

Diane[®]-35 ED (Di-ANNE Ee-Dee)

Contraceptive tablets for women

ethinyloestradiol and cyproterone acetate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Diane-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 Diane-35 ED against the benefits they expect it will 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 DIANE-35 ED IS USED FOR

Diane-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.

Diane-35 ED will also prevent pregnancy in women requiring treatment for androgen dependent diseases.

You may also experience the following benefits:

- more regular and shorter periods and a decrease in the amount of blood you lose each month
- a decrease in anaemia (iron deficiency)
- a decrease in period pain.

Some medical conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy and disorders of the uterus (womb), ovaries and breast are less common in women taking oral contraceptives.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE DIANE-35 ED

When you must not take it

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

- ethinyloestradiol and/or cyproterone acetate the active ingredients in Diane-35 ED
- 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 in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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

- the blood vessels of the legs (deep vein thrombosis)
- the lungs (pulmonary embolism)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body.

Do not take Diane-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 disabilities, or may even be fatal.

You are more at risk of having a blood clot when you take the Pill. But the risk when taking the Pill is less than the risk during pregnancy.

Do not take Diane-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 the Pill, especially if you are older than 35 years of age.

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

- angina pectoris or chest pain
- severe kidney insufficiency or an acute failure of your kidney
- migraine, accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body
- diabetes mellitus with blood vessel damage
- jaundice (yellowing of the skin)
- severe liver disease
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- benign or malignant liver tumour
- unexplained vaginal bleeding.

Do not take this medicine if you are pregnant or think you might be pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine. The active ingredient in Diane-35 ED passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child.

Do not take this medicine after the expiry date printed on the pack and blister. The expiry date is printed on the carton and on each blister after “EXP” (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. 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 this medicine, 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
- you are overweight
- you or anyone in your immediate family has had blood clots in the legs (thrombosis), 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
- epilepsy.

Ask your doctor to check if you have:

- high cholesterol or triglycerides
- liver disease
- gall bladder disease
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- systemic lupus erythematosus (SLE – a disease affecting the skin all over the body)
- haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys)
- sickle cell disease
- 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)
- chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid too much exposure to the sun or ultraviolet radiation
- 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 you suffer from hirsutism and it has only recently appeared or has lately intensified to a considerable extent, your doctor must be informed of this because of the need to determine the cause of the change.

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

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

Taking other medicines

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

Some medicines and Diane-35 ED may interfere with each other. These include:

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

These medicines may be affected by Diane-35 ED, or may affect how well it works. You may need different amounts of your medicines, 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 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 DIANE-35 ED

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 printed on the pharmacist label, ask your doctor or pharmacist for help.

How to take it

Take one tablet daily at about the same time everyday. You must take Diane-35 ED every day even if you do not have sex very often. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

Swallow the tablets whole with a full glass of water.

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

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

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

When to take it

Start taking Diane-35 ED on the first day of your cycle (e.g. the first day of your menstrual bleeding), if you have not used a hormonal contraceptive in the past month. Take a tablet marked with that day of the week from the red section of the pack. For example, if your period starts on a Friday, take the tablet marked Friday from the red section of the pack.

When you start taking DIANE-35 ED you must use an additional non-hormonal method of contraception such as condoms or a diaphragm for the first 14 days of your first pack. The rhythm, temperature and cervical mucus methods are not suitable for this purpose.

Your doctor will advise you when to start if you:

- are taking Diane-35 ED after having a baby
- are breastfeeding – Diane-35 ED should not be used
- have had a miscarriage or an abortion.

You can stop taking Diane-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 Diane-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.

Changing from another combined oral contraceptive:

If you are switching from a 28 day pack combined oral contraceptive, start taking Diane-35 ED on the day after taking the last active tablet in your previous Pill pack or immediately after finishing your last Pill (a withdrawal bleed may not occur until the end of the first pack of Diane-35 ED).

Ask your doctor or pharmacist if you are not sure which the active tablets were in your previous Pill pack. Your previous Pill pack may have different colour tablets to those of Diane-35 ED.

Changing from a progestogen-only pill:

If you are switching from a progestogen-only Pill (minipill), stop taking the minipill on any day and start taking Diane-35 ED at the same time the next day. But make sure you 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 vaginal ring:

If you are switching from a vaginal ring, start on the day of removal but at the latest when the next application is due.

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 Diane-35 ED to be most effective, beige active tablets need to be taken uninterrupted for 7 days.

If you have been taking the beige active tablets for 7 uninterrupted days and miss a beige 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 be protected against pregnancy.

The chance of pregnancy after missing a beige 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 beige active tablets left in a row, you should finish the active tablets in your pack but skip the white placebo

tablets. Start taking the beige active tablets in your next pack 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 beige active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.

If you have been taking the beige active tablets for less than 7 days and miss a beige 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 should 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 beige 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 placebo 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.

(Please refer to diagram on last page of this leaflet for a Summary of advice if you missed a tablet more than 12 hours ago).

If you take too much (overdose)

If you think that you or anyone else may have taken too much Diane-35 ED, immediately telephone your doctor or the Poisons Information Centre (0800 poison or 0800 764 766) 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.

WHILE YOU ARE TAKING DIANE-35 ED

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 Diane-35 ED.

Stop taking Diane-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
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain or swelling in either of your legs.

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking this medicine. 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 or legs in plaster or splints). In women who take the Pill, the risk may be higher. The excess risk of thrombosis is highest during the first year a woman takes a combined oral contraceptive.

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

Consult your doctor if you develop high blood pressure while taking Diane-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 beige 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 beige active tablets at the right time
- you have not been taking medicine(s) that may interfere with Diane-35 ED.
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take Diane-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 Diane-35 ED until your doctor has checked that you are not pregnant.

Diane-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).

For how long should Diane-35 ED be used?

The length of use depends on the severity of your symptoms and response to treatment. Consult your doctor if the symptoms appear again after discontinuing Diane-35 ED.

Things you must not do

Do not take Diane-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 Diane-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 Diane-35 ED.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 your pill. 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
- stomach pain
- changes in weight
- headache, including migraines
- mood changes, including depression
- 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:

- chest pain
- breathlessness and/or difficulty breathing
- painful swelling in your leg(s)
- weakness, numbness or bad ‘pins and needles’ of an arm or leg
- severe, sudden stomach pains
- a bad fainting attack or you collapse

- unusual headaches or migraines that are worse than usual
- sudden problems with your speech or eyesight

The side effects listed above are possible signs of a thrombosis.

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

Thrombosis and the 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 (deep venous thrombosis (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 are a rare occurrence and can develop whether or not you are taking an oral contraceptive. They can also happen during pregnancy. The risk of having blood clots is higher in OC users than in non users, but not as high as during pregnancy.

Therefore, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic diseases.

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

Cancer and the 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 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 Pill.

It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

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. 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 Pill for a long time. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

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.

AFTER TAKING DIANE-35 ED

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 25°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 Diane-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.

PRODUCT DESCRIPTION

What it looks like

Diane-35 ED comes in a box containing 3 blister packs. Each blister pack contains 21 beige active tablets and 7 white placebo tablets. The blister pack is marked with days of the week next to each tablet.

Ingredients

Each beige active tablet contains 35 microgram of ethinyloestradiol and 2 milligram of cyproterone acetate (as the active ingredients).

Each beige tablet also contains:

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

Each white placebo tablet contains:

- lactose
- maize starch
- povidone
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- glycol montanate
- titanium dioxide

Supplier

Made in Germany for:

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
North Shore
Auckland 0627

Date of Preparation

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See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand information leaflet.

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Missed a pill?

See page 5 of this leaflet



Summary of advice if you missed a tablet more than 12 hours ago.

<p>Before missing your tablet, did you take beige active tablets for the previous 7 days?</p>	<p>No</p>	<p>Did you have sex in the 7 days before missing the tablet?</p>	<p>→</p>	<p>No Take the tablet missed AND use extra barrier precaution for 7 days.</p> <p>Yes See your Doctor or Pharmacist for advice.</p>
	<p>Yes</p>	<p>Does your pack still have 7 active beige tablets in a row to follow?</p>	<p>→</p>	<p>No Take the tablet you missed AND complete taking the beige active tablets. Skip the white placebo tablets. Start your next pack with beige active tablets.</p> <p>Yes Take the tablet you missed AND complete the pack as normal.</p>