

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

This medicine is dispensed with a doctor's prescription only

Diane 35

Tablets

Each tablet contains:

ethinylestradiol 35 mcg

cyproterone acetate 2 mg

Inactive ingredients and allergens: see section 6 "Further Information" and section 2 "Important information regarding some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1) WHAT IS THE MEDICINE INTENDED FOR?

Diane 35 is a medicine with hormonal activity (estrogenic and anti-androgenic) and is intended to treat skin problems such as acne, very oily skin and excessive hair growth in women of reproductive age.

Diane 35 is not intended for use in adolescent girls who have not yet begun menstruating.

Only take Diane 35 to treat acne if topical treatment or antibiotics have not worked.

Therapeutic group: Diane 35 belongs to a group of medicines called estrogens and antiandrogens.

Androgens are hormones that stimulate hair growth and activity of the sebaceous glands in your skin. If your body produces too much androgen, or if you are sensitive to the effect of androgens, the sebaceous glands may produce too much sebum. As a result, the sebaceous glands may become blocked, infected and inflamed, causing acne spots. Diane 35 stops the androgens affecting your skin and reduces the amount of androgens produced.

Although Diane 35 also acts as a contraceptive, it is not intended only as a contraceptive, unless your doctor has instructed you to use the medicine to treat skin problems such as acne, very oily skin and excessive hair growth in women of reproductive age.

If you are taking Diane 35 to treat your skin, **do not use another hormonal contraceptive at the same time.**

When your skin condition improves and you stop taking Diane 35, you will have to go back to your original/preferred method of contraception.

Diane 35 does not protect you from contracting sexually transmitted diseases such as chlamydia or HIV (AIDS). Only condoms can help to do that.

2) BEFORE USING THE MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine. For a list of inactive ingredients, see section 6 "Further Information".
- you are using another hormonal **contraceptive**.
- you are **pregnant** or might be pregnant.
- you are **breastfeeding**.
- you have or have ever had **breast cancer**.
- you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
- 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 ischemic attack).
- you have (or have ever had) a **heart attack** or **stroke**.
- you have a condition that may increase the risk of a **blood clot** in your arteries. This applies to the following conditions:
 - **diabetes, which affects the blood vessels,**
 - **very high blood pressure,**
 - very high levels of **blood fats** (cholesterol or triglycerides).
- you have problems with **blood clotting** (e.g., protein C deficiency).
- you have (or have ever had) a **migraine with visual disturbances**.
- 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.
- you have ever had **liver tumors**.
- you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir or glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section "Other medicines and Diane 35").
- you have **meningioma** or have ever been diagnosed with meningioma (a benign tumor usually of the layer of tissue between the brain and the skull).

Tell your doctor if any of the conditions above apply to you before you start using Diane 35. Your doctor may then advise you to use a different treatment.

If you suffer from any of these conditions or get them for the first time while taking Diane 35, stop taking the medicine immediately and contact your doctor as soon as possible. If necessary, use a different form of contraception.

Tell your doctor if you have any medical problems or diseases.

Special warnings regarding use of the medicine

It is important that you understand the benefits and risks of taking Diane 35 before you start taking it, or when deciding whether to continue taking it. Although Diane 35 is suitable for most healthy women it is not suitable for everyone.

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

Diane 35 may 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.

Before starting treatment with Diane 35, tell your doctor if any of the following conditions apply to you

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 anyone in your close family have ever had problems with the heart or blood circulation, such as **high blood pressure**
- if you or anyone in your close family have ever had **blood clotting** problems
- 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 a genetic 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 blood fats (hypertriglyceridemia), since you may be at risk of developing pancreatitis
- if you have **brown patches on your face or body** (chloasma) (see below "Diane 35 and tanning beds or tanning lamps")
- if you have had **an illness that worsened during pregnancy or previous use** of a contraceptive pill or **Diane 35** (see section 4 "Side effects").
- 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 conditions.

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

Psychiatric disorders:

Certain 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 symptoms of depression, contact your doctor for further medical advice as soon as possible.

- **When should you contact your doctor?**
Stop taking the medicine and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms of a blood clot are described below under "Blood clots (thrombosis)" and in section 4 "Side effects".

Diane 35 also works as an oral contraceptive. You and your doctor will have to consider all of 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 developing a blood clot (also called 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 achieved, and 1-2% of the cases may be fatal.

Blood clots in a vein

A blood clot in a vein (also known as venous thrombosis) can block the vein. This effect may happen in veins of the leg, lung (pulmonary embolism), or any other organ.

Using a combined pill increases a woman's risk of developing such blood 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 of using 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 or a contraceptive pill** and are not pregnant, about **5 to 10** will have a blood clot in a year.
- Of 100,000 women who **take Diane 35 or a contraceptive 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 women using a combined pill increases further:

- With increasing age;
- **if you smoke.**
When you use a hormonal contraceptive such as 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 in any other organ at a young age;
- if you are overweight;
- if you must undergo an operation, or if you are off your feet for a prolonged period of time because of an injury or illness, or if 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 anemia.**

If any of these conditions applies to you, it is very important that you tell the doctor that you are using Diane 35, as the treatment may have to be stopped. Your doctor may tell you to stop taking Diane 35 at least four weeks before surgery or while you are less mobile. Your

doctor will also tell you when you can start taking 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 a blood clot in the brain may cause a stroke.

Use of a combined pill is associated with an increased risk of blood clots in the arteries. This risk increases further:

- with increasing age;
- **if you smoke.**
When you use a hormonal contraceptive such as 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 a stroke at a young age;
- if you have high levels of fats in your blood (cholesterol and triglycerides);
- if you get migraines;
- if you have a heart problem (valve disorder, rhythm disturbance);
- 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 anemia.**

Symptoms of blood clots:

Stop taking the medicine and refer to the doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest, which may affect 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 disruption;
- sudden changes in hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe abdominal pain;
- severe pain or swelling in either of your legs.

Full recovery is not always achieved following a blood clot. In rare cases, serious permanent disabilities may occur or the blood clot may 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 your doctor straight away if you develop severe depression, a severe allergic (sensitivity) reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer, or signs of severe liver problems (signs and symptoms are described in section 4 "Side effects").

Diane 35 and cancer

While long-term high dosage of combined oral contraceptive pills reduces your risk of cancer of the ovary and of the womb, it is not clear whether lower dose estrogen and 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 increase may be due to having sex without a condom, rather than taking Diane 35. All women should have regular **cervical smear (pap) tests**.

If you have **breast cancer**, or have had it in the past, do not take Diane 35 or any other contraceptive pill, as they slightly increase your risk of breast cancer. This risk goes up the longer you take 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 number of 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 a contraceptive pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women **who take Diane 35 or a contraceptive 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 a contraceptive pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women **who take Diane 35 or a contraceptive 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 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 noncancerous liver tumors, 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.

Increased risk of benign brain tumor (meningioma) has been reported with high doses (25 mg and up) of cyproterone acetate. If you are diagnosed with meningioma, as a precaution, your doctor will stop all your cyproterone medications including Diane 35, (see section 2 "Before using this medicine").

Other medicines and Diane 35

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor (including the dentist) or pharmacist. 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 in the leaflets of the other medicines you are taking whether they can be taken with hormonal contraceptives.

Certain 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.

It is especially important to inform the doctor or pharmacist if you are taking any of the following medicines used to treat:

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

If you need to take any of these medicines, Diane 35 may not be suitable for you or you may need to use another contraceptive for some time. 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, such as:

- medicines containing cyclosporine
- lamotrigine used to treat epilepsy (taking them at the same time 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 medicines.

Do not use Diane 35 if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir as this may cause increases in liver function blood test results (increase in ALT liver enzyme levels). Your doctor will prescribe another type of contraceptive before starting treatment with these medicines.

Diane 35 can be restarted approximately two weeks after completing treatment with these medicines (see in section 2 "Do not use this medicine if").

If you are taking Diane 35 to treat skin problems, do not use any other hormonal contraceptive at the same time.

In addition, Diane 35 may affect certain blood tests results, so always tell your doctor that you are taking Diane 35 if you must undergo a blood test.

Use of the medicine and food

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

Pregnancy, breastfeeding, and fertility

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

If you become pregnant while taking this medicine, stop taking it immediately and consult your doctor or a teratology center.

Studies in animals have shown that taking the active ingredient cyproterone acetate during pregnancy can affect the unborn baby. Do not take Diane 35 during pregnancy.

Using Diane 35 while breastfeeding may reduce the volume of milk you produce and may affect its composition. Very small amounts of the active ingredient pass into breastmilk. These amounts may affect the baby, especially during the first 6 weeks after birth. Do not take Diane 35 if you are breastfeeding.

Driving and using machines

Diane 35 does not have any known effect on the ability to drive or operate machines.

Diane 35 and tanning beds or tanning lamps

Some women use tanning lamps to treat acne and to tan their skin. This is not a very effective treatment for acne. **Do not use tanning beds** or tanning lamps and avoid prolonged exposure to the sun during the course of treatment with Diane 35. Using them increases the chance of chloasma, a patchy discoloration of the skin (as it does when using ordinary contraceptive pills).

Smoking

When using a hormonal contraceptive like Diane 35 you are strongly advised to stop smoking, especially if you are older than 35 years (see section 2 “Blood clots (thrombosis)”).

If you smoke – inform the doctor before starting treatment with this medicine.

Tests and follow-up

Before you start taking Diane 35

- Your doctor will ask about your medical problems and those of your family, will check your blood pressure, and exclude the possibility of you being pregnant. You may also need other checks, such as a breast examination, but only if you specifically need them or if you have any special concerns.

While you are taking Diane 35

- You will need **regular check-ups** with your doctor, usually every time you need to renew your prescription of Diane 35.
- You will need **regular cervical smear tests (pap smear)**.
- **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 certain tests.
- **If you are due to undergo surgery**, make sure your doctor knows about it. You may need to stop taking Diane 35 at least four weeks before the surgery, to reduce the risk of a blood clot (see section 2 – Blood clots). Your doctor will tell you when you can start taking Diane 35 again.
- **If you have to stop taking Diane 35**, and you rely on Diane 35 as a contraceptive, remember to use another contraceptive (such as condoms).

Important information regarding some of the ingredients of the medicine

Diane 35 contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before using Diane 35.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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 if you are relying on Diane 35 for contraception, it is important to follow the instructions detailed below.

If you are only using Diane 35 for your acne or excessive hair growth, you can still follow the instructions for taking it listed below, but ask your doctor if you are uncertain.

- The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet, every day, at a fixed time, for 21 days, and afterwards a 7-day break.

Do not exceed the recommended dose.

Mode of administration

Swallow the tablet whole, with water if necessary.

Do not crush/halve/chew, so as not to damage the coating of the tablet.

Treatment duration

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

Take Diane 35 every day for 21 days

Diane 35 comes in strips of 21 tablets, each marked with a day of the week. Take your tablet at the same time every day. Start by taking a tablet marked with the correct day of the week. Follow the direction of the arrows on the strip and take the tablets in the direction of the arrows. Take one tablet each day, until you have finished all 21 tablets.

Then have a 7-day tablet-free break

After you have taken all 21 tablets in the strip, you will have 7 days when you take no tablets. Within a few days of taking the last tablet 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 tablets.

If you are relying on this medicine to prevent pregnancy, always take Diane 35 as described here. You do not need to use extra contraception during the seven tablet-free days, as long as you have taken your tablets correctly and start the next strip of tablets 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-day tablet-free break (**on day eight**) – even if you are still bleeding. So if you take the last tablet in the strip on a Friday, you will take the first tablet of the next strip 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 a new strip on the same day of the week.

Starting treatment with Diane 35

New users of Diane 35 or starting 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 tablet.

Switching to Diane 35 from another contraceptive pill

- **If you are currently taking a 21-day contraceptive pill:** Start taking Diane 35 the day after the end of the previous strip. You will have contraceptive protection with your first tablet. You will not have a bleed until after you finish your first strip of Diane 35.
- **If you are currently taking a 28-day contraceptive pill:** Start taking Diane 35 the day after taking the last active tablet. You will have contraceptive protection with your first tablet. You will not have a bleed until after you finish your first strip of Diane 35.
- **If you are currently taking a progestogen-only pill (POP or 'mini pill'):** Start taking 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 protection with your first pill.

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. By starting in this way, you will have contraceptive protection with your first tablet.

If you have had a miscarriage or an abortion after **the third month of pregnancy**, consult your doctor. You may need to use an additional contraceptive method, such as condoms, for a short time.

Using a contraceptive after giving birth

If you have just had a baby, your doctor may advise you to start taking Diane 35 21 days after delivery provided that you are fully mobile and are not breastfeeding. There is no need to wait for a period. Use another method of contraception, such as condoms, until you start using Diane 35 and for the first 7 days of taking the tablets.

Do not take Diane 35 if you are breastfeeding.

A missed tablet

- **If you are less than 12 hours late with a single tablet**, take it straight away. Keep taking your tablets at the usual time. This may mean taking two tablets in one day. Don't worry – your contraceptive protection should not be reduced.
- **If you are more than 12 hours late with a single tablet**, or you forgot more than one tablet, your contraceptive protection may be reduced.
 - **Take the most recently missed tablet** as soon as you remember, even if it means taking two tablets at once. Leave any earlier missed tablets in the pack.
 - **Continue to take a tablet every day for the next 7 days** at your usual time.
 - **If you come to the end of the strip during these 7 days**, start the next strip immediately without taking the usual 7-day break. You probably won't have a bleed until after you finish the second strip of tablets, but there is no reason to be worried. If you finish the second strip of tablets and don't have a bleed, do a pregnancy test before starting another strip.
 - **Use an additional method of contraception**, such as condoms, **for 7 days after missing a tablet.**
 - If you have missed one or more tablets from the first week of your strip (days 1-7) 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 that you use emergency contraception (morning-after pill).

If you have forgotten to take any tablet in a strip, and you do not bleed in the first tablet-free break, you may be pregnant. Consult your doctor or do a pregnancy test yourself.

If you start a new strip of tablets late or make your 'week off' longer than 7 days, you may not be protected from pregnancy. If you had sex in the last seven days, consult the doctor or pharmacist. You may need to use emergency contraception (morning-after pill). In addition, you must use an additional method of contraception, such as condoms, for 7 days.

A lost tablet

If you lose a tablet,

Either take the last tablet of the strip in place of the lost tablet. Then take all the other tablets on their proper days. Your cycle will be one day shorter than normal, but the contraceptive protection will not be affected. After your 7-day tablet-free break your strip will have a new starting day, one day earlier than usual.

Or - if you do not want to change the starting day of your cycle, take a tablet from a spare strip, if you have one. Continue taking the rest of the tablets from your current strip as usual. You can keep the spare strip in case you lose any more tablets.

If you vomit or have diarrhea

If you vomit or have very bad diarrhea, your body may not get its usual dose of hormones from that tablet. **If your condition improves within 12 hours of taking Diane 35**, follow the instructions in section 3 "A lost tablet", which describes how to take an additional tablet.

If you are still vomiting or have diarrhea **more than 12 hours after taking Diane 35**, follow the instructions in section 3 "A missed tablet".

Talk to your doctor if your digestive disturbance persists 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 all your tablets correctly. Start taking the tablets from the new strip at the usual time. If you think that you might be pregnant (for example, if you forgot to take a tablet or if you took other medicines), or if you miss a bleed twice in a row, you should do a pregnancy test. If you are pregnant, stop taking Diane 35 and see your doctor.

If you want to get pregnant

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

If you have accidentally taken a higher dose, consult your doctor or pharmacist. It is unlikely that taking more than one tablet will do you any harm, but you may feel nauseous, 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.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment regimen recommended by the doctor.

Do not stop taking the medicine without consulting the doctor or pharmacist. If you stop taking the medicine, you are impairing the effectiveness of the medicine and the contraceptive protection.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Diane 35 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you develop one or more of the side effects, particularly if it is severe or persistent, or feel any change to your health that you think may be due to Diane, tell 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 about the different risks from taking combined hormonal contraceptives please see section 2 "Before using this medicine".

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

Serious side effects - see a doctor immediately

- **Severe depression:**

Although this effect is not considered a direct side effect of Diane 35, some women have reported depression when using Diane 35. In very rare cases, this effect was also associated with thoughts of ending their lives. If you develop severe depression, stop taking Diane 35 as a precaution, and see a doctor immediately.

- **Signs of a blood clot:**

- sudden, unusual 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 words or speech disability
- sudden changes in hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe abdominal pain
- 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 "Special warnings regarding use of the medicine").

- **Signs of a severe allergic reaction or worsening of hereditary angioedema:**
 - **swelling of the hands, face, lips, mouth, tongue or throat.** Swelling of the tongue/throat can 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 of blood and/or contains blood
 - unusual **vaginal bleeding**
 - **pelvic pain**
 - **pain during sexual intercourse.**
- **Signs of severe liver problems include:**
 - severe **abdominal pain**
 - **yellowing of the skin or eyes** (*jaundice*)
 - **inflammation of the liver** (*hepatitis*)
 - **itching** over the whole body.

If you think you have any of the signs listed above, see a doctor immediately. You may need to stop taking Diane 35.

Less serious side effects

Common side effects - may affect up to 1 in 10 users

- **nausea**
- **abdominal pain**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **tender or painful breasts.**

Uncommon side effects - may affect up to 1 in 100 users

- **vomiting and digestive disturbances**
- **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 users

- **poor tolerance of contact lenses**
- **weight loss**

- **increased interest in sex**
- **vaginal or breast discharge**
- **blood clot in a vein.**

Additional side effects reported

- Spotting and bleeding between periods may occur during the first few months of taking Diane 35, but usually stop once your body gets used to the medicine. If they continue, get worse or start again, consult your doctor (see below "Bleeding between periods should not last long").
- reduced menstrual flow when you bleed or no bleeding
- no menstrual bleeding after you stop using the medicine
- brown-gold patches on the skin, known as "pregnancy patches" (chloasma), may develop even with short-term use of a few months. If this happens, avoid exposure to sunlight or to ultraviolet radiation
- recurrence or deterioration of a movement disorder called chorea
- Crohn's disease or ulcerative colitis
- increase in blood pressure
- high levels of fats in your blood (**hypertriglyceridemia**)
- liver function problems

Conditions which may occur or get worse during pregnancy or previous use of a contraceptive pill or use of Diane 35: yellowing of the skin (jaundice), persistent itching associated with cholestasis, kidney problems, gallstones, rare medical conditions such as systemic lupus erythematosus, blister-like rash during pregnancy, a type of hereditary deafness called otosclerosis, sickle cell anemia, swelling of body parts (hereditary angioedema), a genetic disease called porphyria, hemolytic–uremic syndrome, epilepsy, and uterine myomas.

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Bleeding between periods should not last long

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

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

Consult your doctor if the spotting or bleeding between periods:


- carries on beyond the first few months of taking this medicine
- starts after you have been taking Diane 35 for a while
- carries on even after you have stopped taking Diane 35

Reporting side effects

You can report side effects to the Ministry of Health by following the link “Reporting Side Effects of Drug Treatment” on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not throw away any medicines down  toilet or into a bin. Consult your pharmacist on how to discard medicines you no longer need. This will help protect the environment.

6) FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
lactose monohydrate, sucrose, maize starch, calcium carbonate, talc, macrogol 6000, povidone 25, titanium dioxide (E171), povidone 90, glycerol 85%, magnesium stearate, glycol montanate, ferric oxide pigment yellow (E172).
Each tablet contains 19.371 mg sucrose.
Each tablet contains 30.965 mg lactose monohydrate.
- What does the medicine look like and what are the contents of the package:
Beige-colored, film-coated tablets.
The tablets come in strips (blisters), in packs of 21 tablets.
The back of the blister covering each tablet is marked with a day of the week.
- **Registration holder's name and address:** Bayer Israel Ltd., 36 Hacharash Street, Hod Hasharon 4527702.
- **Manufacturer's name and address:** Bayer AG, Berlin, Germany or Bayer Weimar GmbH und Co. KG, Weimar, Germany.
- Revised in June 2023 according to Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 034 03 25085 00