

## Estelle-35 ED<sup>®</sup>

*cyproterone acetate and ethinylestradiol*

2 mg/0.035 mg

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### What is in this leaflet

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**Please read this leaflet carefully before you start using Estelle-35 ED.**

This leaflet answers some common questions about Estelle-35 ED 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 they expect it will 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

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Estelle 35-ED should be withdrawn 3 to 4 cycles after the treated condition has been completely resolved.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

Your doctor may have prescribed Estelle-35 ED for another reason.

**Ask your doctor if you have any questions about why Estelle-35 ED has been prescribed for you.**

This medicine is available only with a doctor's prescription.

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### Before you take Estelle-35 ED

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#### ***When you must not take it***

**Do not take Estelle-35 ED if you have an allergy to:**

- any medicine containing cyproterone acetate and/or ethinylestradiol (the active ingredients in Estelle-35 ED)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

**Do not take Estelle-35 ED if you have, or have had, a blood clot in:**

- the blood vessels of the legs, deep vein thrombosis - DVT
- the lungs, pulmonary embolism - PE
- the heart, heart attack
- the brain, stroke.

**Do not take Estelle-35 ED if you have, or have had:**

- Angina
- A mini-stroke
- Migraine with visual symptoms or weakness
- Diabetes with blood vessel damage
- Severe liver disease
- Liver tumours
- Cancer that may grow under the influence of sex hormones

- Undiagnosed vaginal bleeding
- Epilepsy or fits
- Pancreatitis.

**Do not take Estelle-35 ED if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribarivin.**

This may cause increases in liver function blood test results (increase in ALT liver enzyme). Estelle-35 ED can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen.

**Do not take Estelle-35 ED if you are taking another hormonal contraceptive.**

**Do not take this medicine if you are pregnant or think you might be pregnant.**

**Do not breastfeed if you are taking this medicine.**

**Do not take it after the expiry date (EXP) printed on the back.** If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is torn or shows signs of tempering.**

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

### ***Before you start to take it***

**Tell your doctor if:**

- 1. you have or have had any of the following medical conditions:**
  - blood clots
  - migraine
  - epilepsy
  - diabetes
  - sickle cell anaemia, a disorder of the blood.
  - high blood pressure
  - Crohn's disease or ulcerative colitis, chronic inflammatory bowel disease
  - superficial phlebitis, inflammation of veins

- varicose veins
- breast cancer
- chloasma, darkening of the skin
- haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys)
- heart rhythm disorders or heart valve disorders
- gall bladder disease
- liver disease.

**2. you have either recently developed hirsutism or you have had a considerable increase in symptoms, as the cause of the changes must be determined.**

**3. you have allergies to any other substances, such as foods, preservatives or dyes.**

**Ask your doctor to check if you:**

- are overweight
- have high cholesterol or triglycerides
- have hereditary angioedema

**If you have not told your doctor about any of the above, tell them before you start taking 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. You should also tell any health professional who is prescribing a new medication for you that you are taking Estelle-35 ED.**

Some medicines may interfere with Estelle-35 ED. These include:

- medicines used to treat epilepsy such as phenytoin, barbiturates (e.g., phenobarbitone), primidone, carbamazepine, oxcarbazepine, topiramate, felbamate, and lamotrigine.
- medicines used to treat tuberculosis such as rifampicin, rifabutin-
- medicines used to treat HIV
- Hepatitis C combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin. See

above, *before you take Estelle-35 ED- When you must not take it.*

- macrolide antibiotics such as clarithromycin and erythromycin
- ketoconazole and griseofulvin- medicines used to treat fungal infections
- cyclosporine- an immunosuppressant medicine
- diltiazem and verapamil- medicines used to treat high blood pressure, chest pain and/or irregular heartbeats
- etoricoxib- an anti-inflammatory
- tizanidine, melatonin or midazolam- medicines used to relax the body
- theophylline- a medicine that helps with breathing
- herbal medicines containing St John's Wort
- grapefruit juice.

These medicines may be affected by Estelle-35 ED, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

**You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines with Estelle-35 ED and for some time after stopping them.**

Your doctor will be able to advise you about how long you will need to use additional contraceptive methods.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Estelle-35 ED.

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## How to take Estelle-35 ED

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### *How much to take*

**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

**Take one tablet daily at about the same time every day. You must take Estelle-35 ED every day regardless of how often you have sex.**

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.

### *How 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.**

**Swallow the tablet whole with water.** You can take it before or after food.

Each blister pack is marked with the day of the week.

**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** (e.g., 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.

A period should begin 2-3 days after starting to take the white non-active tablets (last row) and may not have finished before the next pack is started.

**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 period.**

**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.

### ***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 pack.**

If you are not sure which were the active/inactive tablets 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.

Bleeding may not occur until the end of the first pack of Estelle-35ED.

Changing from a vaginal ring:

Start taking Estelle-35 ED on the day of removal of the last vaginal ring.

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.**

### ***When to take it***

**Take your Estelle -35 ED tablet at about the same time every 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.**

You may have to take Estelle-35 ED for at least 6 months before an improvement is seen in your condition. The length of treatment depends on the severity of your condition and how well it responds to treatment.

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

If you miss an active tablet and take the missing tablet within 12 hours of missing it, you should still 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 active 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 at the same time. You will not need to use additional barrier contraceptive precautions.**

The chance of pregnancy after missing a yellow active tablet depends on when in the cycle you missed the tablet. There is a higher risk of becoming pregnant if you miss a yellow 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, then you should finish the active yellow tablets in your pack but skip the white inactive tablets and start a new pack with the yellow active tablets corresponding to the correct day of the week.

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 then 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 at the same time. 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 in the previous 7 days, there is a possibility of pregnancy and you may need emergency contraception. **You should discuss this with your doctor or pharmacist.**

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. **You should discuss this with your doctor or pharmacist.**

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 should still be protected against pregnancy as white tablets do not contain any active ingredients.

Please refer to the diagram at the end of this leaflet entitled *“Summary of Advice on Missing Active Estelle-35 ED Tablet”*

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

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## While you are taking Estelle-35 ED

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### *Things you must do*

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Estelle-35 ED.

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.

Keep all of your doctor’s appointments so that your progress can be checked.

Your doctor may do some tests e.g., cervical smear, from time to time to make sure the medicine is working and to prevent unwanted side effects. 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.

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 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 does not 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 vomit within 3-4 hours or experience 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, section “If you forget to take it” above.**

Estelle-35 ED will not protect you from HIV-AIDS or any other sexually transmitted infections (STIs) e.g., Chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

**To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g., condoms).**

### ***Things you must not do***

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

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

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## **In case of overdose**

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

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, 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.** You may need urgent medical attention.

Effects expected from taking a number of yellow active 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.

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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 adverse effects.

**Do not be alarmed by this list of possible adverse effects.** You may not experience any of them.

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

The following list includes the more common side effects of Estelle-35 ED. These are usually mild and lessen with time.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea
- abdominal pain
- changes in weight
- headaches, including migraines

- mood changes, including depression
- breast tenderness or pain.

**If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- pain in the arm, chest or below the breastbone
- discomfort radiating to the back
- difficulty breathing and/or breathlessness
- swelling, tenderness or pain of one leg or along a vein in the leg
- sudden numbness or weakness
- bad 'pins and needles' of the arm, face or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of coordination or balance
- severe, sudden abdominal pains
- a fainting attack or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with speech, eyesight or understanding.

The side effects listed above are possible signs of a blood clot.

- yellowing skin or eyes- jaundice
- you cough up blood
- breast lumps
- unexplained vaginal bleeding.

These may be serious side effect of Estelle-35 ED. You may need urgent medical attention. Serious side effects are uncommon.

**Tell your doctor if you notice any other effects.** Other adverse effects not listed above may also occur in some patients.

#### 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.

If a blood clot breaks away from the veins where it has formed, it can reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the contraceptive pill. They can also happen during pregnancy. The risk of having blood clots is higher in contraceptive pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the contraceptive pill for the first time, or after having a break from the Pill for 4 weeks or more.

**If you notice possible signs of a thrombosis, stop taking Estelle-35 ED and consult your doctor immediately.**

**Speak to your doctor if you are concerned about an increased risk of blood clots while on Estelle-35 ED.**

#### Estelle-35 ED and Cancer

Breast cancer has been diagnosed slightly more often in women who take the contraceptive pill than in women of the same age who do not take the contraceptive pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears over the next 10 years after women stop taking the contraceptive pill. It is not known whether the difference is caused by the contraceptive Pill. It may be that these women were examined more often, so that the breast cancer was diagnosed earlier.

**Check your breasts regularly and contact your doctor if you feel any lump.**

Occasionally benign or very rarely malignant liver tumours have been reported in contraceptive pill users. In isolated cases these have caused bleeding into the abdomen.

Contact your doctor immediately if you develop severe abdominal pain.

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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 at or below 30°C.

**Do not store Estelle-35 ED in the bathroom or near a sink. Do not leave it in the car or on a windowsill.** Heat and dampness can destroy some medicines.

**Keep it 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 they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

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## Product description

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### *What it looks like*

Estelle-35 ED active tablets are yellow and round.

Estelle-35 ED inactive tablets are white and round.

Estelle-35 ED comes in a box containing either 1 or 3 blister packs. Each blister pack contains 21 yellow active tablets and 7 white inactive tablets.

## *Ingredients*

### Each yellow active tablet contains:

Active ingredient(s)  
2 mg of cyproterone acetate and 35 micrograms of ethinylestradiol

Inactive ingredients  
Croscarmellose sodium; Lactose monohydrate; Magnesium stearate; Microcrystalline cellulose; Opadry buff; Opadry white; Opaglos white; Povidone; Purified water; Quinoline yellow; and Sucrose.

### Each white inactive tablet contains:

Lactose monohydrate; Magnesium stearate; and Microcrystalline cellulose.

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## Sponsor details

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Estelle-35 ED is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

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## Date of preparation

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23 February 2018

(based on data sheet dated 23 February 2018)



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## Summary of Advice on Missing Active Estelle-35 ED Tablet

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### Question 1:

Before missing your tablet, did you take yellow active tablets for the previous 7 days?

**NO -  
Go to Question 2**

**YES -  
Go to Question 3**

### Question 2

Did you have sex in the 7 days before missing the tablet?

**NO -  
Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 yellow active tablets left in the pack, finish the yellow active tablets and go straight to the yellow active tablets of the next pack. This means you skip the white inactive tablets.**

**YES -  
See your Doctor or Pharmacist for advice.**

### Question 3

Does your pack still have 7 active yellow tablets in a row to follow?

**NO -  
Take the tablet you missed AND complete taking the yellow active tablets. Skip the white inactive tablets. Start your next pack with yellow active tablets.**

**YES -  
Take the tablet you missed AND complete the pack as normal.**