

Package leaflet: Information for the user

Diane-35

cyproterone acetate/ethinylestradiol.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diane-35 is and what it is used for
2. What you need to know before you take Diane-35
3. How to take Diane-35
4. Possible side effects
5. How to store Diane-35
6. Contents of the pack and other information

1. WHAT DIANE-35 IS AND WHAT IT IS USED FOR

Diane-35 contains an oestrogen and an anti-androgen.

Diane-35 is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Diane-35 if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

If you are taking Diane-35 for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Diane-35, you will need to go back to your original/preferred method of contraception.

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Diane-35 stops the androgens affecting your skin and reduces the amount of androgens produced.

Contraception

Diane-35 is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

Diane-35 will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Diane-35 needs to be taken as directed to prevent pregnancy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIANE-35

2.1 Before you take Diane-35

It's important that you understand the benefits and risks of taking Diane-35 before you start taking it, or when deciding whether to carry on taking it. Although Diane-35 is suitable for most healthy women it isn't suitable for everyone.

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Diane-35

- Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you're on Diane-35

- You will need **regular check-ups** with your doctor, usually when you need another prescription of Diane-35.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking Diane-35, because this type of medicine can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking Diane-35 at least 4 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Diane-35 again.
- **If you need to stop taking Diane-35**, remember to use another contraceptive (e.g. condoms) if you are relying on Diane-35 for contraception.

When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in 'Blood clots (Thrombosis)' and in Section 4.

Diane-35 also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

Blood clots (thrombosis)

Taking Diane-35 may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Diane-35 compared with women who do not take Diane-35 or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

Blood clots in a vein

A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman's risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

Your chances of having a blood clot are only increased slightly by taking Diane-35.

- Of 100,000 women who are **not taking Diane-35, not on the Pill** and not pregnant, about **5 to 10** will have a blood clot in a year.
- Of 100,000 women who **take Diane-35 or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;
- **if you smoke.**
When using a hormonal contraceptive like Diane-35 you are strongly advised to stop smoking, especially if you are older than 35 years;
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;
- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome;**
- if you have **recently had a baby;**
- if you have certain rare medical conditions such as **systemic lupus erythematosus, Crohn's disease or ulcerative colitis;**
- if you have **sickle cell disease.**

If this applies to you, it is important to tell your doctor that you are using Diane-35, as the treatment may have to be stopped. Your doctor may tell you to stop using Diane-35 at least 4 weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Diane-35 again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- **if you smoke.**
When using a hormonal contraceptive like Diane-35 you are strongly advised to stop smoking, especially if you are older than 35 years;
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome;**
- if you have **diabetes;**
- if you have certain rare medical conditions such as **systemic lupus erythematosus;**
- if you have **sickle cell disease.**

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- 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.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Diane-35.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Diane-35 and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Diane-35 also provide the same protective effects. However, it also seems that taking Diane-35 slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Diane-35. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Diane-35 or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you're on Diane-35, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Diane-35 users is small. For example:

- Of 10,000 women who have **never taken Diane-35 or the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take Diane-35 or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Diane-35 or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Diane-35 or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
- **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Diane-35 has also been linked to liver diseases, such as jaundice and non- cancer liver tumours, but this is rare. Very rarely, Diane-35 has also been linked with some forms of liver cancer in women who have taken it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice).** You may need to stop taking Diane-35.

For high doses (25mg and above) of cyproterone acetate an increased risk of benign brain tumour (meningioma) has been reported. If you are diagnosed with meningioma, your doctor will stop all cyproterone containing products, including Diane-35 as a precautionary measure (see section 2.2 'Make sure Diane-35 is ok for you').

2.2 Make sure Diane-35 is OK for you

Diane-35 should not be taken by some women

→ **Tell your doctor** if you have any medical problems or illnesses.

Do not use Diane-35 Tell your doctor if any of the following conditions applies to you before starting to use Diane-35. Your doctor may then advise you to use a different treatment:

- If you are using another hormonal **contraceptive**
- If you are **pregnant** or might be pregnant
- If you are **breast-feeding**
- If you have or have ever had **breast cancer**
- If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
- If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or '**mini- stroke**' (transient ischaemic attack)
- If you have (or have ever had) a **heart attack** or **stroke**.
- If you have a condition that may increase the risk of a **blood clot** in your arteries. This applies to the following conditions:
 - **diabetes affecting your blood vessels**
 - very high **blood pressure**
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
- If you have problems with **blood clotting** (e.g. protein C deficiency)
- If you have (or have ever had) a **migraine, with visual disturbances**
- If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver test results are not yet back to normal
- If you have ever had **liver tumours**
- If you have **meningioma** or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull)
- If you are **allergic** (*hypersensitive*) to any of the ingredients in Diane-35.

Do not use Diane-35 if you have hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir / velpatasvir / voxilaprevir (see also in section 'Taking other medicines').

→ **If you suffer from any of these**, or get them for the first time while taking Diane-35, contact your doctor as soon as possible. Do not take Diane-35. If needed, use another form of contraception.

Diane-35 can make some illnesses worse

Some of the conditions listed below can be made worse by taking Diane-35. Or they may mean it is less suitable for you. You may still be able to take Diane-35 but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past
- If you are **overweight** (*obese*)
- If you have the inherited disease called **porphyria**
- If you have **diabetes**
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (*chloasma*) (see below 'Diane-35 and sun-beds or sun-lamps')
- If you have **any illness that worsened during pregnancy or previous use of the Pill or Diane-35** (see section 4)

- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

Diane-35 may increase the risk of gallstone formation and may worsen existing disease

→ **Tell your doctor if any apply to you.** Also tell them if you get any of these for the first time while taking Diane-35, or if any get worse or come back, because you may need to stop taking it.

Psychiatric disorders:

Some women using hormonal contraceptives including Diane-35 have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Taking other medicines

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take Diane-35. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

If you are taking Diane-35 for skin treatment, you must not take any other hormonal contraceptive at the same time.

Some medicines:

- can have an influence on the blood levels of Diane-35 and
- can make it less effective in preventing pregnancy, or
- can cause unexpected bleeding.

These include:

- medicines used for the treatment of
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
 - **tuberculosis** (e.g. rifampicin)
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non- nucleoside reverse transcriptase inhibitors, such as ritonavir, nevirapine, efavirenz)
 - **fungal** infections (e.g. griseofulvin, ketoconazole)
 - arthritis, arthrosis (etoricoxib)
 - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

If you do need to take one of these medicines, Diane-35 may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Diane-35 may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps). Your doctor may need to adjust the dose of your other medicine.

In addition, Diane-35 can also interfere with the results of some blood tests, so always tell your doctor that

you are taking Diane-35 if you have a blood test.

Do not use Diane-35 if you have hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir / velpatasvir / voxilaprevir as these products may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products. Diane-35 can be restarted approximately 2 weeks after completion of treatment. See section 'Do not use Diane-35...'

Taking Diane-35 with food and drink

There are no special instructions about food and drink while on Diane-35.

Pregnancy and breast-feeding

Do not use Diane-35 if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Diane-35.

Driving and using machines

Diane-35 has no known effect on the ability to drive or use machines.

Diane-35 contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Diane-35.

Diane-35 and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Diane-35. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3. HOW TO TAKE DIANE-35

Your doctor has chosen Diane-35 as a treatment for your acne or excessive hair growth on your face and body. However, Diane-35 also has a contraceptive effect, so it is important to follow the advice below if you are relying on Diane-35 for contraception.

If you are only using Diane-35 for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Diane-35.

How to take it

Take Diane-35 every day for 21 days

Diane-35 comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have

finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Diane-35 as described here. You don't need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

Check with your doctor if you are not sure.

Start your next strip on day eight

Start taking your next strip of Diane-35 after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Diane-35 correctly, you will always start each new strip on the same day of the week.

Starting Diane-35

New users or starting Diane-35 after a break

It is best to take your first Diane-35 pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Diane-35 from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Diane-35 the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Diane-35.
- **If you are taking a 28-day Pill:** start taking Diane-35 the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Diane-35.
- **If you are taking a progestogen-only Pill (POP or 'mini Pill'):** start Diane-35 on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Diane-35 after a miscarriage or abortion

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor may tell you to start taking Diane-35 straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Diane-35 should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Diane-35 and for the first 7 days of pill taking.

Do not take Diane-35 if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- **Continue to take a pill every day for the next seven days** at your usual time.

- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won't have a bleed until after you finish the second strip of pills, but don't worry. If you finish the second strip of pills and don't have a bleed, do a pregnancy test before starting another strip.
- **Use extra contraception for seven days after missing a pill**, such as condoms.
- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill- free break, you may be pregnant.

Contact your doctor or do a pregnancy test yourself.

If you start a new strip of pills late, or make your 'week off' longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception.

You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Diane-35**, follow the instructions in section *A lost pill*, which describes how to take another pill.

If you are still sick or have diarrhoea **more than 12 hours after taking Diane-35**, see section *A missed pill*.

→ **Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Diane-35 and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping Diane-35 until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diane-35 can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Diane-35, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you take Diane-35".

The following is a list of the side effects that have been linked with the use of Diane-35:

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Diane-35, some women have reported feeling depressed whilst taking Diane-35. In very rare cases this has been associated with thoughts of ending their lives. If you develop severe depression, you should stop Diane-35 as a precaution, and see your doctor straight away.

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- 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.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIANE-35").

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling of the hands, face, lips, mouth, tongue or throat.** A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching.

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex.**

Signs of severe liver problems include:

- severe **pain in your stomach**

- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching**.

→ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Diane-35.

4.2 Less serious side effects

Common side effects (may affect up to 1 in 10 people)

- **feeling sick**
- **stomach ache**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **sore or painful breasts**

Uncommon side effects (may affect up to 1 in 100 people)

- **being sick and stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

Rare side effects (may affect up to 1 in 1,000 people)

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**
- **vaginal or breast discharge**
- **venous blood clot**

→ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Diane-35. Also tell them if any existing conditions get worse while you are taking Diane-35.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Diane-35, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Diane-35 as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Diane-35 for a while
- carries on even after you've stopped taking Diane-35.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

To report any side effect(s):

The National Pharmacovigilance Centre (NPC).

Fax: + 966 - 11 - 205 - 7662.

SFDA call center: 19999.

E - mail: npc.drug@sfd.gov.sa.

Website: <https://ade.sfd.gov.sa>

5. HOW TO STORE DIANE-35

Keep all medicines out of the reach and sight of children.

Store below 25°C.

Do not use Diane-35 after the expiry date shown on the strip.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What is in Diane-35**

Each box of Diane-35 contains one strip of 21 beige tablets.

Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

Diane-35 also contains the inactive ingredients:

lactose, maize starch, povidone, talc, magnesium stearate (E572), sucrose, macrogol 6000, calcium carbonate (E170), titanium dioxide (E171), glycerol (E422), glycol montanate, yellow ferric oxide pigment (E172).

Manufacturer

Bayer Weimar GmbH und Co. KG
99427 Weimar, Germany.

Marketing authorisation holder

Bayer AG
Kaiser-Wilhelm-Allee 1
51368 Leverkusen, Germany.

This leaflet was last updated in February 2023.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**