

# Estelle<sup>®</sup>-35 ED

ethinyloestradiol and cyproterone acetate

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## 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 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

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Estelle-35 ED should be withdrawn 3 to 4 cycles after the treated condition has been completely resolved.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

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### BEFORE YOU TAKE ESTELLE-35 ED

#### When you must not take it

- 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.
- 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 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:**

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 (e.g. primidone, phenytoin, carbamazepine and barbiturates), those taken for tuberculosis (e.g. rifampicin) and various types of bacterial and fungal infections (e.g. ampicillin, tetracyclines and griseofulvin) and herbal medicines containing St John's Wort.

**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. Thrombosis 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.

Cervical cancer has been reported to occur more often in women using the pill for a long time. This finding may not be caused by the pill but may be related to sexual behaviour and other factors.

### **Taking Estelle-35 ED while breast-feeding**

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.

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## HOW TO TAKE ESTELLE-35 ED

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.**

### **How to take it**

Take one tablet daily at about the same time everyday. You must take Estelle-35 ED every day regardless of how often you have sex. It will also help you remember when to take it.

**Swallow the tablet whole with water.** It does not matter if you take it before or after food. Each blister pack is marked with the day of the week.

**Take your first tablet from the red area on the blister pack corresponding to the day of the week.**

Follow the direction of the arrows on the blister pack until all the tablets have been taken.

**Always start a new blister pack on the same day of the week as your previous pack.**

### **Taking Estelle-35 ED for the first time**

If you are starting Estelle-35 ED after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. on the first day of your menstrual bleeding.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.**

**Your doctor will advise you when to start if you:**

- are taking Estelle-35 ED after having a baby
- have had a miscarriage or an abortion.

### ***Changing from another contraceptive***

#### **Changing from a combined oral contraceptive:**

Start taking Estelle-35 ED on the day after taking the last active tablet in your previous Pill pack. Bleeding may not occur until the end of the first pack of Estelle-35 ED.

#### **If you are not sure which were the active/inactive tablets were in your previous Pill pack, ask your doctor or pharmacist.**

Your previous Pill pack may have different colour tablets to those of Estelle-35 ED.

#### **Changing from a progestogen-only pill ('minipill'):**

Stop taking the minipill on any day and start taking Estelle-35 ED at the same time the next day.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.**

#### **Changing from a progestogen only injection, implant or intrauterine system (IUS):**

Start taking Estelle-35 ED when your next injection is due, or on the day that your implant or IUS is removed.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.**

#### **Stopping Estelle-35 ED**

You can stop taking Estelle-35 ED at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic

acid. It is best that you start taking folic acid tablets before you stop taking Estelle-35 ED and not stop until your doctor advises this. Seek advice from your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

### **If you forget to take it**

If you miss a tablet and take the missing tablet within 12 hours of missing it, you will be protected against pregnancy. If you are more than 12 hours late follow these detailed instructions:

**For Estelle-35 ED to be most effective, yellow active tablets need to be taken uninterrupted for 7 days.**

**If you have been taking the yellow active tablets for 7 uninterrupted days and miss a yellow active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day.** You will not need to use additional barrier contraceptive precautions. The chance of pregnancy after missing a yellow active tablet depends on when you missed the tablet. **There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.**

**If after taking your missed tablet you have less than 7 days of yellow active tablets left in a row, you should finish the active tablets in your pack but skip the white inactive tablets and start a new pack.**

This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the yellow active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.

**If you have been taking the yellow active tablets for less than 7 days and miss a yellow active tablet, take the missed**

tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day. In addition, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.

If you have had sexual intercourse during that time, there is a possibility of pregnancy and you may need emergency contraception.

**If you forget to take more than one yellow active tablet, seek advice from your doctor or pharmacist about what to do.**

If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.

**If you forget to take a white inactive tablet, take it as soon as you remember and take the next tablet at the usual time.**

You are still protected against pregnancy because the white tablets do not contain any active ingredients.

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

**If you take too much (overdose)**

**If you think that you or anyone else may have taken too much Estelle-35 ED, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 poison or 0800 764 766 in New Zealand) for advice, or go to the Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.**

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## **WHILE YOU ARE TAKING ESTELLE-35 ED**

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**Things you must do**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

**Have regular check ups with your doctor.** When you are taking the Pill, your doctor will tell you to return for regular check ups, including getting a pap smear test. Your doctor will advise how often you need a pap smear test. A pap smear test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

**If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Estelle-35 ED.**

**Stop taking Estelle-35 ED and see your doctor immediately if you notice possible signs of thrombosis. These include:**

- an unusual cough
- severe pain in the chest which may reach the left arm
- sudden unexplained breathlessness or rapid breathing
- 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
- severe light headedness, 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.
- Rapid or irregular heart beat

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.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you vomit within 3-4 hours or have severe diarrhoea after taking a yellow active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.**

**If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.** When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

**If you have missed a period, but you have taken all your tablets, it is very unlikely that you are pregnant. Provided that:**

- you have taken the yellow active tablets at the right time

- you have not been taking medicine(s) that may interfere with Estelle-35 ED.
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take Estelle-35 ED as usual. If you have any concerns consult your doctor or pharmacist.

**If you miss your period twice in a row, you may be pregnant and you should seek advice from your doctor. Do not start the next pack of Estelle-35 ED until your doctor has checked that you are not pregnant.**

**Estelle-35 ED will not protect you from HIV-AIDS or any other Sexually Transmitted Diseases (STDs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.** To protect yourself from STDs, you will need to use additional barrier contraceptives (e.g. condoms).

### Things you must not do

**Do not take Estelle-35 ED to treat any other conditions, unless your doctor tells you to.**

**Do not give your medicine to anyone else.**

**Do not stop taking your medicine or change the dosage without checking with your doctor.** You may become pregnant if you are not using any other contraceptive and you stop taking Estelle-35 ED, or do not take a tablet every day.

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## SIDE EFFECTS

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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

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## AFTER TAKING ESTELLE-35 ED

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### Storage

**Keep your tablets in the blister pack until it is time to take them.** If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.** Heat and damp can destroy some medicines.

**Keep Estelle-35 ED where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

**Return any unused medicine to your pharmacist.**

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## PRODUCT DESCRIPTION

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### **What it 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, ethinyloestradiol, lactose monohydrate, 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.

***Supplier***

Amneal Pharma Australia  
Pty Ltd  
12 River Street  
South Yarra VIC 3141  
Australia

***Australian Registration  
Number***

AUST R 93607

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