

CHELSEA®-35 ED

Contraceptive tablets for women

Contains:

21 yellow tablets, each containing the active ingredients cyproterone acetate and ethinyloestradiol (2 mg/35 microgram (µg))

7 white placebo tablets

Consumer Medicine Information

What is in this leaflet

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CHELSEA®-35 ED against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What this medicine is used for

CHELSEA®-35 ED is a hormonal preparation used to treat the following androgen-dependent conditions in women:

- severe acne when other treatments have failed
- mild to moderate increased growth of facial or body hair (hirsutism).

Androgens are male sex hormones, produced by women in small amounts. If a woman's body produces too much of these hormones or is overly sensitive, then androgen-dependent conditions occur. CHELSEA®-35 ED works by blocking the action of these hormones.

CHELSEA®-35 ED is also an effective oral contraceptive, commonly known as the "Pill" or "birth control pill".

As a contraceptive, CHELSEA®-35 ED prevents pregnancy by:

- preventing ovulation
- thickening the cervical mucus to act as a barrier to sperm
- making the lining of the uterus less suitable for implantation of the fertilised egg.

Oral contraceptives such as CHELSEA®-35 ED may have the following theoretical benefits:

- a decrease in the amount of blood you lose each cycle during your period
- a decrease in anaemia
- a decrease in period pain
- a reduced risk of pelvic inflammatory disease
- a reduced risk of developing ovarian cysts
- an improvement in acne
- a reduced risk of tubal (ectopic) pregnancy
- a reduced risk of benign breast disease (breast lumpiness)
- a reduced risk of getting cancer of the uterus (womb) lining and ovaries.

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

Your doctor may have prescribed this medicine for another reason.

CHELSEA®-35 ED is not for use in men.

CHELSEA®-35 ED does not protect against HIV infections (AIDS) or other sexually transmitted diseases (STDs). A barrier form of contraception such as a condom or diaphragm is needed.

CHELSEA®-35 ED is available only with a doctor's prescription.

Before you take this medicine

When you must not take it

Do not take CHELSEA®-35 ED if you are allergic to:

- any other medicines containing cyproterone or ethinyloestradiol
- any other oral contraceptive
- any other medicine known as a progestagen or oestrogen, including injections and implants
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take CHELSEA®-35 ED if you have or have had:

- any condition affecting blood circulation, in particular those conditions relating to thrombosis, (formation of blood clots in the legs, lungs or other parts of the body)
- a heart attack, stroke or angina (chest pain)
- a migraine accompanied by visual symptoms, speech disability or weakness or numbness in any part of the body
- diabetes mellitus with blood vessel complications
- inflammation of the pancreas associated with high triglyceride (blood fats) levels in the blood
- jaundice (yellowing of the skin) or severe liver disease
- benign or malignant liver tumours
- cancer of the breast or genital organs
- unexplained vaginal bleeding.

Do not take CHELSEA®-35 ED if you are pregnant or think you might be pregnant.

This medicine may affect your developing baby if you take it during pregnancy.

Do not take it if you are breastfeeding. CHELSEA®-35 ED passes into breast milk and may affect your baby.

Do not take it after the expiry date printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take CHELSEA®-35 ED if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

A complete medical check-up must be done by your doctor before starting CHELSEA®-35 ED.

This includes determining if you are pregnant or not, a Pap smear, a blood test, and a check of blood pressure, breasts, abdomen and pelvic organs. Your doctor will also note your family medical history.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you smoke.

The use of oral contraceptives like CHELSEA®-35 ED by cigarette smokers may increase the risk of cardiovascular disease, especially if you are over the age of 35. Your doctor or pharmacist can advise you about stopping smoking.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- blood circulation problems, including a positive family history of blood clots, heart attack or stroke
- migraines
- high blood pressure
- a heart valve or rhythm disorder
- varicose veins
- diabetes mellitus
- obesity
- systemic lupus erythematosus, a disease affecting the skin all over the body
- polycystic ovary syndrome
- chronic inflammatory bowel disease, e.g. Crohn's disease, ulcerative colitis
- sickle cell anaemia
- haemolytic uraemic syndrome, a blood clotting disorder causing kidney failure
- breast cancer including a family history of breast cancer
- liver or gall bladder problems
- high blood triglyceride or cholesterol levels, including a family history
- chloasma, dark patches on the skin, especially the face. (If so, avoid too much exposure to the sun or UV radiation).

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking CHELSEA®-35 ED.

The Pill and Thrombosis

A thrombosis is the formation of a blood clot, which may block a blood vessel.

Serious health problems caused by the Pill are rare and as with all medications, the risks need to be balanced against the benefits. The most dangerous risk of the Pill is a blood clot in the veins, usually in the legs or lungs, known as deep vein thrombosis (DVT) or venous thromboembolism (VTE). Warning signs are severe sudden chest pain, shortness of breath, severe pain or swelling in one leg, sudden blurred vision or loss of sight, or sudden severe headache. If you have any of

these symptoms contact your doctor or go to your nearest Emergency Department immediately. It is important to put the risk of blood clots into context.

A thrombosis sometimes occurs in the deep veins of the legs (deep vein thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs (pulmonary embolism). Deep vein thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant. The risk is higher in Pill users than in non-users but not as high as the risk during pregnancy.

The risk of venous thromboembolism (VTE) is increased 2-3 times in users of combined hormonal contraception methods compared to non-users. The risk is highest in the first year of use of a combined contraceptive and gradually decreases with duration of use.

VTE with any combined hormonal method of contraception is much less common than VTE in pregnancy and the immediate post-partum period. Pills containing levonorgestrel or norethisterone appear to have lower VTE risk

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

Biochemical factors (hereditary or acquired) that may indicate a possible predisposition for blood clot formation include having Activated Protein C (APC) resistance, hyperhomocysteinemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency and antiphospholipid antibodies.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke. When using CHELSEA®-35 ED you should stop smoking, especially if you are older than about 35 years of age.

If you develop high blood pressure while using CHELSEA®-35 ED, you may be told to stop using it.

It is recommended that if you are concerned about blood clots speak with your GP or Family Planning clinic to discuss the risks and the full range of available contraceptive choices. Every woman needs to be able to make an informed decision with her doctor about the risks and benefits of any method of contraception. A risk assessment will be based on personal and family health history, age, family history of blood clots and lifestyle factors such as weight and smoking.

Tell your doctor if you:

- plan to have surgery or be in hospital.
- have had recent surgery
- have been confined to bed or immobilized for a prolonged period of time.

These situations may also increase the risk of developing a blood clot. Your doctor may tell you to stop taking CHELSEA®-35 ED 4 weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking CHELSEA®-35 ED again after you are back on your feet.

If you notice possible signs of thrombosis, stop taking CHELSEA®-35 ED and consult your doctor immediately (See 'Side effects').

The Pill and Cancer

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnosis gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that breast cancer was noticed earlier.

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.

Contact your doctor immediately if you have severe pain in your abdomen.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Taking other medicines

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

Some medicines reduce the contraceptive effectiveness of CHELSEA®-35 ED. These include:

- certain medicines used in the treatment of epilepsy, such as barbiturates, primidone, phenytoin, topiramate, oxcarbazepine and carbamazepine
- antibiotics such as ampicillins, tetracyclines
- rifampicin, a medicine used in the treatment of tuberculosis
- griseofulvin, an antifungal
- St John's wort, a herbal remedy.

If you are using any of the above medicines on a short-term basis, use an additional barrier method of contraception (such as a condom or diaphragm) while you are taking it and for 7 days after finishing the other medicine.

If you take rifampicin, use additional contraception for four weeks after finishing the course of rifampicin.

Your doctor may also advise you to skip the 7 white placebo tablets.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CHELSEA®-35 ED.

How to take this medicine

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

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Take one tablet each day, with some water.

How to take it

CHELSEA®-35 ED can be taken with or without food.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

The CHELSEA®-35 ED pack contains 28 tablets. On the pack each tablet is marked with the day of the week on which it is to be taken. The ED in the name refers to the "every day" presentation where 7 white placebo tablets (also known as non-active or sugar tablets) are also included in the pack so that a tablet is taken each day of the month instead of having a break.

Take your first tablet from the red section marked with the appropriate day of the week, e.g., if starting on Sunday - select SUN.

Follow the direction of the arrows on the pack until all 28 tablets have been taken.

Usually a menstrual period will start within 2 to 4 days after taking the last active tablet (i.e. while you are taking tablets from the last row of your pack).

Do not leave a gap between packs, i.e. start taking your next pack on the day after you have finished the current one, even if your period continues.

This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month.

Additional contraceptive methods

When additional contraceptive methods are required, either do not have sexual intercourse or use a barrier method such as a condom or diaphragm plus spermicide.

Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the natural menstrual cycle, e.g. changes in temperature and cervical mucus.

When to start taking it

After a natural cycle

Take the first tablet on the first day of your period from the red section of the pack. Additional contraceptive methods must be used for the next 14 days.

Switching from another combined oral contraceptive

Start CHELSEA®-35 ED on the day after the last active tablet from the previous pill pack has been taken.

If your present pill pack contains placebo (sugar) tablets, you should throw away the placebo tablets and start CHELSEA®-35 ED on the day after taking the last active tablet from your present pack (if you are not sure which this is, ask your doctor or pharmacist). This means no tablet free break. If you follow these instructions, it is not necessary to use an additional contraceptive method. A withdrawal bleed may not occur until the end of the first pack of CHELSEA®-35 ED. This is not harmful.

Switching from progestagen-only contraceptives, e.g. minipill, implant, injectable or a progestogen-releasing intrauterine device (IUD)

CHELSEA®-35 ED may be started on any day when switching from the minipill, or on the day when your implant or IUD is removed or next injection is due. Additional contraceptive methods must be used for the next 14 days.

After having a baby

Your doctor will advise you when it is best to start CHELSEA®-35 ED. If you are breastfeeding, you should discuss this with your doctor first. Additional contraceptive methods must be used for the next 14 days.

After a miscarriage or abortion

Your doctor will advise you. Additional contraceptive methods must be used for the first 14 days.

If you forget to take it

If you forget to take CHELSEA®-35 ED, it may not work as well in protecting you from becoming pregnant.

Additional contraceptive methods

When additional contraceptive methods are required, either do not have sexual intercourse or use a barrier method such as a condom or diaphragm plus spermicide.

If you are less than 12 hours late in taking a tablet, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Additional contraceptive measures are not necessary and contraceptive protection is not reduced.

If you are more than 12 hours late in taking an active (yellow) tablet, take the missed tablet as soon as you remember, even if this means taking two tablets at the same time, then continue to take the next tablet at the normal time.

Additional contraceptive methods must be used for the next 7 days as there is an increased risk of becoming pregnant. If the 7 days include taking any of the white placebo (non-active) tablets, discard the non-active tablets and continue with the small yellow active tablets of the next pack. You are unlikely to have a period until you reach the red section of the second pack. This is not harmful.

See your doctor if you forget to take more than one active tablet in a pack or if you have missed one or more active tablets within the first week of the pack.

There is an increased risk of becoming pregnant. An alternative method of contraception should be used until you are sure that you are not pregnant.

If you have forgotten to take a white placebo (non-active) tablet, discard the missed tablet and continue taking the tablets as you would normally.

No additional contraceptive precautions are needed.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

How long to take it for

Keep taking CHELSEA®-35 ED for as long as your doctor tells you to.

You will probably need to take CHELSEA®-35 ED for about 6 months

before you notice an improvement in your condition. To effectively treat your acne and excess hair you will probably need to take it for much longer. It is possible that acne and excess hair may return when treatment is stopped.

Repeat courses of CHELSEA®-35 ED may be taken, however, it is recommended that you have a "pill-free" period.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CHELSEA®-35 ED. Do this even if there are no signs of discomfort or poisoning.

You may experience nausea, vomiting and vaginal bleeding.

While you are taking this medicine

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking CHELSEA®-35 ED.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking CHELSEA®-35 ED.

Stop taking this medicine and tell your doctor immediately if you fall pregnant or think you are pregnant while taking CHELSEA®-35 ED.

Pregnancy must be ruled out before you continue treatment. In the meantime, use an alternative method of contraception.

Tell your doctor if you plan to have surgery or be immobilized for a long period of time (eg. leg in plaster).

Your doctor may advise you stop taking it during this period.

Avoid excessive sun exposure and use a SPF 30+ sunscreen if you have a tendency to develop chloasma (dark pigments on the face or skin).

If you need to have any blood or urine tests, tell your doctor that you are taking CHELSEA®-35 ED.

This medicine may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

In general, you should have a check-up once every year, including a Pap smear, breast examination and blood pressure check.

Vomiting and Diarrhoea Advice

If you vomit within 3 to 4 hours of taking an active yellow tablet, follow the advice under "If you forget to take it" section. This is like missing a tablet.

If you have severe diarrhoea, please contact your doctor.

Vomiting or diarrhoea while taking the white placebo tablets do not reduce contraceptive reliability.

Unexpected bleeding

Like other contraceptive pills, irregular vaginal bleeding (spotting or break through bleeding) may occur for the first few months. Continue to take your tablets as you would normally. Irregular bleeding should stop once your body adjusts to the pill (usually after about 3 cycles). If bleeding continues or becomes heavy, see your doctor.

Missed period

If you have taken all your tablets as directed, and you have not vomited while taking an active pill, or taken other medicines that interfere with CHELSEA®-35 ED, then you are very unlikely to be pregnant. Continue to take CHELSEA®-35 ED as usual.

If you miss your period twice in a row stop taking CHELSEA®-35 ED and tell your doctor immediately. Pregnancy must be excluded before you start the next pack of CHELSEA®-35 ED. In the meantime, use another form of contraception such as a condom or diaphragm.

Things you must not do

Do not use CHELSEA®-35 ED to treat any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Possible side effects

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

Like all other medicines, CHELSEA®-35 ED may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- nausea, vomiting
- changes in vaginal secretion
- breast tenderness, pain or secretion
- contact lens intolerance
- headache, migraine
- depressed mood
- change in sex drive
- fluid retention
- change in body weight.
- loss of head hair
- acne

See your doctor as soon as possible if you notice any of the following:

- a lump in your breast
- unusual, heavy vaginal bleeding
- sudden increase in facial or body hair
- dark patches of the skin, in particular the face
- yellowing of the skin or eyes
- severe diarrhoea.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any signs of a blood clot, heart attack or stroke:

- sudden severe chest pain that may radiate down your left arm
- severe pain and/or swelling in either leg
- sudden breathlessness
- sudden onset of coughing

- unusual or severe prolonged headache
- sudden partial or complete loss of eyesight, double vision
- dizziness or fainting
- weakness or numbness suddenly affecting any part of the body
- problems with speech or movement
- severe stomach pain.

The symptoms above occur very rarely and can happen whether or not you are taking the pill. They are, however, serious and require urgent medical attention or hospitalisation.

If any of the following allergic reactions occur, see your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- swelling of the face, lips, tongue or throat causing difficulty breathing
- severe itch or rash on the body.

Tell your doctor if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people. Some of these side effects (for example, high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Storage and disposal

Storage

Keep your medicine 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.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store CHELSEA®-35 ED or any other medicine in the bathroom or near a sink.

Do not leave CHELSEA®-35 ED in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking CHELSEA®-35 ED, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What looks like

CHELSEA®-35 ED is available as a calendar pack and contains 2 different tablets:

- 21 yellow round active tablets
- 7 white round placebo tablets.

On the pack each tablet is marked with a day of the week on which it is to be taken.

Ingredients

The yellow active tablets contain two active ingredients: cyproterone acetate 2 mg and ethinyloestradiol 35 microgram (µg).

The white placebo tablets contain lactose. These are also known as "non-active" or "sugar tablets".

The tablets also contain:

- lactose
- maize starch
- povidone
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- purified talc
- glycol montanate
- glycerol
- titanium dioxide
- iron oxide yellow CI77492.

The tablets do not contain gluten, tartrazine or any other azo dyes.

Australian Registration Numbers

CHELSEA®-35 ED Tablet (Blister pack):
AUST R 210583

Sponsor

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