increased risk of a blood clot if you have any of the above risk factors. In addition to these, there may be other risk factors. Talk to your doctor if you have any concerns.

Taking PROGYNOVA® may also increase your risk of coronary heart disease. Tell your doctor if you experience chest pain or discomfort.

Taking PROGYNOVA® may increase your risk of gall bladder disease. This is because estrogen stimulates the liver to remove more cholesterol from blood and divert it to the gall bladder.

Before starting PROGYNOVA®, your doctor should conduct a thorough medical and gynaecological examination (including the breasts). Your doctor should conduct this examination periodically. If you have liver disease, your doctor will also conduct liver function tests from time to time. Your doctor will also note your family medical history and exclude pregnancy.

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

- high blood pressure
- liver disease including jaundice (yellowing of the skin and/or eyes)
- thyroid disease and you are taking medication for it
- heart or kidney disease
- low calcium levels in the blood
- endometriosis (the presence of tissue of the lining of the womb in places in the body where it is not normally found)
- asthma
- diabetes
- epilepsy
- migraine
- porphyria (an inherited disease where the body cannot convert naturally occurring compounds into haem, which contains iron)
- systemic lupus erythematosus (SLE; a chronic inflammatory disease)
- an abnormal build-up of blood vessels in the liver (hepatic haemangioma)
- tumours in your womb or pituitary gland
- chloasma (yellow brown patches on the skin); if so, avoid too much exposure to the sun or ultraviolet radiation
- lumpy or painful breasts (benign breast disease)
- chorea minor (involuntary movement disorder)
- hereditary angioedema (repeated episodes of severe swelling)

Tell your doctor if you are 65 years or older when HRT is initiated. The reason is that there is limited evidence from clinical studies that hormonal treatment may increase the risk of significant loss of intellectual abilities such as memory capacity (dementia).

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®.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

PROGYNOVA® contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking it. 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.

Pregnancy and breastfeeding

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.

HRT and cancer

Endometrial cancer

The risk of cancer of the lining of the womb (endometrial cancer) increases when estrogens are used alone for prolonged periods. Taking a progestogen in addition to the estrogen 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 (lumpy or painful 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. The risk increases with duration of treatment. 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 has been reported to result in an increased number of abnormal mammograms requiring further evaluation.

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

Some observational studies show a slightly increased overall risk of developing ovarian cancer in women who have used HRT compared to women who have never used HRT. In women currently using HRT, this risk was further increased. These associations have not been shown in all studies. There is no consistent evidence that the risk of developing ovarian cancer is related to the duration of use of HRT. However, the risk may be more relevant with long-term use (for several years).

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 has occurred from such tumours into the abdominal cavity. Although such events are rare, you should inform your doctor about any pain in your upper abdomen that does not disappear within a short time.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PROGYNOVA® may interfere with each other. These include:

- medicines to treat high blood pressure, chest pain and/or irregular heartbeat such as ACE inhibitors, verapamil, diltiazem
- medicines used to treat epilepsy such as hydantoins, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate
- rifampicin for the treatment of tuberculosis
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- herbal medicines containing St John's Wort
- medicines used to treat HIV such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole, fluconazole
- grapefruit juice
- medicines used to treat pain and fever (e.g. paracetamol)
- medicines used to treat diabetes, such as insulin or other anti-diabetic medications

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.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PROGYNOVA®.

4. How do I use PROGYNOVA®?

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 much to take PROGYNOVA®

- Take one tablet at the same time each day.
- Swallow the tablets whole with a glass of water.
- Follow the instructions provided and use PROGYNOVA® until your doctor tells you to stop.

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.

How long to take PROGYNOVA®

PROGYNOVA® is only intended for short term use. Your doctor will advise you on how long to use PROGYNOVA®. 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.

HRT is associated with a small increase in the risk of developing breast cancer, heart attacks, strokes, blood clots, including clots in the lungs, and dementia. However, the evidence is inconclusive. On the other hand the risk of hip fractures and bowel cancer may be reduced. Your doctor can discuss these risks and benefits with you, taking into account your particular circumstances.

If you forget to use PROGYNOVA®

PROGYNOVA® should be used regularly at the same time each day. 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.

Do not take a double dose to make up for a dose you missed.

If you use too much PROGYNOVA®

If you think that you have used too much PROGYNOVA®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PROGYNOVA®?

Things you should 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

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.

The use of HRT may affect the results of certain laboratory tests. 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.

Stop taking PROGYNOVA® 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
- swollen veins (phlebitis)
- itching of the whole body
- unusual upper abdominal pain that do not 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 develop jaundice (yellowing of the skin and/or eyes). Tell your doctor immediately if either occurs.

Remind any doctor, dentist or pharmacist you visit that you are using PROGYNOVA®.

Things you should not do

Do not take PROGYNOVA® to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PROGYNOVA® affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Excess intake of alcohol during use of HRT has an influence on the treatment. Your doctor will advise you.

Looking after your medicine

- PROGYNOVA® 1 mg: Store below 30°C.
- PROGYNOVA® 2 mg: Store below 25°C.

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Metabolism and nutrition disorders: • Changes in body weight **Psychiatric disorders:** • feeling depressed and/or anxious • changes in sexual drive **Eye disorders:** • visual disturbances such as partial or complete loss of vision, bulging eyes, double vision • intolerance to contact lenses **Musculoskeletal and connective tissue disorders:** • muscle cramps **Reproductive system and breast disorders:** • changes in vaginal bleeding pattern including spotting • painful menstrual periods • vaginal secretion • premenstrual-like syndrome such as mood swings, bloating, breast swelling and tenderness • breast pain **Gastrointestinal disorders:** • indigestion • nausea • vomiting • stomach pain • increased appetite **Skin and subcutaneous tissue disorders:** • rash • various skin disorders such as itching, hives, acne, excessive hairiness, hair loss or red, painful lumps **Nervous system disorders:** • headache • migraine • dizziness **General disorders and administration site conditions:** • swelling of the hands, ankles or feet • feeling tired	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Immune system disorders: • signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing **Cardiac disorders:** • irregular heartbeat	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PROGYNOVA® contains

Active ingredient (main ingredient)	PROGYNOVA® 1 mg: • 1 mg estradiol valerate PROGYNOVA® 2 mg: • 2 mg estradiol valerate
Other ingredients (inactive ingredients)	PROGYNOVA® 1 mg: • lactose • maize starch • povidone • purified talc • magnesium stearate • sucrose • macrogol 6000 • calcium carbonate • glycerol • glycol montanate • titanium dioxide • iron oxide yellow PROGYNOVA® 2 mg: • lactose • maize starch • povidone • purified talc • magnesium stearate • sucrose • macrogol 6000

	• calcium carbonate • glycol montanate

Do not take this medicine if you are allergic to any of these ingredients.

What PROGYNOVA® looks like

PROGYNOVA® 1 mg are small round beige sugar coated tablets packaged in calendar blister strips containing 28 tablets (Aust R 10708).

PROGYNOVA® 2 mg are small round white sugar coated tablets packaged in calendar blister strips containing 28 tablets (Aust R 323720).

Each pack contains 2 blister strips.

Who distributes PROGYNOVA®

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

www.bayer.com.au

This leaflet was prepared in December 2021.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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