

# Climen®

coated tablet

Active substance: estradiol valerate, cyproterone acetate



## PACKAGE LEAFLET: USER INSTRUCTIONS

### This is a medicament

- ▶ A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ▶ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- ▶ Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists

### Name of medication

**CLIMEN, coated tablet**

Concerns prescription-only medications

### Please read all of this leaflet carefully before taking this medication.

- ▶ Keep this leaflet, you may want to read it again.
- ▶ If you have any further questions or any doubts, feel free to request more information from your doctor or pharmacist.
- ▶ This medication has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- ▶ Please inform your doctor or pharmacist if any of the listed side effects become severe or if you notice side effects that are not listed in this leaflet.

### Leaflet summary

#### In this leaflet:

1. WHAT IS CLIMEN COATED TABLET AND WHAT IS IT USED FOR?
2. WHAT DO YOU NEED TO KNOW BEFORE TAKING CLIMEN coated tablet?
3. HOW IS CLIMEN coated table USED?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
5. HOW SHOULD CLIMEN coated tablet BE STORED?
6. FURTHER INFORMATION

#### 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 your 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-convulsants, antituberculins, or treatment for AIDS such as: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampicin, ritonavir, nelfinavir, nevirapine, efavirenz or herbal preparations containing millepertuis (*Hypericum perforatum*); this also applies for any non-prescription 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 blister pack in such a way that 'Mon' appears just below the beige compartment marked 'start'.

This will ensure that you are taking CLIMEN as directed.

**1st Day:**

Start the blister pack by taking the white tablet from the 'start' compartment.

**Following days:**

Take the subsequent tablets in the order indicated by the arrows.

**Next blister packs:**

After a break of 7 days, you will start your next blister pack regardless of the actual date of any possible menstruation. For example, if you started your first blister pack on a Monday, you should also start the subsequent blister packs on a Monday, even if your are still menstruating.

In any case, you should always strictly follow the prescribed regimen.

Consult your doctor or pharmacist if you think the effect of CLIMEN coated tablet is either too strong or too weak.

*Symptoms and instructions in case of overdose*

**If you take more CLIMEN coated tablets than you should:** Signs of overdose generally include a sensation of pain in the breast area, swollen stomach, flatulence, nausea, vomiting, irritability, bleeding.

No specific treatment is necessary in such cases.

Ask your doctor for advice if any of these symptoms persist.

*Instructions in case of you miss one or more tablets*

**If you forget to take CLIMEN coated tablets:** If you realise that you forgot to take a tablet within 12 hours of the usual time, you then immediately take the missed tablet and continue the treatment as planned, which means that you should take the next tablet at the usual time.

Never take a double dose to compensate for a missed single dose.

Irregular bleeding may occur if you forget to take the tablet for several days in a row.

Consult with your doctor if you are not sure what to do.

*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 +30°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 Pharma AG - Germany

*Leaflet approval date*

**Date this leaflet was last approved August, 2009.**