

## **INFORMATION FOR THE PATIENT**

### **PATIENT PACKAGE INSERT**

CLÉO -35

#### **Acne Treatment**

#### **Composition**

CLÉO -35 is a preparation which contains 2 sex hormones, cyproterone acetate and ethinyl estradiol in a specific ratio. Each tablet of CLÉO -35 contains 2 mg cyproterone acetate and 0.035 mg ethinyl estradiol. The non-medicinal ingredients in CLÉO -35 are alpha lactose monohydrate, maize starch, povidone, magnesium stearate, talc, saccharose, calcium carbonate, polyethylene glycol, titanium dioxide, glycerine, and wax

#### **Warnings**

1. CLÉO -35, as with all estrogen/progestogen combinations must not be used in women with thrombophlebitis, thromboembolic disorders (blood clots), or a history of these conditions.
2. Cyproterone acetate and ethinyl estradiol tablets users appear to have an elevated risk of blood clots compared to users of levonorgestrel-containing combined oral contraceptives. The risk of blood clots with cyproterone acetate and ethinyl estradiol tablets appears to be similar to desogestrel- and drospirenone-containing combined oral contraceptives. Estrogen/progestogen combinations should not be taken during treatment with CLÉO -35
3. CLÉO -35 should not be prescribed for the purpose of birth control alone.
4. Estrogens or progestogens should not be taken during treatment with CLÉO -35.
5. CLÉO -35 should be discontinued 3 to 4 cycles after signs have completely resolved.
6. You should know that cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from CLÉO -35 use. This risk increases with age and heavy smoking (15 or more cigarettes a day) and is more marked in women over 35 years of age. Women who use estrogen/progestogen combinations should not smoke.

Certain drugs may interact with estrogen/progestogen combinations to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. You may also need to use a nonhormonal method of contraception during any cycle in which you take drugs that can make estrogen/progestogen combinations less effective.

Drugs that may interact with **CLÉO -35** include drugs used for the treatment of HIV infections (eg, nevirapine, ritonavir) and Hepatitis C Virus infections (eg, boceprevir, telaprevir).

#### **Properties and Indications**

CLÉO -35 is used for the treatment of women suffering from pronounced forms of acne, accompanied by seborrhea (excess oily secretions of the skin), inflammation or formation of nodes, and mild forms of hirsutism (excess hair on the face, chest, abdomen or legs), and for whom treatment with oral antibiotics or other available treatments has not worked.

The cyproterone acetate in CLÉO -35 reduces the activity of the sebaceous glands which plays an important role in the development of acne. This leads, usually within 3 to 6 months of therapy, to the healing or improvement of existing acne.

You should not take CLÉO -35 for the purpose of birth control alone, however, during treatment with CLÉO -35, ovulation will not take place if the medication is taken as prescribed (see section "**How to Take CLÉO -35** "). Therefore, estrogen/progestogen combinations should not be used during treatment with CLÉO -35, but if you are concerned about occasionally missing a dose of CLÉO -35, you may wish to use other forms of birth control to avoid becoming pregnant.

This type of medication is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of estrogen/progestogen combination tablets should always be supervised by your doctor.

**You should not use CLÉO -35** if you have or have had any of the following conditions:

- Unusual vaginal bleeding that has not yet been diagnosed.
- Blood clots in the legs, lungs, eyes or elsewhere.
- A stroke, heart attack, or chest pain (angina pectoris).
- Known or suspected cancer of the breast or sex organs.
- Known or suspected hormone-dependent disorders.
- Previous or existing liver tumours.
- Jaundice or liver disease if still present.
- Severe diabetes associated with circulatory problems.
- Disturbances of vision.
- Deterioration of a disorder causing worsening deafness (otosclerosis) during a previous pregnancy.
- An allergic reaction to this medication or to its ingredients (See **Composition**).
- If you have been told that you have a condition called hereditary angioedema or if you have had episodes of swelling in body parts such as hands, feet, face or airway passages.

CLÉO -35 should not be taken if you are pregnant, if pregnancy is suspected or if you are breast-feeding.

CLÉO -35 should not be taken if you have diabetes and hypertension associated with obesity.

### **When You Are Taking CLÉO -35**

If you and your doctor have elected for you to use CLÉO -35, you should be aware of the following:

1. Take CLÉO -35 only on the advice of your doctor and carefully follow all directions given to you. You must take the tablets exactly as prescribed. If not taken appropriately, the contraceptive effect may be decreased and you may become pregnant.
2. After the age of 35 years, CLÉO -35 should be considered only in exceptional circumstances and when the risks and benefits has been carefully weighed by both the patient and the physician.
3. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at regular intervals.

4. **You should be alert for signs of serious adverse effects and call your doctor immediately if they occur:**
- sharp pain in the chest which may increase with deep breathing; coughing blood; sudden shortness of breath or rapid breathing; sense of anxiety; severe light-headedness or dizziness; rapid or irregular heartbeat. These symptoms could indicate a possible blood clot in the lung.
  - pain and/or swelling in the calf or along a vein in the leg; pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg; red or discolored skin on the leg. These symptoms could indicate a possible blood clot in the leg.
  - crushing chest pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; fullness, indigestion, or choking feeling; sweating, nausea, vomiting, or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats. These symptoms could indicate a possible heart attack.
  - sudden severe or worsening headache or vomiting; sudden trouble walking, dizziness, loss of balance or coordination; loss of consciousness or fainting with or without seizure; sudden confusion, disturbances of vision, speech, or understanding; sudden weakness or numbness of the face, arm, or leg. These symptoms could indicate a possible stroke.
  - sudden partial or complete loss of vision. This symptom could indicate a blood clot in the eye.
  - other signs of a blood clot can include: sudden pain, swelling, and slight blue discoloration of an extremity; acute abdomen.
  - severe pain or lump in the abdomen. These symptoms could indicate a possible tumour of the liver.
  - severe depression
  - yellowing of the skin (jaundice)
  - itching of the whole body
  - rise in blood pressure
  - unusual swelling of the extremities (hands and feet), face, or airway passages
  - breast lumps. **Ask your doctor for advice and instruction on regular self-examination of your breasts.**
5. CLÉO -35 should never be taken if you think you are pregnant. They will not prevent the pregnancy from continuing and may interfere with the normal development of the baby.
6. If you wish to become pregnant, your doctor may recommend that you discontinue the use of CLÉO -35 and delay pregnancy until at least one spontaneous menstrual cycle has occurred. Contact your doctor for advice on this and for recommendations on appropriate methods of birth control that may be used during this time.
7. Consult your doctor before resuming the use of estrogen/progestogen combinations after childbirth, miscarriage, or therapeutic abortion. Hormones in estrogen/progestogen combinations are known to appear in the milk and may decrease its flow.
8. If for any reason you should require **major** elective surgery, the surgeon should be informed that you are using an estrogen/progestogen so that you can be correctly advised about discontinuing its use one month before surgery and switching to an alternative treatment.

9. **If you see a different doctor, inform him or her that you are taking estrogen/progestogen combination tablets.** Tell the doctor that your estrogen/progestogen combination tablets are CLÉO -35.
10. **Inform your doctor if you are taking or if you start to take other medications.** This applies to both prescription and non-prescription drugs, including natural health products. These medications may change the effectiveness and/or cycle control of your estrogen/progestogen combination tablets. **You may need to use a back-up (barrier) method of birth control.**
11. If you have asthma, epilepsy, cardiac or renal disease or fluid retention (such as swelling of lower legs) or any other chronic condition you will require careful observation and should see your doctor frequently.
12. If you wear contact lenses and develop visual changes or changes in lens tolerance you should be assessed by an ophthalmologist and temporary or permanent cessation of wear should be considered.
13. CLÉO -35 may interfere with laboratory tests. Should you require such tests, please inform your doctor that you are taking CLÉO -35.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

#### **How to Take CLÉO -35**

1. If instructed to do so by your doctor, a non-hormonal method of birth control should be employed while taking CLÉO -35.
2. For your first pack of CLÉO -35, begin taking tablets on the first day of menstrual bleeding.
3. Take one tablet daily for 21 days; no medication is taken for the next seven days.
4. When receiving any medical treatment, be sure to tell your doctor that you are using CLÉO -35.
5. When you have taken all 21 tablets in this pack, wait 7 days and then start a new pack of CLÉO -35. During the 7 days that you are not taking any tablets, you should have your period, usually 2-4 days after you have taken your last tablet.
6. The first tablet in every subsequent pack will always be taken on the same day of the week that you first began taking CLÉO -35 tablets regardless of whether your bleeding has already ceased (which it usually has) or is still continuing.

**Please note:** Irregular tablet-taking, vomiting or intestinal affections with diarrhea, some very rare individual metabolic disturbances or prolonged simultaneous use of certain medical preparations can affect the efficacy of CLÉO -35 tablets.

### **Missed Tablets, Vomiting or Diarrhea**

If you forget to take your tablet at the usual time, you must take it within the next 12 hours at the latest. If more than 12 hours have passed from the time that you normally take your tablet, you must discard the missed tablet and continue to take the remaining tablets in the pack at the usual time to prevent premature bleeding.

Also in case of vomiting or diarrhea you must continue to take the remaining tablets. However, a supplementary non-hormonal method of birth control must be used for the remainder of the cycle of use to prevent pregnancy.

### **Overdose**

There have been no reports of serious effects from overdose. Symptoms of overdose may include nausea, vomiting, or vaginal bleeding. In case of drug overdose, contact a health care practitioner, hospital emergency department, or regional Poison Control Center immediately, even if there are no symptoms.

### **Missed Period**

If bleeding fails to occur during the 7 days that you are not taking any tablets, do not start a new pack and contact your doctor to rule out pregnancy.

### **Unscheduled Period**

If an "unscheduled" period occurs during the 3 weeks in which CLÉO -35 tablets are being taken, continue taking the tablets. Slight bleeding will usually stop spontaneously. However, if the bleeding is heavy, similar to menstrual bleeding, you should consult your doctor.

- **Many women have spotting or light bleeding, or may feel sick to their stomach during the first three months on estrogen/progestogen combination therapy.** If you do feel sick, do not stop taking CLÉO -35. The problem will usually go away. If it does not go away, check with your doctor or clinic.
- **If you miss tablets at any time, you could get pregnant.**

With CLÉO -35, you are on tablets for 21 days and off tablets for seven days. You must not be off the tablets for more than seven days in a row.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### **If you want more information about CLÉO -35:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website [www.aspripharma.com](http://www.aspripharma.com); or by calling Aspri Pharma Canada Inc. at 1-855-868-8440.

This leaflet was prepared by Aspri Pharma Canada Inc.

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