Active substance: estradiol valerate, cyproterone acetate

1. WHAT IS CLIMEN COATED TABLET AND WHAT IS IT USED FOR?

Pharmaceutical form and content
This medication contains a combination of an oestrogen and a progestin (micronised cyproterone acetate). This medication is indicated for the treatment of disorders resulting from oestrogen deficiency associated with menopause. It is prescribed as a hormone replacement therapy (HRT).

Therapeutic indications
CLIMEN coated tablet is indicated for the prevention of menopause-related osteoporosis in women with increased risk of fracture and who do not tolerate, or who are contraindicated for other treatments for the prevention of osteoporosis.

Consult with your doctor before you decide to take this treatment.

Only limited data are available as regards treatment in women aged 65 and over.

2. WHAT DO YOU NEED TO KNOW BEFORE TAKING CLIMEN COATED TABLET?

List of information the user needs before taking the medication
Not applicable

Contraindications
You should never take CLIMEN coated tablet if you have any of the following conditions:
- previous or present venous or arterial thromboembolic disease (phlebitis, pulmonary embolism, chest angina, myocardial infarction, cerebro-vascular stroke),
- cancer of the breast, uterus or other oestrogen-dependent cancer,
- endometrial hyperplasia (overdeveloped uterine mucous),
- undiagnosed genital bleeding,
- certain liver diseases,
- known allergy to any of the components of the transdermal device
- porphyria (hereditary disease),

Precautions for use, special warnings:
Be careful when taking CLIMEN coated tablets
A medical examination needs to be conducted before starting treatment, as well as periodically during treatment. In order to determine whether or not your treatment should be continued, at regular intervals (at least once per year) your doctor will discuss with you the benefits and risks associated with hormone replacement therapy.

Your doctor will perform regular clinical breast examinations, particularly if you have a history of breast cancer in your family, or if you presently have breast cysts or nodules. Your doctor may also ask you to have a mammogram. Contact you doctor if you notice changes in your breasts during treatment.

Women on hormone replacement therapy have an increased risk of developing thromboembolic disease, cancer of the breast or uterus, cardiovascular accident or cerebro-vascular stroke.

Inform your doctor of any illnesses you may have during treatment. Menopause therapy is not contraindicated for the following conditions, but does require special monitoring: arterial hypertension, diabetes, endometriosis (ailment characterised by the presence of uterine mucous outside of the uterus), uterine fibroma, hepatic or biliary disorders, epilepsy, migraine or severe headache, renal or cardiac insufficiency, asthma, lupus, (severe disease affecting the skin in particular), otospongiosis (ear ailment resulting in hearing deterioration).

Inform your doctor immediately if any of the following symptoms appear:
- allergic reactions (difficulty in breathing, thoracic oppression, generalised hives-type rash, itching)
- jaundice (of eyes and skin);
- significant increase in arterial pressure;
- unusual leg pain, weakness in extremities;
• chest pain, irregular pulse, sudden shortness of breath;
• loss of consciousness, confusion, unusual severe headaches, dizziness, impaired vision, slowed speech or voice loss;
• pregnancy;
• lump in breast area.

Inform your doctor if you need to be confined to bed or undergo surgery. Contact your doctor if, despite treatment, oestrogen deficiency symptoms associated with menopause continue to persist. Consult your doctor if you experience profuse bleeding. Because this medication contains lactose, it should not be used by women with galactosemia, malabsorption syndrome involving glucose and galactose or lactase deficiency (rare metabolic diseases). This medication contains sucrose, which should be taken into account in women with fructose intolerance, malabsorption syndrome involving glucose and galactose or sucrase-isomaltase deficiency (rare metabolic diseases).

**Interaction with other medications**

**If you are using other medications:**
Inform your doctor or pharmacist if you have taken any other medication recently, particularly anti-convulsivants, antituberculins, or treatment for AIDS such as: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampicin, ritonavir, nelfinavir, nevirapine, efavirenz or herbal preparations containing miltepoar (Hypericum perforatum); this also applies for any nonprescription medications you may be taking.

**Interaction with foods and beverages**
Not applicable

**Interaction with other phytotherapeutic products or alternative therapies**
Not applicable

**Use during pregnancy and breast-feeding**

**Pregnancy and breast feeding:**
This medication is not indicated for use during pregnancy or breast feeding. If while taking this medication you find out that you are pregnant, you must stop the treatment and contact your doctor.

Accidental exposure to this medication in the course of pregnancy does not constitute grounds for terminating a pregnancy. Ask your doctor or your pharmacist for advice before taking any medications.

**Information for athletes**
Not applicable

**Effects on ability to drive or operate machinery**
Not applicable

**List of excipients with known effects**
List of excipients with known effects: lactose monohydrate, sucrose

**3. HOW IS CLIMEN COATED TABLET USED?**

**Instructions for proper use**
Not applicable

**Dosage, method and/or mode of administration, frequency and duration of treatment**

**Mode of administration:**
Taken orally

**Dosage:**
This treatment consists of 1 tablet per day for 21 days, to be taken without interruption in the following order: take 1 white tablet each day for 11 days, then 1 pink tablet each day for the next 10 days. You will then observe a 7-day break in pill taking. You can start the treatment on any day you wish. However, if you are changing over from a sequential hormone replacement therapy to CLIMEN, it is recommended that you start your treatment after bleeding has stopped, that is to say the day you would have started a new treatment cycle of your sequential hormone therapy. You may experience menstrual-like bleeding during the break in taking pills. This bleeding is normal and slight in nature. If heavy or irregular bleeding occurs, consult your doctor. Carefully detach the disk calendar. Adhere it to the beige disk of the blister pack and position the day of your first pill directly under the beige compartment marked “start”. For example, if you take your first pill on a Monday you adhere the disk calendar to the
Risk of weaning syndrome
Symptoms may appear when treatment with CLIMEN coated tablet is stopped: After cessation of treatment, oestrogen deficiency symptoms associated with menopause may reappear.
In any case, you should always strictly follow your doctor’s prescribed regimen.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Description of possible side effects
As with all medications, CLIMEN coated tablet may also cause side effects, although not all patients experience them.
Frequently observed during hormonal treatment of menopause:
• breast tension,
• genital bleeding,
• abdominal pain and swelling,
• nausea,
• headache,
• painful menstruation,
• vaginal discharge.
Rarely observed:
• vomiting,
• disturbed hepatic function (liver), icterus (jaundice), biliary vesicle disorder,
• disturbances in libido,
• skin disorders.
Inform your doctor or pharmacist if you notice any side effects that are not mentioned in this leaflet, or if any of the side effects become severe.

5. HOW SHOULD CLIMEN COATED TABLET BE STORED?

Keep away from, and out of sight of children.

Expiration date
Do not use CLIMEN coated tablets after the expiration date printed on the box.
Storage conditions
Store below +25°C.
Warning about certain visible signs of deterioration if applicable
Do not use CLIMEN coated tablets if you notice any signs of deterioration.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

*Complete list of active substances and excipients*

**What does CLIMEN coated tablet contain?**

**The active substances are:**
- Micronised estradiol valerate 2.000 mg
  Contained in each white coated tablet.
- Micronised estradiol valerate 2.000 mg
- Micronised cyproterone acetate 1.000 mg
  Contained in each pink coated tablet.

**The other components are:**
- Lactose, corn starch, povidone, talc, magnesium stearate, sucrose, macrogol 6000, calcium carbonate, wax E, glycerol, titanium dioxide, iron oxide yellow, iron oxide red pigment.

*Packaging and contents*

**What is CLIMEN coated tablet and what does the outer package contain?**
This medication is available as a coated tablet. Each box contains 21 tablets.

**Manufacturer**
DELPHARM LILLE S.A.S
ZI DE ROUBAIX EST
RUE DE TOUFFLERS
59390 LYS-LEZ-LANNOY
For Bayer Schering Pharma AG - Germany

**Leaflet approval date**
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