SCHEDULING STATUS
S4

BIJUVA, 1 mg/100 mg, soft gel capsules
estradiol hemihydrate / progesterone
Sugar free.

Read all of this leaflet carefully before you start taking BIJUVA.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIJUVA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet
1. What BIJUVA is and what it is used for.
2. What you need to know before you take BIJUVA.
3. How to take BIJUVA.
4. Possible side effects.
5. How to store BIJUVA.
6. Contents of the pack and other information.

1. What BIJUVA is and what it is used for
BIJUVA is a hormone replacement therapy (HRT). It contains two types of female hormones, an oestrogen and a progestogen. BIJUVA 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 decreases. This can cause symptoms such as feeling hot in the face, neck and chest ("hot flushes"). BIJUVA alleviates these symptoms after menopause.

You will only be prescribed BIJUVA if your symptoms seriously hinder your daily life.

2. What you need to know before you take BIJUVA
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 BIJUVA, 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 BIJUVA.

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

Do not take BIJUVA:
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 BIJUVA.
- if you are hypersensitive (allergic) to estradiol hemihydrate, progesterone or any of the other ingredients of BIJUVA (see **What BIJUVA contains**).
- 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 disorder called **porphyria** which is passed down in families (inherited).

If any of the above conditions appear for the first time while taking BIJUVA, stop taking it at once and consult your doctor immediately.

Warnings and precautions
Tell your doctor if you have or ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with BIJUVA. 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 high level of fat in your blood (triglycerides)
- fluid retention due to heart or kidney problems.

Stop taking BIJUVA and see a doctor immediately
If you notice any of the following when taking BIJUVA:
- any of the conditions mentioned in the ‘Do not take BIJUVA’ section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- 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)** below.
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems.

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

see your doctor as soon as possible.

Unexpected bleeding
You will have a bleed once a month (so-called withdrawal bleed) while taking BIJUVA. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:
- carries on for more than the first 6 months
- starts after you have been taking BIJUVA for more than 6 months
- carries on after you have stopped taking BIJUVA

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.

- 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 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.

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:
- if 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)
- if you are seriously overweight (BMI > 30 kg/m^2)
- if 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
- if you have systemic lupus erythematosus (SLE)
- if you have cancer.

For signs of a blood clot, see "***Stop taking BIJUVA and see a doctor immediately***".

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.

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
BIJUVA should not be used in children.

Other medicines and BIJUVA
Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

BIJUVA can affect the way some other medicines work. Some medicines may interfere with the effect of BIJUVA. This might lead to irregular bleeding. This applies to the following medicines:
- medicines for epilepsy (such as phenobarbitone, 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*)
- ketoconazole, griseofulvin (used for fungal infections)
- ciclosporin (used to suppress the immune system)
- lamotrigine (used to control seizures).

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

Pregnancy, breastfeeding and fertility
BIJUVA is for use in postmenopausal women only. If you become pregnant, stop taking BIJUVA and contact your doctor.

Driving and using machines
BIJUVA can cause side effects, such as dizziness, vertigo, visual impairment or fatigue. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BIJUVA affects you.

BIJUVA contains the colourant Allura Red
Allura Red may cause allergic reactions.

3. How to take BIJUVA

Always take BIJUVA exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of BIJUVA is too strong or too weak, tell your doctor or pharmacist.

Take one capsule every day in the evening with food. Swallow the capsule with water.

The capsule should be taken every day without any break in the treatment.

If you take more BIJUVA than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining BIJUVA with you so the doctor will know what you have taken.

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

If you forget to take BIJUVA
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 BIJUVA
Do not stop taking BIJUVA 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 BIJUVA. You may need to stop taking BIJUVA 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 BIJUVA again.

4. Possible side effects

BIJUVA can have side effects.

Not all side effects reported for BIJUVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIJUVA, please consult your health care provider for advice.

If any of the following happens, stop taking BIJUVA and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIJUVA. You may need urgent medical attention or hospitalisation.

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 occurring frequently:
- tender breasts
- headache, dizziness
- back pain
- abdominal pain, feeling bloated
- breast pain, pain in the pelvic region
- weight gain
- acne
- hair loss
- feeling sick (nausea)
- severe contractions of the uterus, bleeding from the vagina or discharge from the vagina (white or yellowish discharge from the vagina)
- fatigue (feeling tired and weak)

Side effects occurring less frequently:
- pain in extremity (e.g. back pain, arms, legs, wrists, ankles)
- low iron content in blood
- high blood pressure
- excessive fluid in legs
- increased levels of cholesterol

- excessive eating from increase hunger or appetite (hyperphagia)
- muscle pain
- difficulty sleeping or abnormal dreams, difficulty to concentrate
- tumours in uterus or fallopian tube
- memory loss, severe headaches
- tingling or prickling sensation in the hands, arms, legs or feet
- loss of smell
- mood swings, feeling irritable or agitated
- vomiting (being sick)
- dry mouth
- constipation
- diarrhoea
- weight loss
- chills
- acute pancreatitis
- feeling depressed or anxious
- more interest in sex than usual
- hot flushes
- irritation or burning sensation of vagina
- vaginal infections such as thrush
- vaginal discharge or vaginal bleeding
- blood clots
- dry and itchy skin
- rash or small, widened blood vessels on the skin (telangiectasia)
- vertigo (feeling off balance or a spinning feeling)
- excessive hair growth
- impairment of your vision
- abdominal discomfort or tenderness
- flatulence
- gastroenteritis (stomach flu)
- indigestion
- oral discomfort
- taste disturbances
- skin abscesses (boils)
- ear infection
- abnormal liver tests
- breast disorders, benign growths in the breasts, nipple pain
- muscle weakness
- benign growths in the uterus smooth muscle
- cysts close to the fallopian tube
- abnormal biopsy
- dark coloured urine

The following side effects have been reported with other HRTs:
- gall bladder disease
- various skin disorders including 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BIJUVA.

5. How to store BIJUVA

- Store at or below 25 °C.
- Keep the blister in the outer carton to protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIJUVA contains
Each soft capsule contains 1 mg estradiol (as estradiol hemihydrate) and 100 mg progesterone.

The other ingredients are:
Capsule content contains: medium chain mono/diglycerides, lauroyl macrogolglycerides 32
Capsule shell contains: gelatine (200 Bloom), hydrolysed gelatine, glycerin (E422), Allura Red (E129) (colourant), titanium dioxide (E171) (colourant)
Printing ink (Opacode® White WB) contains: propylene glycol (E1520), titanium dioxide (E171) (colourant), polyvinyl acetate phthalate, polyethylene glycol (E1521) and ammonium hydroxide (E527).

What BIJUVA looks like and contents of the pack
Oval, opaque, light pink on one side and dark pink on the other side imprinted ‘1C1’ with white ink.

Clear PVC/PE/PCTFE/aluminium blister strips in an outer carton.
Pack sizes: 28 or 84 soft gelatine capsules.
Not all pack sizes may be marketed.

Holder of certificate of registration
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Customer Care: 0860 ADCOCK / 232625

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SKEDULERINGSTATUS
S4

BIJUVA, 1 mg/100 mg, sagte jelkapsules
estradioolhemihidraat / progesteroon
Suikervry.

Lees hierdie hele biljet noukeurig deur voordat u BIJUVA begin neem.
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- BIJUVA is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet
1. Wat BIJUVA is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u BIJUVA neem.
3. Hoe om BIJUVA te neem.
4. Moontlike newe-effekte.
5. Hoe om BIJUVA te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat is BIJUVA en waarvoor word dit gebruik
BIJUVA is 'n hormoonvervangingsterapie (HVT). Dit bevat twee tipes vroulike hormone, 'n estrogeen en 'n progestogeen. BIJUVA word gebruik in postmenopousale vroue waar ten minste 12 maande (1 jaar) sedert hul laaste natuurlike menstruasie verstryk het.

Verligting van simptome wat na menopouse voorkom
Tydens menopouse verminder die hoeveelheid estrogeen wat deur 'n vrou se liggaam geproduseer word. Dit kan simptome veroorsaak soos ‘n warm gevoel in die gesig, nek en bors ("warm gloede"). BIJUVA verlig hierdie simptome ná menopouse.

BIJUVA sal slegs voorgeskryf word indien u simptome u daaglikse lewe noemenswaardig belemmer.

2. Wat u moet weet voordat u BIJUVA neem
Mediese geskiedenis en gereelde ondersoeke
Die gebruik van HVT hou risiko's in wat in ag geneem moet word wanneer daar besluit word of om dit te begin neem, of om voort te gaan om dit te neem.

Die ervaring in die behandeling van vroue met 'n voortydige menopouse (as gevolg van eierstokversaking of chirurgie) is beperk. Indien u 'n voortydige menopouse het, kan die risiko's van die gebruik van HVT verskil. Raadpleeg asseblief u dokter.

Voordat u met HVT begin (of weer begin), sal u dokter vra oor u eie en u gesin se mediese geskiedenis. U dokter kan besluit om 'n fisiese ondersoek uit te voer. Dit kan 'n ondersoek van u borste insluit, en/of 'n inwendige ondersoek, indien nodig.

Sodra u met BIJUVA begin het, moet u u dokter spreek vir gereelde ondersoeke (ten minste een keer per jaar). By hierdie ondersoeke, bespreek met u dokter die voordele en risiko's om voort te gaan om BIJUVA te neem.

Gaan vir gereelde borsondersoeke, soos aanbeveel deur u dokter.

Moenie BIJUVA neem nie:
Indien enige van die volgende op u van toepassing is. Indien u nie seker is oor enige van die punte hieronder nie, raadpleeg u dokter voordat u BIJUVA neem.
- indien u hipersensitief (allergies) is vir estradioolhemihidraat, progesteroon of enige van die ander bestanddele van BIJUVA (sien **Wat BIJUVA bevat**).
- indien u borskanker het, of al ooit gehad het, of indien daar vermoed word dat u dit het
- indien u **kanker het wat sensitief is vir estrogeen**, soos kanker van die baarmoedervoering (endometrium), of indien u vermoed word dat u dit het
- indien u enige **onverklaarbare vaginale bloeding** het
- Indien u **oormatige verdikking van die baarmoedervoering** het (endometriese hiperplasie) wat nie behandel word nie
- indien u ooit 'n **bloedklont in 'n aar** (trombose) gehad het, soos in die bene (diep veneuse trombose) of die longe (longembolis)
- indien u 'n **bloedstollingsversteuring** het (soos proteïen C-, proteïen S- of antitrombien-tekort)
- indien u 'n siekte het, of onlangs gehad het wat veroorsaak word deur bloedklonte in die are, soos 'n **hartaanval**, **beroerte** of **angina**
- indien u 'n lewersiekte het of ooit gehad het, en u lewerfunksietoetse nie na normaal teruggekeer het nie
- indien u 'n seldsame bloedafwyking genaamd **porfirie** het, wat in gesinne oorgedra word (oorgeërf).

Indien enige van die bogenoemde toestande vir die eerste keer voorkom terwyl u BIJUVA neem, staak die gebruik dadelik en raadpleeg u dokter onmiddellik.

Waarskuwings en voorsorgmaatreëls
Lig u dokter in indien u enige van die volgende probleme het of ooit gehad het, voordat u met die behandeling begin, aangesien dit kan terugkeer of erger word tydens behandeling met BIJUVA. Indien wel, moet u u dokter meer gereeld spreek vir ondersoeke:
- fibroïede in u baarmoeder
- groei van baarmoedervoering buite u baarmoeder (endometriose) of 'n geskiedenis van oormatige groei van die baarmoedervoering (endometriese hiperplasie)
- verhoogde risiko om bloedklonte te ontwikkel, sien **Bloedklonte in 'n aar (trombose)**
- verhoogde risiko om 'n estrogeen-sensitiewe kanker te kry (soos om 'n ma, suster of ouma te hê wat borskanker gehad het)
- hoë bloeddruk
- 'n lewerafwyking, soos 'n nie-kwaadaardige lewergewas
- diabetes
- galstene
- migraine of erge hoofpyn
- 'n siekte van die immuunstelsel wat baie organe van die liggaam aantas (sistemiese eritematose lupus, SLE)
- epilepsie
- asma
- 'n siekte wat die oordrom en gehoor beïnvloed (otosklerose)
- 'n hoë vlak van vet in u bloed (trigliseriede)
- vloeistofretensie as gevolg van hart- of nierprobleme.

Staak die gebruik van BIJUVA en spreek dadelik 'n dokter
Indien u enige van die volgende opmerk wanneer u BIJUVA neem:
- enige van die toestande genoem in die afdeling genaamd 'Moenie BIJUVA neem nie'
- Vergeling van u vel of die wit van u oë (geelsug). Dit kan tekens van 'n lewersiekte wees
- 'n groot styging in u bloeddruk (simptome kan hoofpyn, moegheid, duiseligheid wees)

- migraine-agtige hoofpyn wat vir die eerste keer voorkom
- indien u swanger raak
- Indien u tekens van 'n bloedklont opmerk, soos:
  - pynlike swelling en rooiheid van die bene
  - skielike borspyn
  - probleme met asemhaling.

  Vir meer inligting, sien **Bloedklonte in 'n aar (trombose)** hieronder.
- 'n baie hoë vlak van vet in u bloed (trigliseriede)
- vloeistofretensie as gevolg van hart- of nierprobleme.

Let wel: BIJUVA is nie 'n voorbehoedmiddel nie. Indien daar minder as 12 maande sedert u laaste menstruasie verbygegaan het, of u jonger as 50 jaar is, moet u dalk steeds bykomende voorbehoeding gebruik om swangerskap te voorkom. Raadpleeg u dokter vir advies.

HVT en kanker
Oormatige verdikking van die baarmoedervoering (endometriese hiperplasie) en kanker van die baarmoedervoering (endometriumkanker)
Die neem van estrogeen-alleenlike HVT sal die risiko van oormatige verdikking van die baarmoedervoering (endometriese hiperplasie) en kanker van die baarmoedervoering (endometriese kanker) verhoog.

Die progestogeen in BIJUVA beskerm u teen hierdie ekstra risiko.

Onreëlmatige bloeding
U kan onreëlmatige bloeding of druppels bloed (drupbloeding) ervaar gedurende die eerste 3 – 6 maande tydens die neem van BIJUVA. Indien die onreëlmatige bloeding egter:
- vir langer as die eerste 6 maande aanhou
- begin nadat u BIJUVA vir meer as 6 maande geneem het
- voortgaan nadat u opgehou het om BIJUVA te neem

spreek u dokter so gou as moontlik.

Onverwagte bloeding
U sal een keer per maand bloeding hê (sogenaamde onttrekkingsbloeding) terwyl u BIJUVA neem. Maar indien u onverwagte bloeding of druppels bloed (drupbloeding) behalwe u maandelikse bloeding het, wat:
- vir langer as die eerste 6 maande aanhou
- begin nadat u BIJUVA vir meer as 6 maande geneem het
- voortgaan nadat u opgehou het om BIJUVA te neem

spreek u dokter so gou as moontlik.

Borskanker
Bewyse toon dat die neem van gekombineerde estrogeen-progestogeen of estrogeen-alleen hormoonvervangingsterapie (HVT) die risiko van borskanker verhoog. Die ekstra risiko hang af van hoe lank u HVT gebruik. Die bykomende risiko word binne 3 jaar van gebruik duidelik. Nadat u HVT gestaak het, sal die ekstra risiko mettertyd afneem, maar die risiko kan vir 10 jaar of langer voortduur indien u HVT vir langer as 5 jaar gebruik het.

- Kontroleer gereeld u borste. Spreek u dokter indien u enige veranderinge opmerk soos:
  - kuiltjie-vorming van die vel
  - veranderinge in die tepel
  - enige knoppe wat u kan sien of voel

Daarbenewens word u aangeraai om by mammografie-siftingsprogramme aan te sluit wanneer dit aan u aangebied word. Vir mammogram-sifting is dit belangrik dat u die

verpleegkundige/gesondheidsorg kundige wat die x-straal neem inlig dat u HVT gebruik, aangesien hierdie medikasie die digtheid van u borste kan verhoog, wat die uitkoms van die mammogram kan beïnvloed. Waar die digtheid van die bors verhoog word, kan mammografie nie alle knoppe opspoor nie.

Ovaria-kanker
Ovaria-kanker is baie meer skaars as borskanker. Die gebruik van estrogeen-alleen of gekombineerde estrogeen-progestogeen HVT is geassosieer met 'n effens verhoogde risiko van ovaria-kanker.

Effek van HVT op hart en sirkulasie
Bloedklonte in 'n aar (trombose)
Die risiko van bloedklonte in die are is ongeveer 1,3 tot 3 keer hoër by HVT-gebruikers as by nie-gebruikers, veral gedurende die eerste jaar van die neem daarvan. Bloedklonte kan ernstig wees, en indien een daarvan na die longe reis, kan dit borspyn, asemhaling, floute of selfs die dood veroorsaak.

U is meer geneig om 'n bloedklont in u are te kry soos u ouer word en indien enige van die volgende op u van toepassing is. Stel u dokter in kennis indien enige van hierdie situasies op u van toepassing is:
- indien u vir 'n lang tyd nie kan loop nie as gevolg van 'n groot operasie, besering of siekte (sien ook afdeling 3, Indien u 'n operasie moet ondergaan)
- indien u ernstig oorgewig is (BMI > 30 kg/m^2)
- Indien u enige bloedstollingsprobleem het wat langtermyn-behandeling benodig met 'n medisyne wat gebruik word om bloedklonte te voorkom
- indien enige van u naasbestaandes al ooit 'n bloedklont in die been, long of enige ander orgaan gehad het
- indien u sistemiese lupus eritematose (SLE) het
- indien u kanker het.

Vir tekens van 'n bloedklont, sien "***Staak die gebruik van BIJUVA en spreek dadelik 'n dokter***".

Hartsiektes (hartaanval)
Daar is geen bewyse dat HVT 'n hartaanval sal voorkom nie. Vroue ouer as 60 jaar wat estrogeen-progestogeen HVT gebruik, is effens meer geneig om hartsiektes te ontwikkel as diegene wat geen HVT gebruik nie.

Beroerte
Die risiko om 'n beroerte te kry is ongeveer 1,5 keer hoër by HVT-gebruikers as by nie-gebruikers. Die aantal ekstra gevalle van beroerte as gevolg van die gebruik van HVT sal met ouderdom toeneem.

Ander toestande
HVT sal nie geheueverlies voorkom nie. Daar is sommige bewyse van 'n hoër risiko van geheueverlies by vroue wat ná die ouderdom van 65 jaar HVT begin gebruik. Raadpleeg u dokter vir advies.

Kinders
BIJUVA moet nie by kinders gebruik word nie.

Ander medisyne en BIJUVA
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

BIJUVA kan die manier waarop sommige ander medisyne werk, beïnvloed. Sommige medisyne kan die effek van BIJUVA beïnvloed. Dit kan lei tot onreëlmatige bloeding. Dit geld vir die volgende medisyne:

- medisyne vir epilepsie (soos fenobarbitoon, fenitoïen en karbamasepien)
- medisyne vir tuberkulose (soos rifampisien, rifabutien)
- medisyne vir MIV-infeksie (soos nevirapien, efavirenz, ritonavir en nelfinavir)
- kruiemiddels wat “St John's Wort” (*Hypericum perforatum*) bevat
- ketokonasool, griseofulvien (gebruik vir swaminfeksies)
- siklosporien (gebruik om die immuunstelsel te onderdruk)
- lamotrigien (gebruik om stuipaanvalle te beheer).

Laboratorium toetse
Indien u 'n bloedtoets benodig, lig u dokter of die laboratoriumpersoneel in dat u BIJUVA neem, want hierdie medisyne kan die resultate van sommige toetse beïnvloed.

Swangerskap, borsvoeding en vrugbaarheid
BIJUVA is slegs vir gebruik by postmenopousale vroue. Indien u swanger raak, hou op om BIJUVA te neem en kontak u dokter.

Bestuur en gebruik van masjinerie
BIJUVA kan newe-effekte veroorsaak, soos duiseligheid, vertigo, visuele steurnisse of moegheid. Moenie 'n voertuig bestuur, masjinerie gebruik of enigiets anders doen wat u aandag verg totdat u weet hoe BIJUVA u beïnvloed nie.

BIJUVA bevat die kleurstof “Allura Red”
“Allura Red” kan allergiese reaksies veroorsaak.

3. Hoe om BIJUVA te neem

Neem altyd BIJUVA presies soos beskryf in hierdie biljet of soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Indien u die indruk het dat die effek van BIJUVA te sterk of te swak is, raadpleeg u dokter of apteker.

Neem een kapsule elke dag in die aand saam met kos. Sluk die kapsule met water.

Die kapsule moet elke dag geneem word sonder enige onderbreking in die behandeling.

Indien u meer BIJUVA neem as wat u moes
In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Neem hierdie biljet en die res van die oorblywende BIJUVA saam sodat die dokter sal weet wat u geneem het.

Die volgende effekte kan voorkom; lomerigheid, duiselig, slaperig of moeg.

Indien u vergeet om BIJUVA te neem
Indien u 'n dosis vergeet, neem dit sodra u dit onthou. Indien meer as 12 uur egter verstryk het, slaan die vergete dosis oor.

Moenie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie.

Die waarskynlikheid van deurbraak-bloeding of drupbloeding kan verhoog word.

Indien u ophou om BIJUVA te neem
Moenie ophou om BIJUVA te neem sonder om eers u dokter te raadpleeg nie. Indien u enige verdere vrae het oor die gebruik van hierdie produk, vra u dokter of apteker.

Indien u 'n operasie moet ondergaan
Indien u 'n operasie gaan ondergaan, lig die chirurg in dat u BIJUVA neem. U sal dalk BIJUVA moet staak teen ongeveer 4 tot 6 weke voor die operasie om die risiko van 'n bloedklont te verminder (sien afdeling 2, **Bloedklonte in 'n aar (trombose)**). Vra u dokter wanneer u weer BIJUVA kan begin neem.

4. Moontlike newe-effekte
BIJUVA kan newe-effekte hê.

Nie alle newe-effekte wat vir BIJUVA aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u BIJUVA neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van BIJUVA en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeukerigheid,
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op BIJUVA gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Die volgende siektes word meer gereeld aangemeld by vroue wat HVT gebruik in vergelyking met vroue wat nie HVT gebruik nie:
- borskanker
- abnormale groei of kanker van die baarmoedervoering (endometriese hiperplasie of kanker)
- ovaria-kanker
- bloedklonte in die are van die bene of longe (veneuse trombo-embolis)
- hartsiektes
- beroerte
- waarskynlike geheueverlies indien HVT begin word by dié ouer as 65 jaar.

Vir meer inligting oor hierdie newe-effekte, sien afdeling 2.

Lig u dokter in indien u enige van die volgende opmerk:
Newe-effekte wat gereeld voorkom:
- gevoelige borste
- hoofpyn, duiseligheid
- rugpyn
- buikpyn, opgeblaasde gevoel
- borspyn, pyn in die bekkenstreek
- gewigstoename
- aknee
- haarverlies
- naar voel (naarheid)
- erge kontraksies van die baarmoeder, bloeding uit die vagina of afskeiding uit die vagina (wit of gelerige afskeiding uit die vagina)
- uitputting (moeg en swak voel)

Newe-effekte wat minder gereeld voorkom:
- pyn in ledemate (bv. rugpyn, arms, bene, handgewrigte, enkels)
- lae ysterinhoud in bloed
- hoë bloeddruk
- oormatige vloeistof in bene
- verhoogde vlakke van cholesterol
- oormatig baie eet as gevolg van verhoogde honger of eetlus (hiperfagie)
- spierpyn
- probleme met slaap of abnormale drome, probleme om te konsentreer
- gewasse in baarmoeder of fallopiese buis
- geheueverlies, erge hoofpyn
- tintelende of prikkelende sensasie in die hande, arms, bene of voete
- verlies van reuk
- buierigheid, voel geïrriteerd of opgewerk
- braking (naar word)
- droë mond
- hardlywigheid
- diarree
- gewigsverlies
- kouekoors
- akute pankreatitis
- depressief of angstig voel
- meer belangstelling in seks as gewoonlik
- warm gloede
- irritasie of brandende sensasie van vagina
- vaginale infeksies soos sproei
- vaginale afskeiding of vaginale bloeding
- bloedklonte
- droë en jeukerige vel
- veluitslag of klein bloedvate op die vel wat verwyd is (telangiëktasie)
- vertigo (voel van balans af of 'n draaiende gevoel)
- oormatige haargroei
- verswakking van u visie
- abdominale ongemak of gevoeligheid
- winderigheid
- gastro-enteritis (maaggriep)
- slegte spysvertering
- mondelikse ongemak
- Smaak versteurings
- vel absesse (kook)
- oor infeksie
- abnormale lewertoetse
- borsafwykings, goedaardige groeisels in die borste, tepelpyn
- spier swakheid
- goedaardige groeisels in die baarmoeder gladde spier
- siste naby die fallopiese buis
- abnormale biopsie
- donkerkleurige urine

Die volgende newe-effekte is aangemeld met ander HVT's:
- galblaassiekte
- verskeie velafwykings, insluitend verkleuring van die vel, veral van die gesig of nek, bekend as "swangerskapkolle" (chloasma), pynlike rooierige velknoppies (*erythema*

nodosum), uitslag met teikenvormige rooiheid of sere (*erythema multiforme).*

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter of apteker. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BIJUVA te verskaf.

5. Hoe om BIJUVA te bêre

- Bêre teen of benede 25 °C.
- Hou die stulpstrook in die buitenste kartonboksie om teen lig te beskerm.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die kartonboksie gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat BIJUVA bevat
Elke sagte kapsule bevat 1 mg estradiool (as estradioolhemihidraat) en 100 mg progesteroon.

Die ander bestanddele is:
Kapsule-inhoud bevat: mediumketting mono-/digliseriede, laurielmakrogol-gliseriede 32
Kapsule-dop bevat: gelatien (200 “Bloom”), gehidroliseerde gelatien, gliserien (E422), “Allura Red” (E129) (kleurstof), titaandioksied (E171) (kleurstof),
Drukink (Opacode® White WB) bevat: propileenglikol (E1520), titaandioksied (E171) (kleurstof), polivinielasetaatftalaat, poliëtileenglikol (E1521) en ammoniumhidroksied (E527).

Hoe BIJUVA lyk en die inhoud van die verpakking
Ovaal, ondeursigtig, ligpienk aan die een kant en donkerpienk aan die ander kant, met '1C1' met wit ink opgedruk.

Deurskynende PVC/PE/PCTFE/aluminium stulpstroke in 'n buitenste kartonboksie.
Verpakkingsgroottes: 28 of 84 sagte gelatienkapsules.
Nie alle verpakkingsgroottes word dalk bemark nie.

Houer van Sertifikaat van Registrasie
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