

Estelle™-35 ED

Cyproterone acetate 2 mg and ethinylestradiol 35 µg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Estelle-35 ED. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Estelle-35 ED against the benefits it is expected to have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine, you may need to read it again.

What Estelle-35 ED is used for

Estelle-35 ED 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Estelle-35 ED should be withdrawn 3 to 4 cycles after the treated condition has been completely resolved.

Estelle-35 ED provides effective oral contraception in women being treated for androgen-dependent diseases.

Before you take Estelle-35 ED

When you must not take it

Do not take Estelle-35 ED 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 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-35 ED tablets.
- 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.

If you are not sure whether you should start taking Estelle-35 ED, talk to your doctor.

Before you start to take 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-35 ED.

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.

What else you should know

Estelle-35 ED 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-35 ED.

Estelle-35 ED should be stopped in certain situations or its reliability may be reduced as described in this information. If such situations develop you should either stop having sex or use a condom or other barrier method for extra precaution. Since Estelle-35 ED alters body temperature and causes changes in cervical secretion during the menstrual cycle, rhythm or temperature contraceptive methods should not be used.

Estelle-35 ED and Blood clots

The formation of a clot in the blood is called a thrombosis. The clot may sometimes block a blood vessel. Deep vein thrombosis (DVT) occurs when the clot forms in the deep veins of one or both legs. A blood clot may cause pulmonary embolism, heart attack or stroke if it falls off the vein wall where it formed, and travels through the circulation to block the arteries feeding either the lungs, heart or brain. DVT is very uncommon but may develop either naturally or while you are taking Estelle-35 ED. Pregnancy can also cause DVT. The rate of development of thrombosis is higher in pregnant women than in non-pregnant women with the rate being in-between for Estelle-35 ED users. Blood clots may occur in other parts of the body as well but this is extremely rare. Examples include the gut, liver, kidney and eye. Symptoms of thrombosis can include: unilateral leg pain and/or swelling, sudden severe chest pain, sudden breathlessness, sudden onset of coughing, unusual or severe prolonged headache, sudden partial or complete loss of vision, slurred speech, giddiness and weakness or numbness of one part or side of the body. The risk of thrombosis increases with age, smoking (especially in women over 35), family history, obesity, high blood pressure, heart disease and in surgery. You may need to stop taking Estelle-35 ED well before surgery and not start again until your doctor tells you to.

Can Estelle-35 ED cause cancer?

There appears to be a slightly increased risk of breast cancer in women using the "pill" compared to women not using the pill who are the same age. On stopping the pill, the excess risk disappears over the next 10 years. Breast cancer is rare in women under 40 years of age. This means that the increase in number of breast cancers diagnosed in current and recent pill users is much less than the overall risk of breast cancer. The apparent increase in risk may be due to either earlier diagnosis, or the biological effects of the pill or a combination of both. Breast cancers found in pill users tend to be less advanced than breast cancers found in non-pill users.

Occasionally benign or very rarely malignant tumours of the liver have been reported in pill users. In isolated cases these have caused bleeding into the abdomen. If you develop severe abdominal pain, contact your doctor immediately.

Taking other medicines with Estelle-35 ED

Estelle-35 ED does not interfere with the effects of any typical acute treatment. Medicines that can interfere with Estelle-35 ED 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-35 ED. Your doctor or pharmacist will give you advice on additional contraception that may be required.

Taking Estelle-35 ED while breastfeeding

It is recommended that you do not use Estelle-35 ED if you are breastfeeding.

Use of Estelle-35 ED in pregnancy

Do not use Estelle-35 ED if you are pregnant or if you think you may be pregnant.



DOUGLAS
PHARMACEUTICALS

Estelle-35 ED and driving

Estelle-35 ED is not likely to impair your ability to drive or use machinery.

How to take Estelle-35 ED

How much to take

Take Estelle-35 ED only when prescribed by your doctor.

To achieve effective clinical efficacy or contraception, Estelle-35 ED is to be taken every day. The same rules apply to taking Estelle-35 ED as to the taking of 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-35 ED regularly.

Continuous protection against pregnancy is provided by Estelle-35 ED 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-35 ED 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 take it

Take your Estelle-35 ED tablets every day.

Take your Estelle-35 ED tablet at about the same time each day. This will help you remember when to take the tablets.

How long to take it

Take Estelle-35 ED until your doctor tells you to stop taking it.

Starting your first pack of Estelle-35 ED

When hormonal contraception has not been used in the past month

Starting on the first day of your period take the tablet for the corresponding day of the week in the red area on the calendar pack (eg. if your period starts on a Monday take your first tablet from the spot marked Monday in the red section). Continue taking one tablet daily until all tablets in the calendar pack have been taken. This includes all of the small yellow active tablets and the white non-active tablets. Start taking the next tablet from the next calendar pack on the day after the last tablet in the first calendar pack. Follow the arrows on the pack for the corresponding day of the week.

You must use an additional barrier contraceptive method such as condoms or a diaphragm for the first 14 days after starting your first pack of Estelle-35 ED. Do not use rhythm, temperature or cervical mucus methods. Additional contraceptive methods are not required when starting your second or subsequent packs after completing your first pack provided you have taken Estelle-35 ED on a regular daily basis i.e. no tablets have been missed.

When changing from a combined oral contraceptive

Start Estelle-35 ED the day after you take the last active tablet from your present pill pack (this means no tablet-free break). If you are not sure which tablets are active and non-active ask your doctor or pharmacist.

Use a barrier contraceptive method for the first 14 days of taking Estelle-35 ED if having intercourse.

How to change from a pill containing only progestogen (minipill)

Stop taking the minipill. Start Estelle-35 ED on the next day taking the tablet at the same time of day that you were taking the minipill. Use an additional barrier contraceptive method such as condoms or a diaphragm (but not rhythm, temperature or cervical mucus methods) for the first 14 days of Estelle-35 ED if having intercourse.

How to change from a contraceptive injection or implant

Start Estelle-35 ED on either the day your injection is due or your implant is removed. Use an additional barrier contraceptive method such as condoms or a diaphragm (but not rhythm, temperature or cervical mucus methods) for the first 14 days of Estelle-35 ED if having intercourse.

What to do after giving birth

If you have just given birth, it is recommended that you do not start Estelle-35 ED until you have had your first normal period. It is, however, possible to start sooner if advised to do so by your doctor. It is recommended that you do not use Estelle-35 ED while breastfeeding without first seeking your doctor's advice.

What to do after an abortion or miscarriage

Talk to your doctor.

Special Circumstances

Situations may occur which require you to alter the way you use Estelle-35 ED. Additional barrier contraceptive methods are required in circumstances where protection cannot be relied upon. Such circumstances include missed tablets, or you are taking other medicines including OTCs that may interact with Estelle-35 ED or you have vomited shortly after taking Estelle-35 ED.

If you forget to take 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 (also known as the "7-day rule") 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 a yellow active tablet but remember within 12 hours, you will still be protected against pregnancy. Take the missed tablet and then take your next tablet at the usual time even if this means taking two tablets in one day.
- If you have missed taking a yellow active tablet and it is more than 12 hours later when you remember, then protection against pregnancy is lost. You need to take the missed tablet immediately and then take the next tablet at your usual time even if this means you take two tablets on the same day. Extra barrier contraceptive methods will be required according to the 7 day rule. Information about this is given below.
- If the forgotten tablet or tablets occurred in the first week of yellow active tablets from your pack, and you had intercourse in any of the seven days preceding that week, you need to seek advice from your doctor to exclude the possibility of pregnancy.
- Where you may have forgotten to take the yellow active tablets for a few days, see your doctor to exclude the possibility of pregnancy. Follow the 7 day rule after disposing of the missed tablets in your pack.

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

- Refrain from having intercourse; or
- Use a barrier contraceptive method such as a cap with spermicide or condom.

Rhythm, temperature or cervical mucous methods must not be used since oral contraceptives alter normal menstrual cycle changes.

The 7 day rule

- Do not stop taking your tablets.
- You need to take your yellow active tablets for seven consecutive days before you will be protected from pregnancy.
- Refrain from intercourse or use barrier contraceptive methods while taking the seven yellow active tablets referred to in the above bullet point.
- If less than seven yellow active tablets remain in your current blister strip, finish these and go straight onto the yellow active tablets of the next blister strip missing out the white inactive tablets. It is possible you may not have a period until you reach the end of the next blister strip, however, you will not be harmed by this.

What to do if you vomit soon after taking Estelle-35 ED

Vomiting within 3 to 4 hours of taking your Estelle-35 ED 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.

Taking other medicines with Estelle-35 ED

Some medicines can interfere with the beneficial clinical effect of Estelle-35 ED. These medicines are: phenytoin, barbiturates such as primidone and phenobarbitone, antiepileptics such as carbamazepine, oxcarbamazepine and antibiotics/antifungals such as rifampicin, ampicillin, tetracyclines and griseofulvin. While taking these medicines and for the next 7 days, follow the advice given for missed tablets. Ask your doctor for advice about the length of time you need to use extra contraceptive precautions if you are on continuous medication or taking rifampicin.

How to delay a period

By missing out the white non-active tablets of one blister strip and going straight onto the yellow active tablets of the next, you can delay the start of your period until you begin taking the white non-active tablets of the second blister strip. Some breakthrough bleeding or spotting may occur, however, while you are taking the yellow active tablets from the second blister strip.

How to change the day your period starts

By taking the tablets as directed, your period will start on about the same day every four weeks. To change this, shorten (you must never lengthen) the number of days in which you take the white non-active tablets. If you shorten the number of days to 3 or less, this may stop you having a bleed during the break but you may have breakthrough bleeding or spotting while taking the yellow active tablets from the second blister strip.

What to do if unexpected bleeding occurs

During the first few months of taking Estelle-35 ED, you may have spotting or breakthrough bleeding from your vagina in between periods. Continue to take your tablets as directed. Such spotting or breakthrough bleeding usually stops after about 3 cycles of tablet taking. However, tell your doctor if it continues, changes to heavy bleeding or starts again.

If you take too much (overdose)

Serious harmful effects resulting from taking too many Estelle-35 ED 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-35 ED tablets.

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 764 766 in NZ or 13 11 26 in Australia) if you think that you or anyone else may have taken too much Estelle-35 ED. Do this even if there are no signs of discomfort or poisoning.

While you are using Estelle-35 ED

Things you must do

Stop taking Estelle-35 ED 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 including 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-35 ED.

Regular medical followup

While taking Estelle-35 ED you need to have regular medical checkups. It is recommended that such checkups should be at least once a year.

Things you must not do

Do not give Estelle-35 ED to anyone else, even if they have the same condition as you.

How long should Estelle-35 ED be used?

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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Estelle-35 ED.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment for 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-35 ED" develop, stop taking Estelle-35 ED and tell your doctor immediately or go to casualty 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.

After using Estelle-35 ED

- 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.
- 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.

Further Information

You can get more information on Estelle-35 ED from your doctor or pharmacist.

Product Description

What Estelle-35 ED looks like

Estelle-35 ED is supplied in a calendar pack containing 21 small yellow active tablets and 7 large white non-active tablets per blister strip.

Available as packs of 28 tablets and 84 tablets.

Ingredients

The ingredients in Estelle-35 ED small yellow active tablets are cyproterone acetate, ethinylloestradiol, lactose, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, Opadry white, Opadry buff, Opaglos white, Quinoline yellow, and sucrose.

The ingredients in Estelle-35 ED white non-active tablets are lactose, microcrystalline cellulose, and magnesium stearate.

Marketed By:

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