BIJUVA® 1/100

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.

1. Why am I using BIJUVA 1/100?

BIJUVA 1/100 contains the active ingredient estradiol (as hemihydrate) and progesterone. BIJUVA 1/100 is used during continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women who still have a uterus with at least 12 months (1 year) since their last natural period.

For more information, see Section 1. Why am I using BIJUVA 1/100? in the full CMI.

2. What should I know before I use BIJUVA 1/100?

Do not use if you have ever had an allergic reaction to BIJUVA 1/100 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. BIJUVA 1/100 is only for use in postmenopausal women who still have a uterus.

For more information, see Section 2. What should I know before I use BIJUVA 1/100? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BIJUVA 1/100 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 BIJUVA 1/100?

- BIJUVA 1/100 should be taken at the same time every day in the evening, to ensure it works effectively. Follow all instructions given to you by your doctor.

More instructions can be found in Section 4. How do I use BIJUVA 1/100? in the full CMI.

5. What should I know while using BIJUVA 1/100?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using BIJUVA 1/100.

	• Monitor your health and contact your doctor if you notice any changes. • Keep all of your doctor's appointments and go for regular check-ups.
Things you should not do	• Do not stop using this medicine suddenly without telling your doctor.
Driving or using machines	• BIJUVA 1/100 is not expected to affect your ability to drive or operate machinery. If you experience any side effects which impact your ability to drive or operate machinery when taking this medicine, act appropriately and contact your doctor.
Drinking alcohol	• Alcohol is not expected to interact with BIJUVA 1/100. If you drink alcohol, talk to your doctor about the possible effects of taking alcohol with this medicine.

Looking after your medicine	• Store BIJUVA 1/100 in a cool dry place, out of direct light, where the temperature is below 25°C. • Keep BIJUVA 1/100 in the original packaging, in a safe place, away from children.

For more information, see Section 5. What should I know while using BIJUVA 1/100? in the full CMI.

6. Are there any side effects?

The most common side effects are breast tenderness, headache, vaginal bleeding, vaginal discharge, and pelvic pain. Serious side effects include heart attack, stroke, blood clots, breast cancer, ovarian cancer, cancer of the womb, gall bladder disease and dementia.

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 *estrogen 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 hysterectomised 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.

BIJUVA® 1/100

Active ingredient(s): *estradiol (as hemihydrate) and progesterone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BIJUVA 1/100. **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 BIJUVA 1/100.**

Where to find information in this leaflet:

1. Why am I using BIJUVA 1/100?
2. What should I know before I use BIJUVA 1/100?
3. What if I am taking other medicines?

4. How do I use BIJUVA 1/100?
5. What should I know while using BIJUVA 1/100?
6. Are there any side effects?
7. Product details

1. Why am I using BIJUVA 1/100?

BIJUVA 1/100 contains the active ingredients estradiol (as hemihydrate) and progesterone.
BIJUVA 1/100 is a Hormone Replacement Therapy (HRT).

BIJUVA 1/100 is used during continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women who still have a uterus with at least 12 months (1 year) since their last natural period.

BIJUVA 1/100 contains two types of female hormones, an estrogen and a progestogen. During menopause, the amount of estrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). BIJUVA 1/100 alleviates these symptoms after menopause.

2. What should I know before I use BIJUVA 1/100?

Warnings

Do not use BIJUVA 1/100 if:

- you are allergic to estradiol or progesterone, or any of the ingredients listed in Section 7. Always check the ingredients to make sure you can use this medicine.
- you have or have ever had breast cancer, or if you are suspected of having it
- you have cancer which is sensitive to estrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- you have any unexplained vaginal bleeding
- you have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- 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)
- you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency)
- you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke, or angina
- you have or have ever had a liver disease and your liver function tests have not returned to normal

- 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 BIJUVA 1/100, stop taking it at once and consult your doctor immediately.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

If you have had any of the following conditions, tell your doctor before starting BIJUVA 1/100 as these may return or become worse during treatment with this medicine:

- 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 estrogen-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
- hereditary or acquired angioedema.

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?

Pregnancy and breastfeeding

BIJUVA 1/100 is for use in postmenopausal women only. If you become pregnant, stop taking BIJUVA 1/100 and contact your doctor.

HRT and cancer

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

- Taking estrogen-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 BIJUVA 1/100 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 BIJUVA 1/100. However, if the irregular bleeding:

- carries on for more than the first 6 months
- starts after you have been taking BIJUVA 1/100 for more than 6 months
- carries on after you have stopped taking BIJUVA 1/100

See your doctor as soon as possible.

Breast cancer

Evidence shows that taking combined estrogen-progestogen or estrogen-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 estrogen-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 estrogen-progestogen HRT for 5 years, there will be 13 to 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 estrogen-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 estrogen-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 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 much rarer than breast cancer. The use of estrogen-only or combined estrogen-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).

Effect 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
- 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 any other organ
- you have systemic lupus erythematosus (SLE)
- you have cancer

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 estrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e., an extra 5 cases).

Stroke

The risk of having a 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).

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 may interfere with BIJUVA 1/100 and affect how it works. This may 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, rifabutin)
- medicines for HIV infection (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- herbal remedies containing St John's Wort (Hypericum perforatum)
- bromocriptine used for problems with the pituitary gland or Parkinsons disease
- ketoconazole, griseofulvin (used for fungal infections) ciclosporin (used to suppress the immune system)

HRT medicines like BIJUVA 1/100 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 combined hormonal contraceptives containing ethinylestradiol. BIJUVA 1/100 contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using BIJUVA 1/100 with this HCV combination regimen.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BIJUVA 1/100.

4. How do I use BIJUVA 1/100?

How much to take

- Take one capsule every day in the evening.
- Follow the instructions provided and use BIJUVA 1/100 until your doctor tells you to stop.

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 take BIJUVA 1/100

- BIJUVA 1/100 should be taken every day in the evening.

How to take BIJUVA 1/100

- Capsules should be taken with food and swallowed with water.

If you forget to use BIJUVA 1/100

BIJUVA 1/100 should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If more than 12 hours have lapsed, skip the missed dose.

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

If you use too much BIJUVA 1/100

If you think that you have used too much BIJUVA 1/100, 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 BIJUVA 1/100?

Things you should do

Keep all of your doctor's appointments and become familiar with potential risks associated when taking combined hormone replacement therapy.

Call your doctor straight away if you:

- have yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- have swelling in your face, tongue and/or throat and/ or difficulty swallowing or hives, together with difficulty breathing as this is suggestive of an angioedema
- have a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- have migraine-like headaches which happen for the first time
- become pregnant
- 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)
- have a very high level of fat in your blood (triglycerides)

- have fluid retention due to cardiac or kidney problems

Remind any doctor or dentist you visit that you are using BIJUVA 1/100.

Things you should not do

- Do not take BIJUVA 1/100 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BIJUVA 1/100 affects you.

BIJUVA 1/100 is not expected to affect your ability to drive or operate machinery. If you experience any side effects which impact your ability to drive or operate machinery when taking this medicine, act appropriately and contact your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol is not expected to interact with BIJUVA 1/100. If you drink alcohol, talk to your doctor about the possible effects of taking alcohol with this medicine.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your capsules in the original pack until it is time to take them. If you take your capsules out of the pack, they may not keep well.

Store BIJUVA 1/100 in a cool dry place below 25°C, 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
• irregular vaginal bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible) • tender, painful, or swollen breasts or painful nipples • vaginal itching, burning sensation, inflammation, or fluid discharge (white or yellowish discharge) • infection of the ear • swelling of the lower legs, ankles, fingers, or abdomen due to fluid retention • muscle spasms or pain, pain in extremities or joints • nausea (feeling sick), abdominal cramps, vomiting, heartburn, wind, diarrhoea, constipation • loss of smell or taste	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• weakness or dizziness • headaches • hair loss or excessive growth of hair (hirsutism) • back pain, pain in the pelvic region • hot flushes • change in sex drive • depression, nervousness, changes in mood, difficulty sleeping or abnormal dreams • disturbance in attention, memory loss • loss of coordination • visual impairment, blurred vision • numbness or tingling in an arm or leg • benign breast or uterine tumour (cysts in uterus), • vertigo • excessive eating • weight gain or weight loss • acne, itchy or dry skin, skin discolouration	

Less serious side effects	What to do
• dry mouth • rash or appearance of red lines on the skin • pain in extremity (e.g. back pain, arms, legs, wrists, ankles) • high blood pressure	

Serious side effects

Serious side effects	What to do
• sudden signs of allergy such as rash, itching or hives on the skin, swelling of face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing • pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea, and vomiting • blood clots in the veins of the legs or lungs (venous thromboembolism)	**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.**

Serious side effects	What to do
• breast cancer • stroke • slurred speech • itching, dark coloured urine	

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 BIJUVA 1/100 contains

Active ingredient **(main ingredient)**	Estradiol (as hemihydrate) and progesterone
Other ingredients **(inactive ingredients)**	Capsule content contains: • Mono di-glycerides • Lauroyl Macrogolglycerides Capsule shell contains: • Gelatin • Hydrolyzed gelatin • Glycerol • Opatint® Red DG-15001(PI-141454) • Opatint® Concentrated Colour Dispersion G-18006 (PI-140158) Printing ink: • Opacode® WB water based Monogramming Ink NSP-78-18022 White (PI 3883)

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

What BIJUVA 1/100 looks like

BIJUVA 1/100 1 mg/100 mg capsules

BIJUVA 1/100 is presented in PVC/PE/PCTFE Aluminium backed blister strips containing either 14 or 28 soft gel capsules.

The blister strips are packed in a carton to protect BIJUVA 1/100 from light.

- The 28-pack carton contains either 1 blister strip with 28 soft gel capsules or 2 blister strips each containing 14 soft gel capsules.
- The 84-pack carton contains either 3 blister strips each containing 28 soft gel capsules or 6 blister strips each containing 14 soft gel capsules.

All packs contain a Consumer Medicines Information leaflet.

BIJUVA 1/100 soft gel capsules are opaque, light pink on one side and dark pink on the other, imprinted with “1C1” in white ink. Capsules are approximately 5.2- 6 mm in size.

Australian Registration Number

AUST R 367690

Who distributes BIJUVA 1/100

Theramex Australia Pty Ltd

Level 22, 60 Margaret Street,

Sydney NSW 2000

1800 THERAMEX or 1800 843 726

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