Package leaflet: Information for the patient

BIJUVE 1mg/100mg Capsules, soft

estradiol / progesterone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your pharmacist has told you. Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4. - You must talk to a doctor or pharmacist if you do not feel better or if you feel worse.

What is in this leaflet

1. What BIJUVE is and what it is used for
2. What you need to know before you take BIJUVE
3. How to take BIJUVE
4. Possible side effects
5. How to store BIJUVE
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1. What BIJUVE is and what it is used for

BIJUVE is a Hormone Replacement Therapy (HRT).
It contains two types of female hormones, an oestrogen and a progestogen. BIJUVE is used in postmenopausal women with at least 12 months (1 year) since their last natural period.

Relief of symptoms occurring after menopause

During the menopause, the amount of oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). BIJUVE alleviates these symptoms after menopause.
You will only be prescribed BIJUVE if your symptoms seriously hinder your daily life.

2. What you need to know before you use BIJUVE

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 BIJUVE, 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 BIJUVE.

Go for regular breast screening, as recommended by your doctor.

Do not take BIJUVE:
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 BIJUVE,

Do not take BIJUVE

- if you are allergic to estradiol hemihydrate or progesterone or any of the other ingredients of this medicine (listed in section 6).
- 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 venous 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 any of the above conditions appear for the first time while taking BIJUVE, stop taking it at once and consult your doctor immediately.

When to take special care with BIJUVE
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 BIJUVE. 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 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 and acquired angioedema.

Stop taking BIJUVE 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 BIJUVE' 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)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems.

Note: BIJUVE 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).

The progestogen in BIJUVE 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 BIJUVE. However, if the irregular bleeding:
- carries on for more than the first 6 months
- starts after you have been taking BIJUVE for more than 6 months
- carries on after you have stopped taking BIJUVE

see your doctor as soon as possible.

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.

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 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 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 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 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).

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 (see also section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m2)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- 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.

For signs of a blood clot, see "Stop taking BIJUVE 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 have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

Heart disease (heart attack)
There is no evidence that HRT will prevent a heart attack. 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.

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).

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.

Children
BIJUVE is not to be used in children.

Other medicines and BIJUVE
BIJUVE can affect the way some other medicines work. Some medicines may interfere with the effect of BIJUVE. This might 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 can affect the way some 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 sofobuvir/velatasvir/voxilaprevir may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. BIJUVE contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using BIJUVE with this HCV combination regimen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

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

Pregnancy and breast-feeding
BIJUVE is for use in postmenopausal women only. If you become pregnant, stop taking BIJUVE and contact your doctor.

BIJUVE contains the colorant Allura Red
BIJUVE contains 0.042 mg Allura Red (E129)
May cause allergic reactions.

3. How to take BIJUVE

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

Take one capsule daily with a meal.

Take this medicine every day without any break in the treatment

If you take more BIJUVE than you should

If you take more BIJUVE than you should, talk to your doctor or go to a hospital. Take the medicine pack with you.

The following effects may happen: feeling drowsy, dizzy, sleepy or tired.

If you forget to take BIJUVE
If you forget a dose, take it as soon as you remember it. However, if more than 12 hours have lapsed, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

The likelihood of breakthrough bleeding or spotting may be increased.

If you stop taking BIJUVE

Do not stop taking BIJUVE without first talking to your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking BIJUVE. You may need to stop taking BIJUVE about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start taking BIJUVE again.

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:

• 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.

Tell your doctor if you notice any of the following side effects while using BIJUVE:

Very common (affects more than 1 in 10 people)
• tender breasts

Common (affects less than 1 in 10 people)
• headache
• dizziness
•fatigue
• back pain
• abdominal pain, indigestion
• pain in the pelvic region
• weight gain
• acne
• breast pain
• feeling sick (nausea)
• discharge from the vagina (white or yellowish discharge from the vagina)
• bleeding from the vagina or severe contractions of the uterus
• hairloss
• abdominal swelling

Uncommon (affects less than 1 in 100 people)
• low iron content in blood
• high blood pressure
• excessive fluid in legs
• increased levels of cholesterol
• excessive eating

• muscle pain
• muscle spasm
• breast cancer
• tumours in uterus or fallopian tube
• memory loss
• severe headaches
• tingling sensation
• abnormal smell
• difficulty in sleeping or abnormal dreams
• drowsiness
• mood swings or feeling irritable
• vomiting
• dry mouth
• constipation
• diarrhoea
• weight loss
• chills
• pancreatitis acute
• anxiety, feeling depressed
• more interest in sex than usual
• hot flushes
• vaginal infections such as thrush causing irritation or burning sensation of vagina
• blood clots (inflammation in a vein under your skin leading to a blood clot)
• dry and itchy skin or skin discoloration
• rash or appearance of red lines on the skin
• spinning sensation
• excessive hair
• visual impairment
• abdominal discomfort
• abdominal tenderness,
• oral discomfort,
• taste disturbance
• flatulence,
• allergic reactions
• furuncle,
• infection of the middle ear
• liver function test abnormal,
• cyst of organs adjacent to the uterus
• disturbance in attention,
• agitation,
• breast problems such as common harmless breast changes, nipple pain, or non-cancerous breast lumps
• Problems affecting the womb or the neck of the womb, such as abnormal cell changes, small growths, fluid-filled sacs, or unexpected bleeding.
• endometrial excessive growth
• abnormal biopsy
• high levels of uric acid in your blood
• joint pain
• pain in extremity (e.g arms, legs, wrists, ankles)

The following side effects have been reported with other HRTs:

• gall bladder disease
• various skin disorders: - discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma);
• 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 pharmacist, doctor or other healthcare professional. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme Website : www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can provide more information on the safety of this medicine.

5. How to store BIJUVE

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

This medicinal product does not require any special temperature storage conditions. Keep the blister in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after *exp* used for expiry date. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

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 BIJUVE contains
The active substances are estradiol (as estradiol hemihydrate) and progesterone.
The other ingredients are: medium chain mono/diglycerides, lauryl Macrogolglycerides 32, gelatin, 200 Bloom, hydrolysed gelatin, glycerine (E422), allura red (E129), titanium dioxide (E171), propylene glycol (E1520), polyvinyl acetate phthalate, polyethylene glycol (E1521) and ammonium hydroxide (E527).

What BIJUVE looks like and contents of the pack
BIJUVE capsules are oval, opaque, light pink on one side and dark pink on the other side imprinted '1C1' with white ink.
They come in blister packs containing 28 or 84 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Theramex Ireland Limited
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D01 YE64
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Manufacturer

Pfizer Italia S.R.L.,
Localita Marino Del Tronto
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This medicinal product is authorised in the Member States of the EEA under the following name:

Belgium	:	Bijuva 1 mg/100mg zachte capsules
France	:	Bijuva
Germany	:	Bijuva 1mg/100mg Weichkapseln
Italy	:	Bijuva
Luxembourg	:	Bijuva
Netherlands	:	Bijuva 1 mg/100mg zachte capsules
Poland	:	Bijuva
Spain	:	Bijuva 1 mg/100 mg cápsulas blandas
Malta	:	Bijuva
Portugal	:	Bijuva 1 mg/100 mg capsule molle

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Other sources of information

Detailed information on this medicine is available on the website of Medicines and Healthcare products Regulatory Agency (MHRA)

For information in large print, tape, CD or Braille, telephone 0800 198 5000