

ESTELLE-35 TABLET

(Cyproterone acetate 2mg and ethinylestradiol 0.035mg)

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What ESTELLE tablet is used for

ESTELLE tablet is used to treat women who suffer from conditions arising from increased secretion of or increased response to androgen (male) hormones. Such conditions include acne, or moderately increased growth of facial and body hair (hirsutism).

ESTELLE tablet should be withdrawn 3 to 4 cycles after the treated condition has been completely resolved.

ESTELLE tablet provides effective oral contraception in women being treated for androgen-dependent diseases.

How ESTELLE tablet works

ESTELLE tablet contains two ingredients, ethinylestradiol and cyproterone. Ethinylestradiol is an oestrogen, which is a female sex hormone. Cyproterone is an anti-androgen. Androgens are responsible for stimulating the glands on your skin which produce sebum (grease) and they also encourage hair growth. Too much androgen can cause the glands in your skin to become blocked and inflamed, causing acne spots to develop

ESTELLE tablet works by reducing the amount of androgen you produce, which helps to clear acne and reduces excess hair growth.

Before you use ESTELLE tablet

- When you must not use it

Do not take ESTELLE tablet if:

- You are pregnant or breast-feeding.
- You have had severe disturbances of liver function, jaundice (yellowing of the skin) or other problems associated with the liver.
- You have or have had blood clots in your legs.
- You have or have had any pro-coagulant disorder such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other familial disorders.
- You have or have had the first signs of a heart attack or stroke.
- You presently have, or have a history of: breast cancer, cancer of the genital organs or suspected oestrogen related cancer.
- You are a diabetic and have damaged blood vessels.
- You have an allergy to one or more of the ingredients in **ESTELLE tablet**
- You have sickle-cell anaemia.
- You have had undiagnosed vaginal bleeding or migraines.
- The package shows signs of damage or tampering or if the tablets do not look quite right.

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

If you are not sure whether you should start taking **ESTELLE tablet**, talk to your doctor.

- Before you start use it

Tell your doctor if:

- You have a history of migraine or epilepsy.
- You are a diabetic.
- You have a disorder of the blood called sickle cell anaemia.
- Your blood pressure is high.
- You are suffering from disorders of the bowel such as Crohn's disease or ulcerative colitis.

- You have problems with your veins.
- You have a family history of breast cancer.
- You have a history of or currently have yellowish-brown pigmentation patches on the skin, particularly on the face (called chloasma). If so, you must avoid being exposed for any great length of time to the sun or other sources of ultraviolet radiation such as sun beds.
- You are a smoker.
- You have kidney failure as a result of a blood coagulation problem called haemolytic uraemic syndrome.
- You experience irregular heart rhythms or a heart valve does not work properly.
- You are suffering from disease of the gall bladder or liver.
- You have a family history of high cholesterol or fats (triglycerides) in the blood.
- You have a weight problem
- You have ever had any blood clots
- You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have either recently developed hirsutism or you have had a considerable increase in symptoms, tell your doctor, as the cause of the changes must be determined.

If you have not told your doctor about any of the above, tell them before you take **ESTELLE tablet**

- Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work.

ESTELLE tablet does not interfere with the effects of any topical acne treatment. Medicines that can interfere with

ESTELLE tablet include those used in epilepsy such as primidone, phenytoin, carbamazepine and barbiturates; those used in tuberculosis such as rifampicin; and various types of antibacterials and antifungals such as ampicillin, tetracyclines and griseofulvin. Always tell your doctor or pharmacist if you are taking other medicines, including OTCs, when prescribed **ESTELLE tablet**. Your doctor or pharmacist will give you advice on additional contraception that may be required.

Do not use 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.

How to use ESTELLE tablet

- *How much to use*

Take ESTELLE tablet only when prescribed by your doctor.

To achieve effective clinical efficacy or contraception, **ESTELLE tablet** is to be taken every day. The same rules apply to taking **ESTELLE tablet** as with any other contraceptive pill. Bleeding between one period and the next, and/or reduced therapeutic or contraceptive effectiveness can be caused by not taking **ESTELLE tablet** regularly.

Continuous protection against pregnancy is provided by **ESTELLE tablet** when it is taken regularly. Extra precautions are, however, required when either starting your first pack or when other circumstances such as forgetting to take a tablet occur. This is because the effectiveness of **ESTELLE tablet** can be reduced by circumstances preventing regular intake.

Carefully follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet. If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

- *When to use it*

Take your **ESTELLE tablet** tablets every day.

Take your **ESTELLE tablet** at about the same time each day. This will help you remember when to take the tablets.

- *How long to use it*

Take **ESTELLE tablet** until your doctor tells you to stop taking it.

The severity of your acne or hirsutism will determine how long you should remain on treatment. Several months are generally required with continuation for another 3 to 4 months after the acne or hirsutism is controlled. Further treatment with Estelle –35 ED can be initiated if the conditions recur. It is likely that longer treatment will be required for treating the symptoms of polycystic ovary syndrome.

- *If you forget to use it*

Forgetting to take your tablets means that there is a risk you may become pregnant. That risk increases as the number of tablets missed increases. Risk of pregnancy is particularly high if active tablets at the beginning or end of the pack are missed. If you have forgotten to take a tablet or tablets, the following instructions apply.

- If the forgotten tablet or tablets are the white, non-active tablets, do not worry. Take the next tablet on the indicated day as usual.
- If you have missed taking one or two yellow active tablet take the missed tablet and then take your next tablet at the usual time even if this means taking two tablets in one day. Continue taking the remaining tablets at the usual time. You do not require additional contraceptive protection. You do not require emergency contraception.

If you have missed three or more active tablets at any time, take the most recent tablet as soon as you remember. Continue taking the remaining tablets daily at your usual time. Use condoms or abstain from sex until you have taken active tablets for 7 days in a row.

Vomiting within 3 to 4 hours of taking the **ESTELLE tablet** is similar to missing a tablet as it may mean that the amount of active ingredients absorbed into your bloodstream is reduced. You need to follow the same advice that is given for missed tablets.

- *If you use too much (overdose)*

Serious harmful effects resulting from taking too many **ESTELLE tablet** tablets have not been reported. Effects expected from taking a number of tablets at the same time are: nausea, vomiting or bleeding from the vagina. Seek medical advice if a child has taken any **ESTELLE tablet**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think that you or anyone else may have taken too much **ESTELLE tablet**. **Do this even if there are no signs of discomfort or poisoning.**

While you are using it ESTELLE tablet

- *Things you must do*

Stop taking **ESTELLE tablet** and immediately see your doctor if you get a blood clot. Possible symptoms of a blood clot are:

- Any abnormal cough.
- Severe chest pain that may also include the left arm.
- Difficulty in breathing or coughing for no apparent reason.
- An abnormal, relentless or long lasting headache or migraine.
- Changes in your vision including loss of or double vision.
- Changes in your speech, slurring of words.
- Changes in your senses of hearing, smell or taste.
- Changes in your balance such as dizziness or fainting.
- Total or partial body weakness.
- Severe abdominal pain.
- Relentless leg pain or serious swelling of one or both legs.

If you notice any enlarged veins in your legs or have sharp pains in your legs or chest contact your doctor immediately.

You must contact your doctor as soon as you can if:

- You experience changes in your personal health.
- A lump appears in your breasts.
- You start using other medicines including OTC medicines.
- You need surgery or are going to be kept immobile. Talk to your doctor at least four weeks before the surgery or immobilisation is planned.
- Abnormal, heavy bleeding occurs from your vagina.
- You missed taking active yellow tablets in the first week of any pack and had intercourse during the preceding 7 days.
- Your period doesn't occur twice in a row or you think you may be pregnant. Talk to your doctor before continuing with your next pack of **ESTELLE tablet**

Regular medical follow up

While taking **ESTELLE tablet** you need to have regular medical check ups. It is recommended that such check ups should be at least once a year.

- Things you must not do

Do not give **ESTELLE tablet** to anyone else, even if they have the same condition as you.

If extra contraceptive precautions are required, you need to either:

- Do not have sex; or
- Use a cap plus spermicide; or
- Use a condom

Do not use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives alter the usual menstrual cycle changes such as changes in temperature and cervical mucus.

- Things to be careful of

ESTELLE tablet is not likely to impair your ability to drive or use machinery but be careful driving or operating machinery until you know how Estelle-35 tablets affect you

It is recommended that you do not use **ESTELLE tablet** if you are breast-feeding.

Do not use **ESTELLE tablet** if you are pregnant or if you think you may be pregnant.

ESTELLE tablet cannot protect you against infection with HIV or development of AIDS. Neither can it protect you against any other form of sexually transmitted disease (STD).

Men must not use **ESTELLE tablet**.

ESTELLE tablet should not be stopped in certain situations or its reliability may be reduced as described in this leaflet. If such situations develop you should either stop having sex or use a condom or other barrier method for extra precaution. Since **ESTELLE tablet** alters body temperature and causes changes in cervical secretion during the menstrual cycle, rhythm or temperatureED contraceptive methods should not be used.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **ESTELLE tablet**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Rarely, serious side effects may occur. If any of the symptoms listed in the section "While you are using **ESTELLE tablet**" develop, stop taking **ESTELLE tablet** and tell your doctor immediately or go to the Casualty Department at your nearest hospital.

Also, tell your doctor if you notice any skin rash or itchiness. Other side effects listed below may also occur in some patients. Tell your pharmacist or doctor if you notice any of these effects.

- Tender and/or painful breasts with or without secretion
- Gastric upsets
- Headache
- Feeling depressed
- Libido changes
- Reduced tolerance to contact lenses
- Feeling or being sick
- Any change in normal secretion from the vagina including change in menstrual flow
- Rash, allergy, sensitivity to sunlight, itchiness
- Appetite and/or body weight changes including fluid retention

Do not be alarmed by this list of possible side effects. They do not occur often and you are unlikely to experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the [website npra.gov.my](http://www.npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of **ESTELLE tablet**

- Storage

- Store below 30°C. Protect from light and moisture.
- Keep the pack away from sources of heat
- Keep this medicine out of the reach and sight of children.
- This medicine must not be used after the expiry date printed on the pack, or if the tablets show any signs of deterioration.
- If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

- Disposal

- Return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.
- REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Product Description

- *What it looks like*

ESTELLE-35 TABLET contain 21 active tablets that are described as yellow buff, round biconvex coated plain tablets, plain on both faces.

- *Ingredients*

- Active ingredient

Ethinylestradiol and cyproterone

- Inactive ingredient

Lactose, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, Opadry white, Opadry buff, Opaglos white, Quinoline yellow, and sucrose

- *MAL number:*

ESTELLE-35 TABLET:

MAL05090010A

Manufacturer

Douglas Manufacturing Ltd

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Product Registration Holder

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