

EstelleTM - 35ED

Cyproterone acetate 2mg/ Ethinylloestradiol 0.035mg tablets

A guide to using Estelle-35ED



Release the Woman within

The Pill has created a new freedom for women everywhere.

Freedom from skin conditions that can plague some women through their teens and into adulthood with an added benefit of providing contraception.

Estelle-35ED is a Pill, which offers new freedoms. See what it can do for you.

What is in this booklet?

This booklet answers some common questions about Estelle-35ED. 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-35ED against the benefits he/she expects it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this book with the medicine; you may need to read it again.

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Introducing Estelle-35ED

What are the active ingredients in Estelle-35ED?

One calendar pack contains 21 yellow active tablets and 7 white inactive tablets. Each active tablet is a yellowish, round tablet, containing 2mg cyproterone acetate and 0.035mg ethinylloestradiol. Each inactive tablet is a white, round tablet, containing lactose.

How does Estelle-35ED differ from other “Pills”?

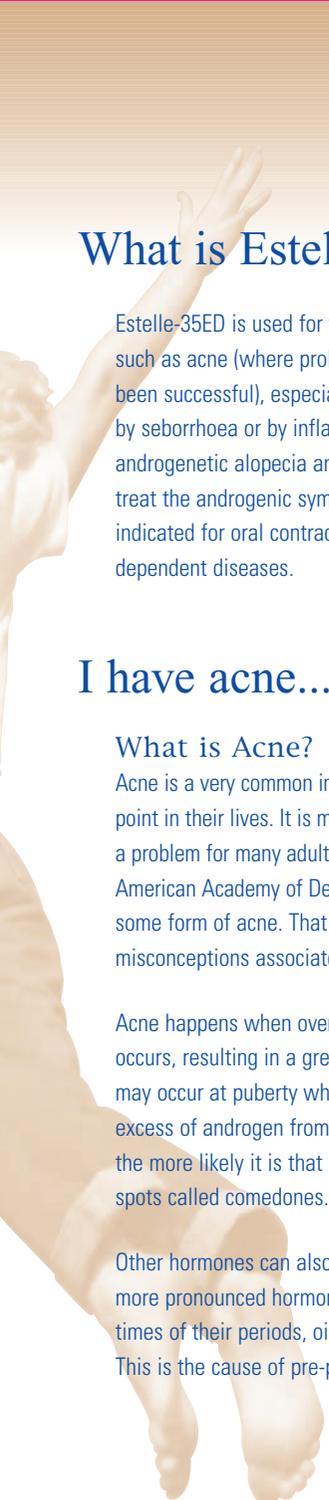
Most oral contraceptives contain both an oestrogen and progestogen. Estelle-35ED is different in that it contains an oestrogen, ethinylloestradiol, and an anti-androgen, cyproterone acetate. The substance cyproterone acetate contained in Estelle-35ED inhibits the influence of the male hormones, called androgens, which are also produced by the female system. It is thus possible to treat diseases caused by either an increased production of androgens or a particular sensitivity to these hormones.

What are Androgens?

Androgens are male sex hormones such as testosterone. They stimulate the growth of some hair and the sebaceous glands (oil glands in the skin) by triggering androgen receptors found in the skin and hair. Your ovaries have to make androgens in order to make female sex hormones such as oestrogens. If your ovaries make too many androgens or if your skin is very sensitive to circulating androgen levels, you may find that you suffer from a greasy skin (also called seborrhoea). This can lead to other problems such as pimples. High levels of circulating androgens or an oversensitivity to androgens may lead to excessive hair growth. Sometimes the high levels of androgens or oversensitivity can lead to scalp hair loss (androgenetic alopecia).

What is Cyproterone acetate?

Cyproterone acetate in Estelle-35ED acts on the androgen receptors by attaching to them. This means that when an androgen molecule tries to attach to the same receptor it cannot get in and therefore can't have an effect on your skin or hair. The second action of Estelle-35ED is to reduce the level of androgens being produced in your ovaries.



What is Estelle-35ED used for?

Estelle-35ED is used for the treatment of androgen-dependent diseases in women, such as acne (where prolonged oral antibiotics or local treatment alone has not been successful), especially pronounced forms and those which are accompanied by seborrhoea or by inflammation, the formation of nodes or the risk of scarring, androgenetic alopecia and mild forms of hirsutism. Estelle-35 ED is also used to treat the androgenic symptoms of polycystic ovary syndrome. Estelle-35ED is also indicated for oral contraception in women requiring treatment for these androgen-dependent diseases.

I have acne...

What is Acne?

Acne is a very common inflammatory skin disorder. It affects most people at some point in their lives. It is most often seen in the teenage years, but can continue to be a problem for many adults. In a study published in October 1999 by the Journal of the American Academy of Dermatology, 54% of women and 40% of men suffered from some form of acne. That acne is only a teenager's disease is just one of the many misconceptions associated with the condition.

Acne happens when over-stimulation of the skin's oil-producing (sebaceous) glands occurs, resulting in a greater production of the oily substance called sebum. This may occur at puberty when sebaceous glands first become active or if there is an excess of androgen from elsewhere. The more sebum that is produced by the skin, the more likely it is that a skin pore will become blocked, resulting in early acne spots called comedones.

Other hormones can also be involved. Some women are genetically prone to having more pronounced hormone swings, with higher levels of androgens, and, at certain times of their periods, oil glands that are more sensitive to circulating hormones. This is the cause of pre-period breakouts of acne that so many women complain of.



Some women battle acne into their adult years. And increasingly, many of them are trying a new approach that goes beyond the traditional treatments. They are using the birth control pill to control acne.

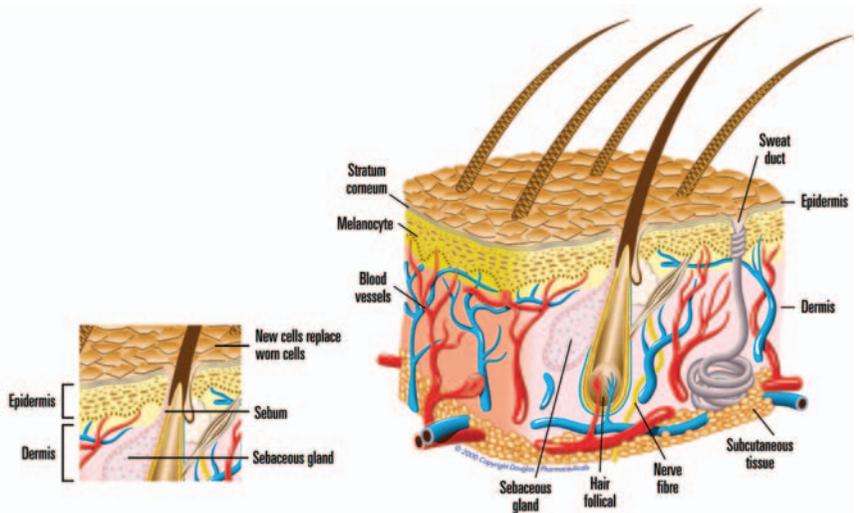
Hormone manipulation (which is how the pill works) becomes an option especially for women wanting both birth control and acne treatment. These pills reduce androgens (male hormones) and regulate a woman's menstrual cycle. While all women have some level of androgens, an excessive amount can lead to acne.

The Pill sometimes helps acne

Breaking out with spots can sometimes just be an inconvenience. For some acne sufferers, their skin problems may interfere with their quality of life.

There used to be a view that "The Pill" made acne worse. But on the contrary, today there is Estelle-35ED, a low-dose oral contraceptive pill that can clear acne and help keep acne at bay.

Having skin with a tendency towards acne may also be associated with lank, greasy hair. Estelle-35ED has the opposite effect. It can clear the skin and make your hair less greasy, too.



So what causes acne?

Acne is not a superficial thing. Mostly it is caused by what is happening under the skin. No amount of washing will make it go away, in fact, over washing can aggravate acne. Acne is triggered by over-activity in the sebaceous (oil-producing) glands. And at the same time, keratin, which is a protein in the lining of your pores, begins to form little lumps. The build up of dead skin cells and sebum clogs the skin pores and forms a plug. This plug stops the excess sebum getting out. Bacteria then multiply and irritate the skin. That's when angry red, black or yellow pustules form.

Diet

Despite what you will read in many magazines diet has never clearly been implicated in acne. There isn't a scientific reason for any particular diet although some women are convinced that a particular food aggravates their acne, and it is reasonable that they avoid the offending food.

Cosmetics

Some cosmetics promote the formation of comedones (blocked skin pores) through oils in the application. Some cosmetics may cause chemical irritation leading to inflamed papules and pustules. Using oil-free cosmetics or those labelled non-comedogenic is recommended.

Sunshine

Acne frequently improves in the hot summer months, although it can become worse in some humid climates. Acne can be improved by both visible and ultraviolet light. Sunshine and swimming in salt water seem anecdotally to be beneficial in many cases. However, in a small number of people, acne can be aggravated by the sun. The use of an effective, oil-free sunscreen agent is important.

Stress

Stress is common in so many women's lives with the number of roles they have to fill. Many blame stress for an exacerbation of their acne. Acne itself is likely to be a significant cause of further stress, especially when a person tends to pick the lesions, making them appear worse.





How does Estelle-35ED help?

Your body produces female sex hormones called oestrogens. As part of the normal hormone production process your body also produces male sex hormones called androgens.

Androgens stimulate the growth of the skin. Androgens also stimulate the grease glands (sebaceous glands) to produce large amounts of sebum. It is the sebum that gives you greasy skin. Sometimes your skin may be particularly sensitive to the effects of androgens, or if your ovaries produce excess androgens, the glands can produce excess sebum.

In this way, the glands can become blocked and up pops another pimple.

The hormones in your body can only act when they become attached to the right receptors in the right tissue. The hormone in Estelle-35ED, cyproterone acetate – acts by sticking itself to the androgen receptors in the skin and blocking those receptors. This stops the androgens in your blood from stimulating the grease glands.

Within a few weeks your skin should not be as greasy and after three months your acne should have started to improve with fewer and fewer new spots appearing.

With Estelle-35ED, some women find their skin clears completely and quite quickly. Others find it takes longer.

How long will I need to take Estelle-35ED for?

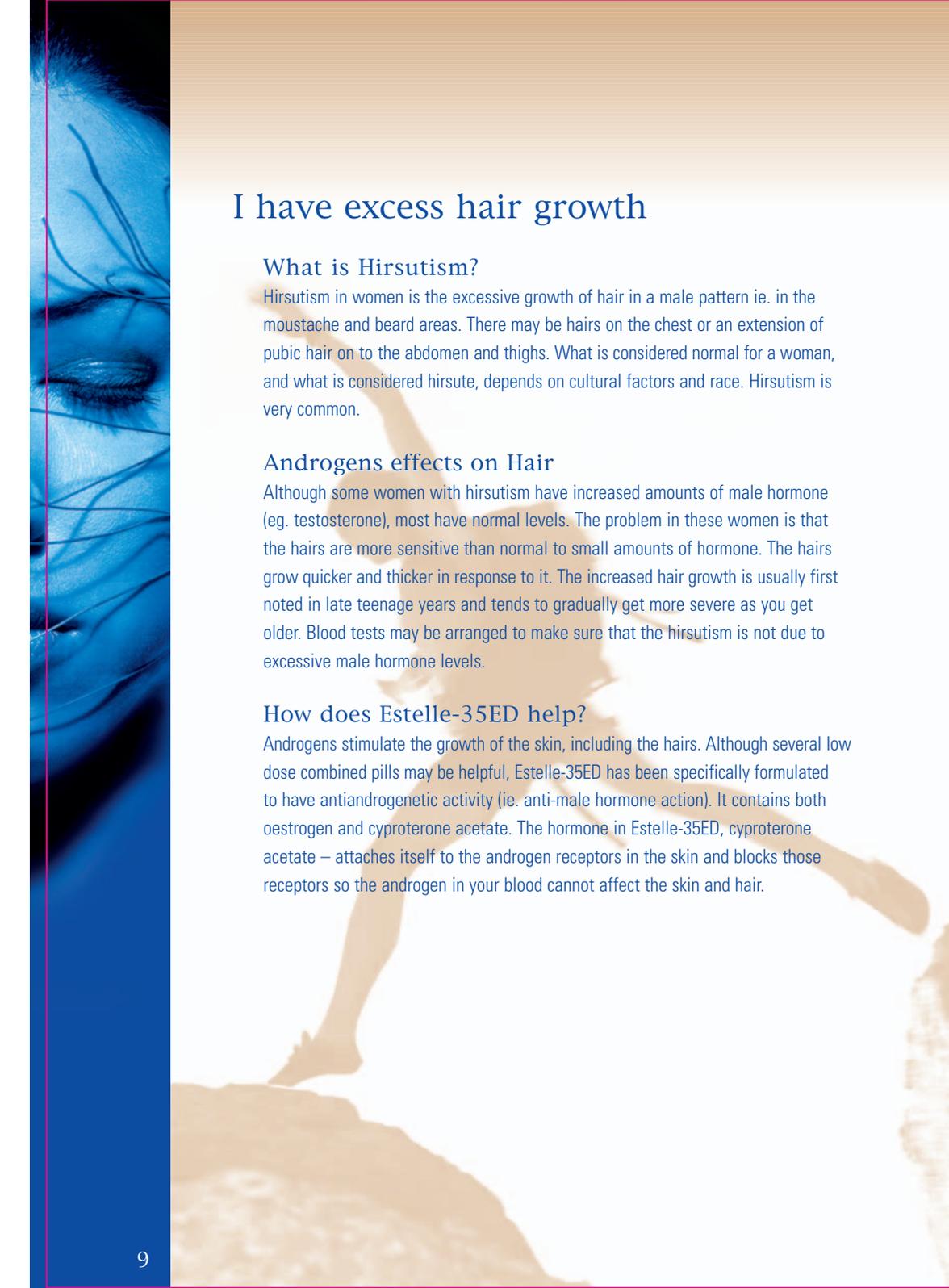
The length of use depends on the severity of the clinical picture; in general, treatment should be carried out over many months. It is recommended to take Estelle-35ED for at least another 3 to 4 cycles after the signs have subsided. Should there be a recurrence weeks or months after discontinuation of tablet taking, treatment with Estelle-35ED may be resumed.

What else can I do to help improve my skin?

Use water based skin products and avoid oil-based make-ups containing ingredients such as lanolin or petrolatum which can block your pores. Do not pick at spots and blemishes – it'll only cause them to get worse. It will spread the inflammation and it may also cause permanent scarring. Excessive washing and cleansing of the skin may irritate the skin and worsen acne. There is no evidence that the amount of oil in the diet affects acne to any degree.

Don't wear tight clothing on affected areas or rough textured clothing such as wool. Don't cover acne on your forehead by wearing a hat or headband. These can irritate the skin and spread the inflammation.



The page features a vertical blue bar on the left side containing a close-up of a woman's face with blue hair. The background is a light beige color with a faint silhouette of a woman in a white dress walking. The main text is in a dark blue font.

I have excess hair growth

What is Hirsutism?

Hirsutism in women is the excessive growth of hair in a male pattern ie. in the moustache and beard areas. There may be hairs on the chest or an extension of pubic hair on to the abdomen and thighs. What is considered normal for a woman, and what is considered hirsute, depends on cultural factors and race. Hirsutism is very common.

Androgens effects on Hair

Although some women with hirsutism have increased amounts of male hormone (eg. testosterone), most have normal levels. The problem in these women is that the hairs are more sensitive than normal to small amounts of hormone. The hairs grow quicker and thicker in response to it. The increased hair growth is usually first noted in late teenage years and tends to gradually get more severe as you get older. Blood tests may be arranged to make sure that the hirsutism is not due to excessive male hormone levels.

How does Estelle-35ED help?

Androgens stimulate the growth of the skin, including the hairs. Although several low dose combined pills may be helpful, Estelle-35ED has been specifically formulated to have antiandrogenetic activity (ie. anti-male hormone action). It contains both oestrogen and cyproterone acetate. The hormone in Estelle-35ED, cyproterone acetate – attaches itself to the androgen receptors in the skin and blocks those receptors so the androgen in your blood cannot affect the skin and hair.

Helping Polycystic Ovary Syndrome (PCOS)

What are some of the symptoms of PCOS?

- Period problems
- Acne, excessively oily skin or hairiness (hirsutism) due to excess male hormones
- Infertility
- Weight gain

Menstrual disturbance

PCOS often comes to light during puberty due to period problems, which affects many of those with the disease. Infrequent, irregular or absent periods are all common variations, many finding their periods particularly heavy when they do arrive. The period disturbance may be a sign that there is a problem with regular monthly ovulation. Many teenagers use the contraceptive pill to control their periods as irregularity or heaviness is a common complaint at this time, even in the absence of PCOS. This often leads to a delay in the diagnosis of PCOS, many not presenting until the pill is stopped and then finding periods cease or become irregular.

Androgenetic symptoms

Androgens are a group of hormones, such as testosterone, found at high levels in men but present in women at much lower levels. PCOS sufferers often have higher than normal levels of androgens, which most often cause excess hairiness, but can also cause the reverse, a male pattern of hair loss called androgenetic alopecia.

Infertility

Given that the period disruption with PCOS is due to irregular or absent ovulation it is not surprising that it is a common cause of infertility. Some women with PCOS will ovulate normally, some will ovulate less frequently (leading to a delay in getting pregnant) and some will not ovulate at all, meaning that for some treatment will definitely be necessary.



I have excess hair growth

Helping Polycystic Ovary Syndrome



Obesity

Around 40% of PCOS sufferers are overweight. Unfortunately obesity itself simulates the symptoms of PCOS in some women who would not have otherwise suffered had they remained of normal weight. It will worsen the symptoms for those who do have PCOS and, unfortunately, the hormone changes associated with PCOS make weight loss more difficult.

What is happening to me when I have PCOS?

With PCOS, your body produces too much androgen, which counteracts your ovaries' ability to make the progesterone necessary for a normal cycle. The androgen levels interfere with your follicle-stimulating hormone, which you need to trigger progesterone. As a result, your follicles don't develop, and instead turn into small cysts on your ovaries. This can cause your ovaries to enlarge. Excessive androgen can also cause hirsutism, the development of facial hair and hair on other parts of your body. It may even cause a balding problem. Obesity and acne are other recognised outcomes. Women who are thin or of normal weight can also have PCOS. Your periods may be irregular, and as a result you might be at greater risk for a thickening of uterine lining. This is called endometrial hyperplasia.

Other effects of Estelle-35ED

Estelle-35ED and its effect on Period Regularity

In most cases the Pill is taken for 21 consecutive days. This is followed by seven White Pill (inactive tablets) days during which levels of oestrogen and progestogen in the blood go down. As a result, the lining of the womb – which so far has been preparing for pregnancy – is shed, and a monthly bleeding occurs just as in normal menstruation.

Most women taking the Pill find that monthly bleeding is shorter, lighter, more regular and less painful.

During the first 3 or 4 months some women experience some irregular bleeding while taking the tablets. This happens with all different kinds of Pills. This bleeding may be scanty, called spotting, or heavier, called breakthrough bleeding. If this happens it is not necessary to stop taking the Pill. The bleeding usually settles in a few days, as the body adjusts itself to the Pill. It is advised to persist with the same Pill for at least three months. However, if bleeding is heavy or lasts for a long time, it is advised to see your doctor.





Does Estelle-35ED have an oral contraceptive effect?

In addition to being an anti-androgen, cyproterone acetate has the effect of a female sex hormone (progestogen) and, when combined with ethinyloestradiol in Estelle-35ED, makes an effective contraceptive.

Like other combined oral contraceptives, the reduction of the activity of the ovaries by Estelle-35ED includes prevention of release of eggs (ova). Additional actions are to make the mucous in the neck of the cervix thick so that sperm cannot penetrate it and to make the lining of the uterus unsuitable for a fertilized egg to grow on. These actions mean that Estelle-35ED is a reliable contraceptive.

How to start Estelle-35ED

If you are not currently using a hormonal contraceptive, the first tablet of Estelle-35ED must be taken on the first day of the cycle (first day of bleeding). Starting a bit later, on day 2 through to day 5 of your cycle is allowed, but during the first cycle a barrier method of contraception is recommended for the first two weeks.

Start taking the tablet in the red section marked with the appropriate day of the week. Take the small yellow hormonal tablets daily until all 21 of the small yellow hormonal tablets have been taken. Continue by taking the white non-hormonal tablets daily for 7 days. Withdrawal bleeding should usually occur within 2 to 4 days after taking the last small yellow hormonal tablet.

In the first cycle only, an additional form of contraception (except the rhythm and temperature methods) must be used for the first 14 days of tablet taking.

Tablets should be taken at the same time each day if possible.

Changing from another combined oral contraceptive (COC)

You should start with Estelle-35ED preferably on the day after the last hormonal tablet of your previous oral contraceptive. At the latest, you can start Estelle-35ED on the day following the usual tablet free or non-hormonal tablet interval of your previous oral contraceptive. You should start Estelle-35ED in the red section on the day after the last hormonal tablet of your previous oral contraceptive.

Changing from a progestogen only method (minipill, injection, implant)

You may change any day from the minipill (from an implant on the day of its removal, from an injectable when the next injection would be due) but in all cases you should use an additional form of contraception (barrier methods) for the first two weeks.

Following first trimester abortion (ie within the first 3 months of pregnancy)

You may start immediately. When doing so, you do not need to take additional contraceptive measures.

Following delivery or second trimester abortion (ie between 3 and 6 months of pregnancy)

You should start 21 to 28 days after delivery or second trimester abortion. When starting later, you should use additional contraception (barrier methods) for the first 7 days of tablet taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of Estelle-35ED. Alternatively you can wait for your next menstrual period before starting.

What do I do if I am late taking a tablet?

If you are more than 12 hours late in taking any hormonal tablet, the contraceptive protection may be reduced. If it is less than 12 hours, the contraceptive protection is not reduced. If you have forgotten to take a tablet, you should take the next tablet as soon as you remember. Then you should take further tablets at the usual time.





There is a particularly high risk of pregnancy if hormonal tablets are missed at the beginning or near the end of the pack. If tablets are missed in the first week of taking hormonal tablets and intercourse took place in the preceding 7 days the possibility of pregnancy should be considered.

Errors in taking the non-hormonal tablets contained in Estelle-35ED can be ignored.

A missed tablet will not have any effect on the treatment of acne, hirsutism or androgenetic alopecia. It is only important for oral contraception.

The management of missed tablets can be guided by the following two basic rules:

- Tablet taking must never be discontinued for longer than 7 days.
- 7 days of uninterrupted tablet taking is required to attain adequate suppression of the hypothalamic-pituitary-ovarian axis.

Extra Contraceptive Precautions

When you need extra contraceptive precautions, either;

- Don't 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.

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.

Advice in case of vomiting and diarrhoea

Vomiting and diarrhoea can interfere with the absorption of Estelle-35ED and reduce its contraceptive effect. If vomiting occurs within 3-4 hours after tablet taking, absorption may not be complete. FOLLOW THE 7 DAY RULE as outlined above. If you do not want to change your normal tablet-taking schedule, you need to take the extra tablet(s) needed from another pack.

How to shift periods or how to delay a period

To delay a period you should continue with the small yellow hormonal tablets from another pack of Estelle-35ED without a tablet-free interval or the white non-hormonal tablets. The extension can be carried on for as long as desired until the end of the second pack. During the extension you may experience breakthrough bleeding or spotting.

To shift your periods to another day of the week than you are used to with your current scheme, you can shorten your forthcoming tablet-free interval or omit the non-hormonal tablets in Estelle-35ED by as many days as you like. The shorter the interval, the higher the risk that you will not have a withdrawal bleed and will experience breakthrough bleeding and spotting during the second pack (just as when delaying a period).





Are there any unwanted side effects from Estelle-35ED

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

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-35ED" occur, stop taking Estelle-35ED and tell your doctor immediately or go to casualty at your nearest hospital. Also, tell your doctor if you notice a 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.

- Breast tenderness, pain and secretion.
- Headache.
- Changes in sexual drive; depressive moods.
- Contact lens intolerance.
- Nausea, vomiting and feeling sick.
- Changes in vaginal secretion.
- Various skin reactions.
- Fluid retention.
- Changes in body weight.
- Hypersensitivity reactions.

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.

What should I do and not do?

Things you must do

You should stop treatment and see your doctor immediately if you get a blood clot while you are taking Estelle-35ED. Warning signs to look out for are:

- An unusual cough.
- Severe pain in the chest, which may reach the left arm.
- Breathlessness.
- Any unusual, severe, or prolonged headache or migraine attack.
- Partial or complete loss of vision, or double vision.
- Slurring or speech disability.
- Sudden changes to your hearing, sense of smell or taste.
- Dizziness or fainting.
- Weakness or numbness in any part of your body.
- Severe pain in your abdomen.
- Severe pain or swelling in either of your legs.

Contact your doctor as soon as possible if:

- You notice any changes in your own health, especially involving any of the items mentioned in this leaflet.
- You feel a lump in your breast.
- You are going to use other medications.
- 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 forgot tablets in the first week of the pack and had intercourse in the seven days before.
- You miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

Regular check-ups

When you are using Estelle-35ED, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

Things you must not do

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



Consumer Medicine Information

ESTELLE-35ED

Cyproterone acetate 2 mg and ethinylloestradiol 35 µg

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 this medicine 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 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-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.

Estelle-35 ED does not interfere with the effects of any topical acne treatment. Medicines that can interfere with Estelle-35 ED include those taken for epilepsy such as primidone, phenytoin, carbamazepine and barbiturates; those taken for 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 non prescription medicines, when prescribed Estelle-35 ED. Your doctor or pharmacist will give you advice on additional contraception that may be required.

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 take Estelle-35 ED.

Estelle-35 ED 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-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 Estelle-35 ED while breast-feeding

It is recommended that you do not take Estelle-35 ED if you are breast-feeding.

Use of Estelle-35 ED in pregnancy

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

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 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-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 taken 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 on 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 mucous 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 mucous 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 take Estelle-35 ED while breast-feeding 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 take 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 non prescription medicines 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 mucus 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 non-active 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 the 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 from bleeding 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 your 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 National Poisons Information Centre (New Zealand: telephone 0800 POISON or 0800 764 766; Australia: 13 11 26) for advice or go to your nearest Casualty Department (Accident and Emergency Centre) 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, 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 non prescription 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 follow up

While taking Estelle-35 ED 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-35 ED to anyone else, even if they have the same condition as you.

How long should Estelle-35 ED be taken?

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 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-35 ED" develop, stop taking Estelle-35 ED 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.

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 taken 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.



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- 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 a calendar pack containing 21 small yellow active tablets and 7 larger 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.

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Notes



