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|   |                       | <b>LEÓN FARMA</b><br>MATERIAL TYPE: <b>LEAFLET</b>   | Drawing: <b>P030</b><br>Scale: <b>100 %</b> Dimensions: <b>222 x 340 ± 1 mm</b> |
| Material # / Product: <b>900633-01 PR PROG GEPRETIX 100MG X15 EXELTIS UK</b>  |                       |  |   |
| Version: <b>A</b>   | Date: <b>26.01.24</b> | Substitutes mat. #: <b>590023</b>  |   |
| <b>Folded:</b><br><input type="checkbox"/> NO <input type="checkbox"/> YES  |                       | <b>Folded dimensions:</b><br>FOLD TO 170 X 37 MM   |   |
| Other: (if not specify) _____   |                       |  |   |
| <b>Pantones:</b><br>LINE 1: FRONT SIDE <input type="checkbox"/> BLACK<br>LINE 2: BACK SIDE <input type="checkbox"/> BLACK   |                       | <b>Cause:</b><br><input type="checkbox"/> LAUNCH<br><input type="checkbox"/> CUSTOMER CHANGE<br><input type="checkbox"/> INTERNAL CHANGE |   |
| LINE 3: TECHNICAL COLOUR <input type="checkbox"/> DIE CUT <input type="checkbox"/> PRINT SECURITY MARGINS <input type="checkbox"/> FINAL FOLDED   |                       | <b>Laetus: 47145</b><br><br><b>47145</b>                |   |
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|   |                       | <small>(***) PLEASE, MAKE SURE THE IMAGES HAVE A RESOLUTION AT LEAST 300 PP</small>  |   |

**Drawed by:**  
(Chemo Artwork Technician)

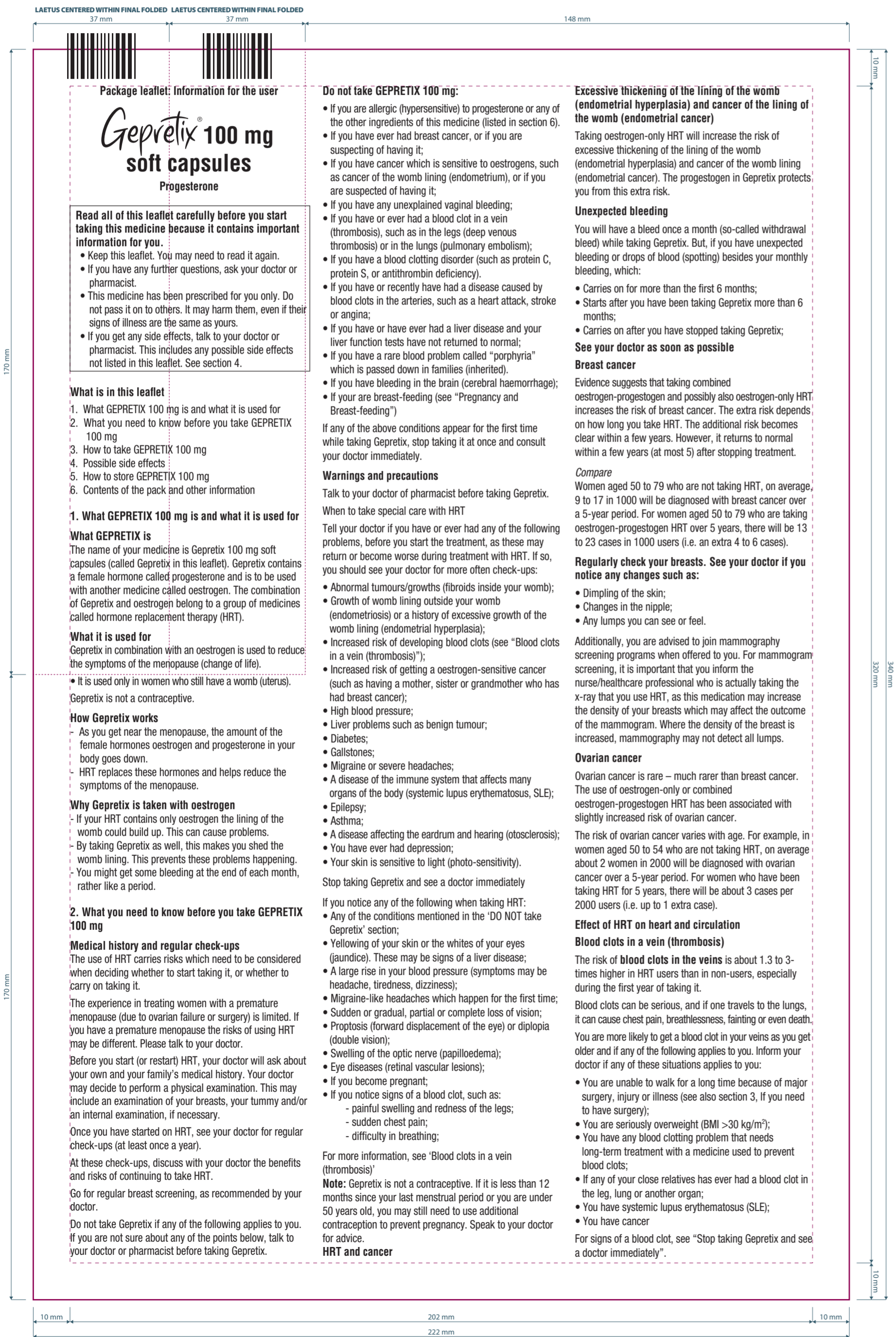
**Manuel Mancilla**

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(Regulatory Affair or Quality Assurance) / Signature & Date

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*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 getting 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**

Gepretix is not for use in children.

**Other medicines and GEPRETIX 100 mg**

Gepretix can affect the way some other medicines work. Also other medicines may interfere with the effect of Gepretix or HRT. This applies to the following medicines:

- Medicines for epilepsy (such as phenobarbital, phenytoin and carbamazepin);
  - 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 Parkinson's Disease.
  - Cyclosporin (used to suppress the immune system).
  - Ketoconazole (used for fungal infections).
  - Water tablets (spironolactone);
  - Antibiotics (ampicillins, tetracyclines);
  - Antiestrogens (medroxyprogesterone acetate, megestrol);
  - Medicines to prevent blood clots (such as coumarins, phenindione)
  - Diabetic medicines;
  - Emergency contraceptives (ulipristal acetate);
  - Diazepam
  - Tizanidine (used in multiple sclerosis).
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or other natural products.

**Laboratory tests**

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

**GEPRETIX with food and drink**

Do not take Gepretix with food. See Section 3 "How to take Gepretix" for more information on when to take this medicine

**Pregnancy, breast-feeding and fertility**

- Do not take Gepretix if you are pregnant or might become pregnant.
- Gepretix is for use of postmenopausal women only. If you become pregnant, stop taking Gepretix and contact your doctor.
- Talk to your doctor before taking this medicine if you are breast-feeding.

**Driving and using machines**

You may feel sleepy or dizzy while taking Gepretix. If this happens, do not drive or use any tools or machines. Taking Gepretix at bedtime can reduce these effects.

**GEPRETIX contains soya bean lecithin.**

If you are allergic to peanut or soya, do not use this medicinal product.

**3. How to take GEPRETIX 100 mg**

Always take this medicine exactly as your doctor has told you. Always read the label. 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.

The recommended dose is 200 mg daily at bedtime, for twelve days in the last half of each therapeutic cycle (beginning on Day 15 of the cycle and ending on Day 26). Alternatively, 100 mg can be given at bedtime from Day 1 to Day 25 of each therapeutic cycle.

**Taking this medicine**

- Take this medicine by mouth.
- Swallow the capsule whole with a glass of water.
- Take this medicine at bedtime.
- Do not take this medicine with food.
- Take your oestrogen HRT at the same time as Gepretix

**How much to take**

- Take two capsules at bedtime on days 15 to 26 of your 28- day cycle.
- You will usually have a few days withdrawal bleeding (like a period) after this time.
- Continue to take your oestrogen HRT every day.
- If you have any problems with the withdrawal bleed, your doctor may change the way that you take Gepretix. This will help to reduce the amount of withdrawal bleeding.

**If you need to have surgery**

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

**If you take more GEPRETIX 100 mg than you should**

If your take more Gepretix 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 GEPRETIX 100 mg**

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

**If you stop taking GEPRETIX 100 mg**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**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. The following side effects have been reported since Progesterone 100 mg capsules came on the market and may happen with Gepretix taken orally:
- Stomach pain
  - Nausea (sickness in the stomach)
  - Tiredness
  - Headache
  - Drowsiness
  - Dizziness
  - Vaginal bleeding
  - Intense itching (pruritus)

During clinical trials the following side effects have also been observed:

**Frequency not known** (frequency cannot be estimated from the available data):

- Bloating of the stomach
- Depression
- Breast tenderness
- Hot flashes
- Vaginal discharge
- Joint pain
- Urinary problems

The following side effects have been reported with other HRTs:

- Gallbladder disease
- Various skin disorders:
  - Discolouration 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)
- Breast pain (mastodynia)
- Fluid retention (oedema)
- Weight changes
- Increase or decrease in sexual desire
- Depression
- Rashes
- Urticaria (itchy, lumpy rash)
- Patchy brown or dark brown skin discoloration (melasma)
- Fever
- Insomnia (inability to obtain an adequate amount or quality of sleep)
- Alopecia (hair loss)
- Irregular menstruation
- Lack of menstruation

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the website Yellow Card Scheme on the MHRA website [www.mhra.gov.uk/yellowcard](http://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 help provide more information on the safety of this medicine.

**5. How to store GEPRETIX 100 mg**

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not store above 30°C.

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 GEPRETIX 100 mg contains**

The active substance is progesterone. Each capsule contains 100 mg of progesterone. The other ingredients are grape seed oil and soya bean lecithin.

The capsule itself is made of gelatin, glycerol and titanium dioxide (E171).

See section 2 "GEPRETIX contains lecithin from soya.

**What GEPRETIX 100 mg looks like and contents of the pack**

100 mg, soft capsules: Ovoid soft gelatine capsules off-white coloured approx. 12 mm long and approx. 8 mm wide.

Each blister contains 15 soft capsules. Each box contains 15, 30, 45, 60 or 90 soft capsules

**Marketing Authorisation Holder**

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**Manufacturer**

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