

CYBELLE 2mg / 0.035mg film-coated tablet

Cyproterone acetate 2mg / Ethinylestradiol 0.035mg

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WHAT CYBELLE IS USED FOR

Note: Cybelle should not be prescribed for the purpose of contraception alone. However, when taken as recommended, Cybelle will provide reliable contraception in patients treated for the above clinical conditions. If patient compliance is uncertain and contraception is necessary, then a supplementary non-hormonal contraceptive method should be considered.

Cybelle is used for the treatment of moderate to severe acne related to androgen-sensitivity (with or without seborrhoea) and/or excessive hair growth (hirsutism) in women of reproductive age. This includes patients with polycystic ovary syndrome requiring treatment of these symptoms.

For the treatment of acne, Cybelle should only be used after courses of antibiotic treatment have failed.

Since Cybelle is also a hormonal contraceptive, it should not be used in combination with other hormonal contraceptives.

HOW CYBELLE WORKS

Cyproterone acetate is an anti-androgen. Your ovaries produce androgens (male sex hormones) to change into oestrogens (female sex hormones). Androgens can stimulate growth of hair on the face and body, and production of sebum (oil from your skin). If your skin produces too much oil, the pores of your skin will become blocked, which can lead to acne. Cyproterone acetate acts by reducing the amount of androgens released by your ovaries and by reducing the amount that can act in your body.

Ethinylestradiol is an oestrogen (female sex hormone) which should be given in combination with cyproterone acetate.

Cybelle also acts like an oral contraceptive, by preventing the release of eggs, thickening the mucus in the neck of the womb to stop sperm passing through, and making the lining of the womb unsuitable for an egg to grow on. You should not take another oral contraceptive whilst taking Cybelle.

BEFORE YOU USE CYBELLE

When you must not use it

- Presence or a history of venous or arterial thrombotic/ thrombo-embolic events [blood clot in the blood vessel that blocks blood flow] (e.g. deep venous thrombosis [blood clot in a vein deep beneath the skin],

pulmonary embolism [blood clot that breaks off and travels to the lungs], myocardial infarction [heart attack]) or of a cerebrovascular accident [stroke].

- Presence or a history of prodromi of a thrombosis [early symptom of blood clot] (e.g. transient ischaemic attack [mini-stroke], angina pectoris [chest pain or discomfort])
- A high risk of venous or arterial thrombosis [blood clot in the blood vessel] (see 'Special warnings and precautions for use').
- History of migraine with focal neurological symptoms.
- Diabetes mellitus with vascular involvement.
- Severe hepatic disease as long as liver function values have not returned to normal.
- Presence or history of liver tumors (benign or malignant).
- Known or suspected sex-steroid influenced malignancies (e.g. of the genital organs or the breasts).
- Undiagnosed vaginal bleeding.
- Concomitant use with another hormonal contraceptive (see section 'Indication(s)').
- Known or suspected pregnancy
- Lactation
- Hypersensitivity to the active substances or to any of the excipients.

Do not use CYBELLE if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir.

CYBELLE 2mg/0.035mg film-coated tablet is not for use in men.

Before you start to use it

Your doctor should check your medical history and that of your family before you start taking these

tablets. He will also take your blood pressure and may check your breasts, abdomen and pelvic organs if considered necessary. You may also need to have a pap smear. Your doctor will also make sure you are not pregnant.

Taking other medicines

Interactions of other drugs (enzyme inducers, certain antibiotics) with estrogen / progestogen combinations like CYBELLE 2mg/0.035mg film-coated tablet may lead to break-through bleeding and / or contraceptive failure. Women on treatment with any of these drugs should temporarily use a barrier method in addition to CYBELLE 2mg/0.035mg film-coated tablet or choose another method of contraception.

Women on treatment with antibiotics (except rifampicin and griseofulvin) should use the barrier method until 7 days after discontinuation. If the period during which the barrier method is used runs beyond the end of the tablets in the CYBELLE 2mg/0.035mg film-coated tablet pack, the next pack should be started without the usual tablet-free interval.

Please inform your doctor or pharmacist if you are taking these drugs:
phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, cyclosporine, griseofulvin, antiretroviral drugs, antibiotic (i.e. penicillins and tetracyclines) and products containing St. John's wort).

Do not use CYBELLE if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir. Your doctor will prescribe another type of contraceptive before starting the treatment with these medicinal products.

1. HOW TO USE CYBELLE

How much to use

Take one tablet daily, following the direction of the arrows, until you have taken all the 21 tablets in the pack. After taking all the 21 active tablets, rest for 7 days without taking any active tablet. During the 7 tablet-free day, bleeding will likely to occur.

When to use it

You should take the tablet at the same time every day.

How long to use it

The duration of treatment depends on seriousness of the clinical picture; in general this can be several months. It is recommended to keep taking Cybelle for at least 3 to 4 more cycles after disappearance of the symptoms.

Your doctor will stop treating you with this medicine when your skin is completely clear or your hair growth has decreased. If the problem comes back, you can take further courses for as long as necessary, with the consultation of doctor.

Do not stop the treatment prematurely.

If you forget to use it

If you forget to take CYBELLE and are relying on it for contraceptive cover

• If you have missed one tablet by 12 hours or less

If you have only missed one tablet, and you were due to have taken it 12 hours ago or less, take it straight away. Take the rest of your tablets as normal and your contraceptive cover will not be affected.

• If you are more than 12 hours late in taking your tablet, or if you have missed more than one

Your contraceptive protection may be reduced. Follow the instructions for the 7 day rule: if it happens during the:

First week

You should take the last missed tablet as soon as you remember this, even if this means that you have to take 2 tablets at the same time. Hereafter, continue taking the tablets at the usual time. You should use a barrier method for the next 7 days. If intercourse has taken place during the previous 7 days, the possibility of pregnancy must be considered. The more forgotten tablets and the closer to the usual tablet-free period this takes place, the greater the risk of pregnancy.

Second week

You should take the last forgotten tablet as soon as you remember this, even if this means that you have to take 2 tablets at the same time. Hereafter, continue to take the tablets at the usual time of the day. Provided that the tablets have been taken correctly during the 7 days preceding the forgotten tablet, it is not necessary to take further contraceptive measures. However, if this is not the case, or if more than 1 tablet has been forgotten, you should use another contraceptive method for 7 days.

Third week

By following one of the following two alternatives, it is not necessary to take further contraceptive precautions, provided that all tablets have been taken correctly during the 7 days preceding the forgotten tablet. If this is not the case, you should follow the first of the two alternatives and use another contraceptive method for the next 7 days.

1. You should take the last forgotten tablet as soon as you

remember this, even if this means that you have to take 2 tablets at the same time. Hereafter, continue to take the tablets at the usual time. Start the next blister pack immediately after taking the last tablet in the present blister pack, i.e. there should be no tablet-free interval between the blister packs. This may mean you do not have period until after the end of the second pack, and may have some bleeding on tablet-taking days, but this is normal. If you do not have a period at the end of the second pack, you must talk to your doctor before starting another pack.

2. Stop taking tablets from the present blister pack. In this case you should have a period without tablets of up to 7 days, including the days you forgot tablets, and continue with the next blister pack hereafter.

The possibility of pregnancy must be considered, if there have been forgotten tablets in a course and the menstruation is not occurring in the following tablet free period.

If you use too much (overdose)

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are: nausea, vomiting and, in young girls, slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic.

WHILE YOU ARE USING IT

Things you must do

While you are using Cybelle you should see your doctor regularly at least twice a year.

Contact your doctor as soon as possible if:

- you have severe pain or swelling in either of your legs,

unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis).

- you have a sudden, severe stomach ache or look jaundiced (possibly indicating liver problems);
- you feel a lump in your breast (possibly indicating breast cancer);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are pregnant

Liver toxicity has been reported to be fatal in a few cases in which the patient consumes more than 100mg of cyproterone acetate.

Most cases are report in men with prostate cancer. Toxicity is dose-related and develops, usually, several months after treatment has begun. Liver function tests should be performed before the treatment and whenever any symptoms or signs suggestive of liver failure occur.

If liver failure is confirmed, cyproterone acetate should be stopped, unless the liver toxicity can be explained by another cause, in which case cyproterone acetate should be continued only if the perceived benefit outweighs the risk.

Things you must not do

Avoid smoking as it increase the risk of thrombosis.

If you are pregnant, you must

not take CYBELLE. If you become pregnant while taking Cybelle you must stop immediately and contact your doctor.

Things to be careful of

If you experience any unusual symptoms when you are taking CYBELLE, please consult your healthcare professionals immediately.

SIDE EFFECTS

The common side effects of CYBELLE reported include:

- Nausea
- Abdominal Pain
- Weight changes
- Headache
- Mood changes
- Breast pain/tenderness

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

STORAGE AND DISPOSAL OF CYBELLE

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Keep in a cool and dry place.

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.

PRODUCT DESCRIPTION

What it looks like

Cybelle is yellow round biconvex film-coated tablet. Each blister pack containing 21 tablets.

Ingredients

Active Ingredients

- cyproterone acetate 2 mg/tablet
- ethinylestradiol 0.035 mg/tablet

Other Ingredients

lactose monohydrate, povidone, sodium starch glycollate type A, anhydrous colloidal silica dioxide, colloidal aluminium oxide, magnesium stearate, Opadry II yellow.

Product Registration Number

MAL14125068ACZ

MANUFACTURER

LABORATORIOS LEON

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PRODUCT REGISTRATION HOLDER

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