

Jene-35 ED™

cyproterone acetate 2 mg and ethinylestradiol 35 mcg film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Jene-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 Jene-35 ED™ against the benefits this medicine is expected to have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

What Jene-35 ED™ is used for

Jene-35 ED is used for the treatment of signs of androgenisation in women, such as severe acne where other treatments have not been successful, or for excessive growth of facial or body hair (known as hirsutism) of a mild to moderate degree, where no underlying cause has been found.

Jene-35 ED can also be used as a contraceptive to prevent pregnancy in women who are taking it for the treatment of signs of androgenisation as described above. Jene-35 ED contains a progestogen and an oestrogen hormone, and therefore works similarly to the combined oral contraceptive birth control pill. It should not be used in combination with another hormonal contraceptive.

While taking Jene-35 ED you may also experience the following benefits:

- more regular and lighter periods – potentially resulting in a decrease in anaemia (iron deficiency);
- a decrease in period pain; and/or
- reduction of greasiness in skin and hair.

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy, fibrocystic breast changes and cancer of the uterus (womb) and ovaries may be less common in women taking Jene-35 ED.

Your doctor, however may have prescribed Jene-35 ED for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

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

Before you take Jene-35 ED

When you must not take it

Do not take Jene-35 ED if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

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

- the blood vessels of the leg (deep vein thrombosis – DVT);
- the lungs (pulmonary embolism – PE);

- the heart (heart attack);
- the brain (stroke); or
- other parts of the body.

Studies have suggested an association between the use of combined hormonal contraceptives (CHCs) containing ethinylestradiol and an increased risk of cardiovascular diseases such as heart attack, stroke, blood clots or blockage of blood vessels by clots. These events have shown to occur rarely in women with average risk.

If you think you may have symptoms of any of the above cardiovascular diseases seek urgent medical attention.

Do not take Jene-35 ED if you are concerned about an increased risk of blood clots.

Blood clots are rare. Very occasionally blood clots may cause serious permanent disability and may even be fatal.

All combined oral contraceptive pills, including Jene-35 ED, increase the risk of having a blood clot. However, the risk of having a blood clot when taking the contraceptive pill is less than the risk of having a blood clot during pregnancy.

Do not take Jene-35 ED if you are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking Jene-35 ED, especially if you are older than 35 years of age.

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

- angina (chest pain);
- a mini-stroke (also known as transient ischaemic attack (TIA));
- migraine, accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body;
- diabetes mellitus with blood vessel damage;
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood;
- severe liver disease and your liver function has not returned to normal;
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs);
- a benign or malignant liver tumour; or
- unexplained vaginal bleeding.

If any of these conditions appear for the first time while using the contraceptive pill, stop taking it at once and tell your doctor. In the meantime use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).

Do not take Jene-35 ED™ if you are using **another hormonal contraceptive**.

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

Do not breast-feed if you are taking this medicine.

Do not give this medicine to a child.

Do not take this medicine after the expiry date printed on the pack and blister. If you take it after the expiry date has passed, it

may not work as well. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering. If the packaging is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you smoke; or
- you, or anyone in your immediate family has had blood clots in the legs (DVT), a heart attack, a stroke, breast cancer or high cholesterol.

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

- diabetes;
- high blood pressure;
- heart valve disorders or certain heart rhythm disorders;
- inflammation of your veins (superficial phlebitis);
- varicose veins;
- migraine; or
- epilepsy.

Ask your doctor to check if you:

- are overweight;
- have high cholesterol or triglycerides;
- have liver disease;
- have gall bladder disease;
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over the body);
- have haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys);
- Have sickle cell disease;
- Have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea);
- Have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation; or
- Have hereditary angio-oedema – you should see your doctor immediately if you experience symptoms of angio-oedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

If any of the above conditions appear for the first time, recur, or worsen while taking Jene-35 ED, you should contact your doctor.

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.

Jene-35 ED contains lactose and sucrose. If you have an intolerance to some sugars, contact your doctor before you start taking Jene-35 ED.

If you have not told your doctor about any of the above, tell them before you use Jene-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 and Jene-35 ED may interfere with each other. These include:

- medicines used to treat tuberculosis such as rifampicin or rifabutin;
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate or lamotrigine;
- medicines used to treat HIV, such as ritonavir or nevirapine;
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir;
- antibiotics such as penicillin, ampicillin, erythromycin or tetracycline;
- medicines used to treat fungal infections, such as ketoconazole or griseofulvin;
- cyclosporine, an immunosuppressant medicine; or
- herbal medicines containing St John's Wort.

These medicines may be affected by Jene-35 ED, or may affect how well it works. Your doctor may need to alter the dose of your medicine or prescribe a different medicine.

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 Jene-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 and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

How to take it

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 much to take

Take one tablet daily at about the same time every day. You must take Jene-35 ED every day regardless of how often you have sex. This 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 it for the first time

If you are starting Jene-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 cap or diaphragm plus spermicide) for the first 14 days of tablet-taking when having intercourse.

Your doctor will advise you when to start if you:

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

Changing from another contraceptive

Changing from a combined oral contraceptive:

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

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

Your previous contraceptive pill pack may have different colour tablets to those of Jene-35 ED.

Changing from a vaginal ring:

Start taking Jene-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 Jene-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 Jene-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.

How long to take it

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

You may be advised by your doctor to stop Jene-35 ED 3 to 4 months after your symptoms have completely resolved. You should have regular check-ups with your doctor to determine how long to keep taking Jene-35 ED.

Stopping it

You can stop taking Jene-35 ED at any time.

It is possible that the original condition may recur one Jene-35 ED is stopped. Do not start

taking Jene-35 ED again without seeing your doctor first.

If you do not wish to fall pregnant, you should use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) when you stop taking Jene-35 ED.

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 Jene-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, contraceptive efficacy is not reduced.

If you are more than 12 hours late follow these detailed instructions:

For Jene-35 ED to be most effective, the 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 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 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, you should finish the active 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, 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 preceding 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. The contraceptive efficacy against pregnancy is not reduced 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)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to the Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Jene-35 ED. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

While you are taking it

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 results of some tests.

Have regular check-ups with your doctor. When you are taking the contraceptive pill, your doctor will tell you to return for regular check-ups, including getting a Pap (cervical) smear test. Your doctor will advise how often you need a Pap (cervical) smear test. A Pap (cervical) 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 Jene-35 ED.

Stop taking Jene-35 ED and immediately see your doctor if you notice possible signs of thrombosis (blood clot). Possible symptoms of a blood clot include:

- an unusual cough;
- severe pain or heaviness in the chest;
- breathlessness;
- any unusual, severe, or prolonged headache or migraine attack;
- partial or complete loss of vision, 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; or
- severe pain, swelling or discolouration in either of your legs.

Common symptoms associated with the use of oral contraceptive pill are:

- acne;
- breast tenderness; or
- nausea.

Other symptoms which may/may not be due to the oral contraceptive pill but may be concerning you and need review by your doctor are:

- weight gain;
- excessive hairiness (hirsutism); or
- unusual hair loss or thinning (alopecia).

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking Jene-35 ED. The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg(s) in plaster of splints). In women who take the contraceptive pill, the risk may be higher.

Your doctor may tell you to stop taking Jene-35 ED several weeks before surgery, or at the time of immobilisation, and when you can start taking it again. If you notice possible signs of a thrombosis, stop taking Jene-35 ED and consult your doctor immediately.

Consult your doctor if you develop high blood pressure while taking Jene-35 ED – you may be told to stop taking it.

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 contraceptive pill, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant, as long as:

- you have taken the yellow active tablets at the right time;
- you have not been taking medicine(s) that may interfere with Jene-35 ED; and
- you have not vomited or had severe diarrhea during this cycle.

If this is so, continue to take Jene-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 even if you have taken the contraceptive pill correctly. Stop taking Jene-35 ED and seek advice from your doctor. You must use a non-hormonal method of contraception, (such as condoms or a diaphragm) until your doctor rules out pregnancy.

Jene-35 ED will not protect you from HIV-AIDS or any other sexually transmitted infections (STIs), such as 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 take Jene-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.

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 Jene-35 ED, or do not take a tablet every day.

Side Effects

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

This medicine helps most women, but it may have unwanted side effects in some women.

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.

Do not be alarmed by the following lists of side 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 Jene-35 ED. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- Nausea;
- abdominal pain;
- changes in weight;
- headache, including migraines;
- mood changes, including depression; or
- breast tenderness or pain.

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately, or go to the Emergency Department at your nearest hospital:

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

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

- jaundice (yellowing skin or yellowing eyes);
- you cough up blood;
- breast lumps; or
- unexpected vaginal bleeding.

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

Other side effects not listed above may also occur in some people.

Thrombosis and the contraceptive pill

Thrombosis is the formation of a blood clot that may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (DVT). If a blood clot

breaks away from the veins where it has formed, it may 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 Pill. They can also happen during pregnancy. The risk of having blood clots is higher in 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 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 Jene-35 ED and consult your doctor immediately.

If you are concerned about an increased risk of blood clots while on Jene-35 ED, speak to your doctor.

Cancer and the contraceptive pill

Breast cancer has been diagnosed slightly more often in women who take the 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 during the course of the 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 noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lump.

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

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

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

After taking it

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 your tablets or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave medication in the car.

Heat and damp can destroy some medicines.

Keep Jene-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.

Further Information

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

Product Description

What Jene-35 ED™ looks like

Jene-35 ED™ is a calendar pack containing 21 small yellow active tablets and 7 larger white non-active (placebo) tablets per blister strip.

Available as packs of 28 and 84 tablets (not all pack sizes may be marketed).

Ingredients

Each yellow active tablet contains:

- 35 micrograms of ethinyloestradiol; and
- 2 mg of cyproterone acetate.

Inactive ingredients:

- lactose;
- microcrystalline cellulose;
- povidone;
- croscarmellose sodium;
- magnesium stearate;
- Opadry white;
- Opadry buff;
- Opaglos white;
- Quinoline yellow; and
- sucrose.

Each white inactive tablet contains:

- lactose;
- microcrystalline cellulose; and
- magnesium stearate.

Tablets do not contain gluten.

Sponsor/Marketing Authorisation Holder



Eris Pharmaceuticals (Australia) Pty Ltd
6 Eastern Road
South Melbourne, Victoria, 3205
Australia
www.ERIS-pharma.com.au

(Toll free - Australia) 1800 233 588

Australian Registration Number: AUST R
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