

**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

**Package leaflet: Information for the user**  
**Diane®-35**  
**0.035 mg/2 mg coated tablets**  
Active substances: ethinylestradiol/cyproterone acetate

- This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. Further information

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

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

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

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

- 2.1. Do not take Diane-35**
- Tell your doctor before you start using Diane-35 if any of the following points apply to you.
- Your doctor may then advise you to use a different treatment:
- if you are using another hormonal **contraceptive**;
  - if you have (or have ever had) a **blood clot** in your leg (thrombosis), your lungs (pulmonary embolism) or any other part of the body;
  - if you have a known personal or family history of vein blockage caused by a blood clot of unknown origin (known, idiopathic venous thromboembolism (VTE)) (with the family history referring to blood vessel blockage in a sibling or parent at a relatively young age)
  - if you have (or have ever had) an illness that may be a precursor to a heart attack (e.g. angina pectoris, causing severe chest pain) or **mild stroke** (transient ischaemic attack);
  - if you have (or have ever had) a **heart attack or stroke**;
  - if you have any complaints that may increase the risk of **blood clots** in your arteries. This applies to the following complaints:
    - **diabetes with vascular changes**
    - very high **blood pressure**
    - very high **blood fat levels** (cholesterol or triglycerides);
  - if you have problems with **blood clotting** (e.g. protein C deficiency);
  - if you suffer (or have ever suffered) from **migraine with visual disturbances**.
  - if you have a certain blood disease (sickle cell anaemia),
  - if you have a past or present history of pancreatitis, accompanied by a sharp increase in blood fat levels and/or other fat metabolism disorders,
  - if you have severe liver dysfunction (including impaired excretion such as Dubin-Johnson and Rotor syndrome), unless liver function values have returned to normal,
  - if you have a past or present history of liver tumours (non-cancerous or cancerous),
  - if you have vaginal bleeding, the cause of which has not been medically diagnosed,
  - if you smoke (see "Take special care with Diane-35").
  - if you have a known or suspected cancer of the breast or genital organs influenced by sex hormones
  - if jaundice, persistent itching or a blistery rash (herpes gestationis) occurred during an earlier pregnancy or in women with middle-ear deafness (otosclerosis) whose hearing deteriorated during an earlier pregnancy,
  - if you are currently wishing to conceive, are pregnant or are breast-feeding,
  - if you are allergic (hypersensitive) to ethinylestradiol, cyproterone acetate or any of the other ingredients of Diane-35.

Diane-35 should not be used by men.

If any of the above-mentioned cases occurs while you are taking Diane-35, you must stop the medicine immediately and consult your doctor. In the meantime, you should use a different, non-hormonal contraceptive method. For more information, see also "General comments".

**2.2. Take special care with Diane-35**  
*General comments*

Diane-35 also acts as an oral contraceptive. You and your doctor must consider all the points that normally apply to the safe use of oral hormonal contraceptives.

This leaflet describes several cases in which you should stop Diane-35 immediately or in which contraceptive effectiveness may be reduced. In these cases, you should either not have sexual intercourse or you should use other non-hormonal methods of contraception, e.g. condoms or other barrier methods. However, do not use the calendar or temperature methods.

**Diane-35 offers no protection against HIV infection (AIDS) or other sexually transmitted diseases.**

**When should you consult your doctor?**  
**Stop taking the tablets immediately and consult your doctor at once if you notice possible signs of a blood clot. The symptoms are described in section 2 under "Blood clots (thrombosis)".**

**2.2.1. You should stop taking Diane-35 immediately and consult your doctor**

- if migraine-like headaches occur for the first time or become more severe, or if unusually frequent or unusually severe headaches occur,
- if you experience acute visual or hearing problems or impaired movement, especially paralysis (possible first sign of a stroke) or other problems in perception,
- at the first signs of vein inflammation with blood clot formation (thrombophlebitis) or thromboembolic symptoms (see section 2.2.2 "Special medical monitoring is required"),
- 6 weeks before scheduled surgery (e.g. in the abdomen, orthopaedic), (see section "Certain factors can increase the risk of a blocked vein or artery")
- at the onset of jaundice, hepatitis or itching over the entire body,
- if you experience an increase in epileptic fits
- if you experience a major increase in blood pressure,
- if you start experiencing severe depression,
- if you experience severe upper abdominal pain or if your liver becomes enlarged,
- if there is a significant deterioration of any conditions known to get worse during the use of hormonal contraceptives or pregnancy,
- if you suspect or know for certain that you are pregnant. Pregnancy is a reason for immediate discontinuation, as some studies suggest that oral contraceptives taken in early pregnancy might possibly cause a slight increase in the risk of foetal deformities. You must talk to your doctor if you suspect that you are pregnant.

- 2.2.2. Special medical monitoring is required**
- if you have diabetes mellitus,
  - if you have a blood pressure reading of more than 140/90 mm Hg (high blood pressure),
  - if you are prone to inflammation of surface veins (phlebitis) or have pronounced varicose veins,
  - if you suffer from a certain form of hearing impairment (otosclerosis),
  - if you have epilepsy,
  - if you suffer from a certain form of St. Vitus' dance (chorea minor/Sydenham's chorea),
  - if you suffer from a certain haemoglobin production problem (porphyria), which occurs as attacks and you suffer an attack while using Diane-35.
  - if you are 40 years or older.

It should be borne in mind that there is an increased risk of experiencing thromboembolic events in the puerperium (period immediately after childbirth) (see also "What should you remember during pregnancy and breast-feeding?")

Other disorders in which vascular complications may occur are diabetes mellitus, ovarian cysts (polycystic ovarian syndrome, PCOS), systemic lupus erythematosus (a certain disorder of the immune system), a form of kidney impairment (haemolytic-uraemic syndrome) and chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis).

Biochemical factors may indicate a hereditary or acquired disposition for occlusive vascular diseases. These factors include resistance to activated protein C (APC), hyperhomocysteinaemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, as well as antiphospholipid antibodies (e.g. anticardiolipin antibodies, lupus anticoagulant).

Diane-35 is similar in composition to combined preparations for hormonal contraception (the "pill"). For this reason, the following warnings for the pill also apply to Diane-35.

**2.2.3. The pill and vascular disorders**  
*Blood clots (thrombosis)*

When taking Diane-35, the risk of a blood clot (also called a thrombosis) may be slightly increased. The likelihood of a blood clot is only slightly increased when taking Diane-35 compared with women not taking Diane-35 or any other birth control pill. A full recovery does not always happen and 1-2% of cases may be fatal **Blood clot in a vein**

A blood clot in a vein (also called a "venous thrombosis") can block the vein. This may occur in the veins of the legs, lungs (pulmonary embolism) or any other organ.

When using a combined pill, a woman's risk of developing such clots is increased compared to a woman not taking a combined pill. The risk of developing a blood clot in a vein is highest in the first year of pill use. The risk is not as high as that of getting a blood clot during pregnancy.

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

- with increasing age;
- **if you smoke.**
- If you take a hormonal contraceptive such as Diane-35, you are strongly advised to stop smoking, especially if you are over 35 years of age;**
- if a close relative has had a blood clot in a leg, lung or any other organ at an early age;
- if you are overweight;
- if you need to undergo surgery, or if you have been bedridden over a prolonged period due to an injury or illness, or if your leg is in a cast.

If this applies to you, it is important that you tell your doctor you are using Diane-35, as treatment may have to be discontinued in some cases. Your doctor may tell you to stop using Diane-35 for several weeks before surgery or if you have only limited mobility. Your doctor will also tell you when you can start using Diane-35 again, once you are back on your feet.

**Blood clot in an artery**

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

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

- with increasing age;
- **if you smoke.**
- If you take a hormonal contraceptive such as Diane-35, you are strongly advised to stop smoking, especially if you are over 35 years of age;**
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at an early age;
- if you have high blood fat levels (cholesterol or triglycerides);
- if you get migraines;
- if you have a heart problem (heart valve defect, heart rhythm disorders).

**Symptoms of blood clots**

**Stop taking the tablets at once and consult your doctor immediately if you notice possible signs of a blood clot, such as:**

- sudden cough of unclear cause;
  - severe chest pain, which may radiate into the left arm;
  - shortness of breath;
  - unusual, severe or prolonged headaches or worsening of migraine;
  - partial or complete loss of vision or double vision;
  - slurred speech or problems in speaking;
  - sudden changes in the sense of hearing, smell or taste;
  - dizziness or fainting fits;
  - weakness or numbness in any part of the body;
  - severe abdominal pain;
  - severe pain or swelling in a leg.
- A full recovery does not always happen after a blood clot. Rarely, serious permanent disabilities may occur or the blood clot may be fatal.
- Immediately after childbirth, women are at increased risk of blood clots, which is why you should ask your doctor how soon after giving birth you can start taking Diane-35.

**2.2.4. The pill and cancer**

Cervical cancer has been reported somewhat more frequently in women taking the pill over a long period of time. To what extent this is also due to sexual behaviour (e.g. frequent changes of partner) or other factors, rather than to taking the pill itself, is not clear.

Breast cancer is found somewhat more frequently in women taking the pill than in non-pill users of the same age. After discontinuation of the pill, the breast cancer figures slowly start to level out and, after 10 years, there is no longer any noticeable difference between former pill users and other women. As breast cancer rarely occurs in women below 40 years of age, the number of additional breast cancer cases in previous or current users of the pill is low compared with the overall risk of breast cancer. The studies provide no information about the causes. The higher risk observed may be due to earlier detection of breast cancer in users of the pill, the biological effects of the pill or a combination of both.

In rare cases, non-cancerous and (more rarely) cancerous liver tumours have been found in pill users. In a few cases, these tumours have led to life-threatening internal bleeding. If you suddenly experience severe abdominal pain, you must consult your doctor immediately.

**2.2.5. Reduced effectiveness**

The effectiveness of Diane-35 may be reduced if, for example, you forget to take a tablet (see 3. "If you forget to take Diane-35"), in the event of gastrointestinal disorders or if you are also taking certain other medicines (see 3. "What can reduce the contraceptive effect?").

**2.2.6. Medical consultation/examination**

Before starting to use hormone-containing medicines such as Diane-35, a thorough general examination (body weight, blood pressure, heart, legs and skin, urine glucose testing and, if appropriate, a specific liver diagnostic test) and gynaecological tests (including the breasts and a cervical smear) should be performed and a careful family history taken (cases of disease in the family). Before using Diane-35, pregnancy must be ruled out. Blood clotting disorders must be ruled out if blood clot formation (thromboembolic disease, e.g. deep vein thrombosis, stroke, heart attack) has occurred in blood relatives at a relatively young age. Check-ups at approximately six-monthly intervals are recommended during use.

**2.3. Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Interactions between hormone preparations such as Diane-35 and other medicines can lead to bleeding between periods and/or failure of contraceptive effectiveness.

The following medicines can impair the effect of Diane-35:

- medicines used to treat epilepsy, such as hydantoins (e.g. phenytoin), barbiturates (e.g. barboxalone), primidone, carbamazepine, oxcarbazepine, topiramate and felbamate
- medicines used to treat tuberculosis (e.g. rifampicin)
- some antibiotics prescribed to treat certain infections (e.g. penicillins, tetracyclines and griseofulvin)
- medicines used to treat HIV infections (e.g. ritonavir, nevirapine)
- medicines containing St. John's wort (*Hypericum*)

Pills can also affect the metabolism of other medicines. For example, the effectiveness or tolerability of ciclosporin (a medicine used to suppress the immune system) or lamotrigine (a medicine used to treat epilepsy) can be impaired by Diane-35.

Women treated with a medicine from the above substance classes should use additional barrier methods during this time in addition to Diane-35, i.e. while taking the co-medication and for another 28 days thereafter.

Women treated with an antibiotic should also use additional barrier methods during this time, i.e. while taking the co-medication and for another 7 days thereafter.

If the use of an additional barrier method extends beyond the end of the pack, the next pack should be started without a 7-day tablet-free interval.

It is also possible that the need for medications to treat diabetes (mellitus) may change.

Please note that this information may also apply to recently used medicines.

Note:

Diane-35 must not be combined with medicines used for the purposes of hormonal contraception; if applicable, such medicines should be stopped before the start of therapy with Diane-35 (for more details, see also "How to take Diane-35").

**2.4. Pregnancy and breast-feeding**

If you are pregnant or think you may be pregnant, Diane-35 must not be used. If pregnancy occurs whilst you are using Diane-35, the product must be discontinued immediately. However, previous use of Diane-35 does not constitute grounds for terminating a pregnancy.

You should not use Diane-35 during breast-feeding, as milk production may be reduced and small amounts of active substance pass into human milk.

Ask your doctor or pharmacist for advice before taking any medicine.

**2.5. Driving and using machines**

No special precautions are required.

**2.6. Important information about some of the ingredients of Diane-35**

Each single tablet of this medicine contains lactose and sucrose (sugar). If you have been told that you have an intolerance to some sugars, please talk to your doctor before taking Diane-35.

**3. HOW TO TAKE DIANE-35**

**When, how often and for how long is Diane-35 used?**

Diane-35 suppresses ovulation and thus has a contraceptive effect. Patients using Diane-35 should therefore not use any extra hormonal contraceptive, as this will lead to a hormone overdose and is not required for effective contraceptive protection. For this same reason, women wishing to conceive should not use Diane-35. The following information applies unless you have been prescribed Diane 35 otherwise by your doctor. Please always follow the instructions for use, as Diane-35 may otherwise not work properly.

Diane-35 should be started on day 1 of a monthly period. Only women who do not have periods should start the therapy prescribed by their doctor immediately; in this case, the first day of tablet-taking should be the same as day 1 of their cycle and counting is continued according to the following recommendations.

Remove the first tablet from the unit marked with the day of the week on which tablet-taking is started (e.g. "Mon" for Monday). Swallow it whole (not chewed), with some liquid if required. If you start taking Diane-35 very soon after childbirth or miscarriage, you should ask the doctor whether additional protective measures are required during the first cycle, so that pregnancy can be reliably prevented.

Then, take one further tablet daily in the direction of the arrows until the calendar pack is finished. Once you have selected a time of day for taking your tablet, you should keep to it. During the subsequent 7-day tablet-free interval, bleeding will start 2-4 days after the last tablet.

After the 7-day pause, continue to take tablets from the next calendar pack, regardless of whether or not bleeding has stopped.

Note:

Contraceptive protection starts on the first day of tablet-taking and is also maintained during the 7-day pauses. You must therefore not use other hormonal contraceptives at the same time.

**When do you start taking Diane-35?**

- If you have not taken a contraceptive pill in the previous month:
- Start taking Diane-35 on the first day of your cycle, i.e. on the first day of your monthly period. If you start taking it between days 2 and 5, additional use of a barrier method of contraception (e.g. condoms) is recommended.
- If you have been using a pill (with two hormonal active substances, a so-called combined oral contraceptive), vaginal ring or transdermal patch:

You should preferably start taking Diane-35 on the day after the last hormonal tablet of your previous pill (or after removal of the vaginal ring or transdermal patch), but by no later than the day after the usual tablet-free (ring-free, patch-free) interval. If the pack of your previous pill also contains tablets without any active substance, you must start taking Diane-35 on the day after taking the last inactive tablet.

- If you have been taking a pill containing only one hormone (progesterone) (so-called minipill): You can start the minipill on any day you wish and start taking Diane-35 the very next day. For the first 7 days, additional use of a barrier method of contraception (e.g. condom) is required.
- Switching from an injection, an implant or the coil:

Start taking Diane-35 at the time when the next injection should normally be given, or on the day when the implant or coil is removed. For the next 7 days, additional use of a barrier method of contraception (e.g. condom) is required.

► After childbirth:

If you have just had a baby, you should start taking Diane-35 no earlier than 21 to 28 days after the delivery. If you start taking it any later, you should also use a barrier method of contraception for the first 7 days. If you have already had sexual intercourse, pregnancy must be ruled out before you start taking Diane-35 or you must wait until your first monthly period.

- After a miscarriage or abortion:
- Please talk to your doctor.

**What can reduce the contraceptive effect?**

Dosing errors, vomiting or intestinal diseases with diarrhoea, prolonged concomitant use of certain oral medicines (see "Interactions with other medicines") and very rare individual metabolic disorders can cancel the contraceptive effect. Mild laxatives have no impact on reliability.

**For how long should you take Diane-35?**

Your doctor will tell you how long you have to take Diane-35 for.

If, exceptionally, you have experienced no bleeding during the tablet-free interval, you should firstly stop using Diane-35 and seek medical advice.

When treating signs of androgenisation, immediate success cannot generally be expected. In these cases, treatment over several months is required. It is recommended that treatment be stopped 3 to 4 cycles after the signs of illness have completely disappeared.

In cases where the success of therapy for

- severe acne or seborrhoea over at least 6 months, or
  - abnormally increased facial and body hair (hirsutism) over at least 12 months
- is absent or insufficient, combined use of Diane-35 and Androcur® 10 mg tablets or Androcur® 50 mg tablets should be considered or the therapeutic approach reviewed.

However, as soon as the signs of androgenisation have disappeared, a woman still wanting contraceptive protection should, if appropriate, be switched to a low-dose oral contraceptive. If androgenetic symptoms reappear, treatment with Diane 35 can be resumed. If you start taking Diane-35 again after an interval of 4 weeks or more, you should bear in mind that there is an increased risk of venous thrombosis and pulmonary embolism (see section "The pill and vascular disorders").

**If you take more Diane-35 than you should**

Possible signs of an overdose are nausea and vomiting (usually after 12 to 24 hours, in some cases lasting up to a few days) and mild vaginal bleeding. If relatively large amounts have been taken, you must consult a doctor, who will be able to treat the symptoms.

**If you forget to take Diane-35**

- If you are **less than 12 hours** late in taking **any one tablet**, the contraceptive effect of Diane-35 is still assured. You must then take the missed tablet as soon as possible and then revert to taking the next tablets at your usual time.
- If you are **more than 12 hours** late in taking any one tablet, the contraceptive effect is no longer assured. The risk of unwanted pregnancy is particularly high if a tablet has been missed at the start or end of the blister. In this case, you should follow the instructions below (see also diagram).

**You have missed more than 1 tablet in the current blister:**

Ask your doctor for advice.

**You have forgotten 1 tablet in week 1:**

Take the missed tablet as soon as possible, even if this means taking two tablets at the same time. You can then continue taking your tablets as normal, but you must use extra contraceptive protection (e.g. a condom) for the next 7 days. If you have had sexual intercourse in the week before you forgot to take the tablet, there is a risk of pregnancy. In this case, tell your doctor immediately.

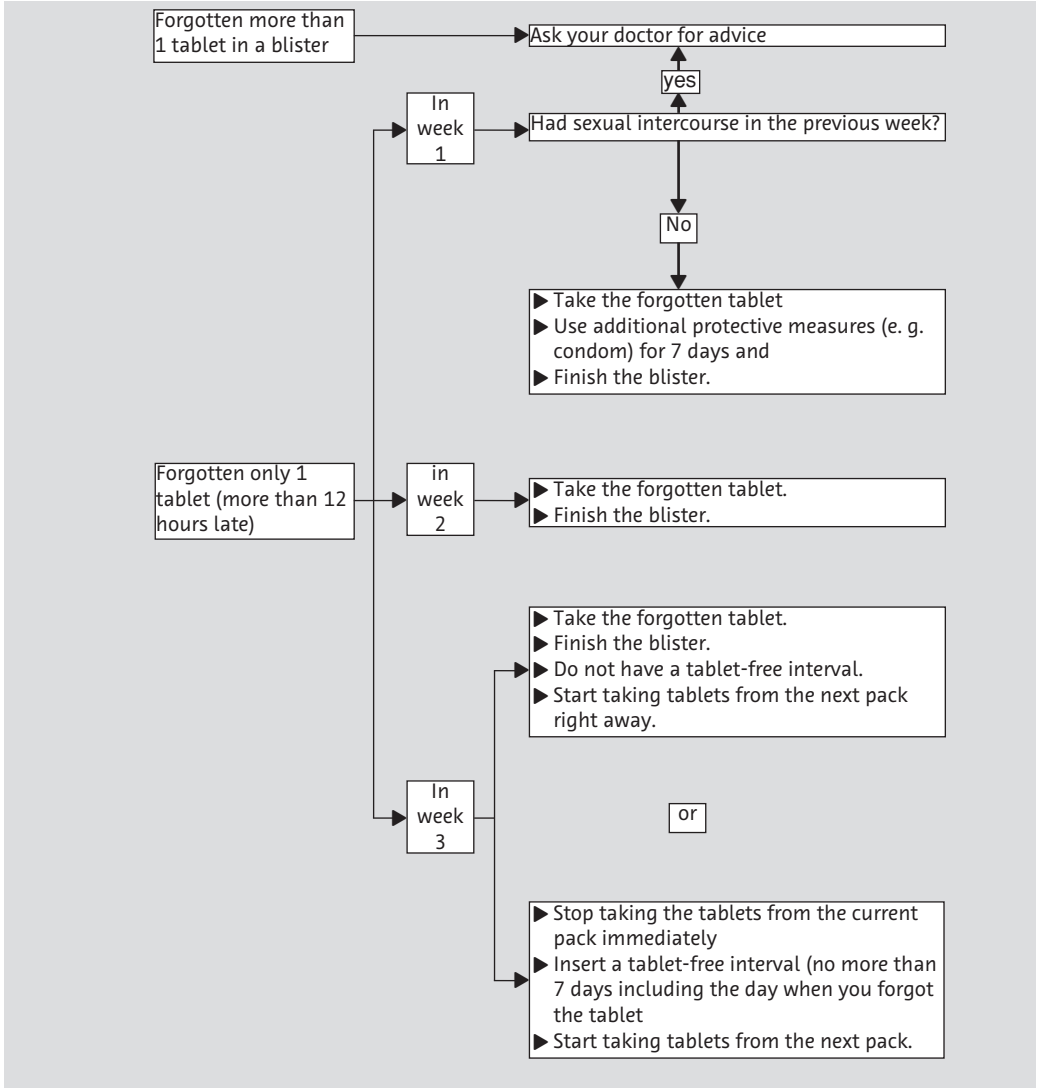
**You have forgotten 1 tablet in week 2:**

Take the missed tablet as soon as possible, even if this means taking two tablets at the same time. Provided that you have been taking Diane-35 regularly on the previous 7 days before the forgotten Diane-35 tablet, the contraceptive effect is assured and you need not use extra protective measures.

**You have forgotten 1 tablet in week 3:**

You can choose between two options:

1. Take the missed tablet as soon as possible, even if this means having to take two tablets at the same time. You can then revert to taking your next tablets at your usual time. Skip the tablet-free interval and start taking tablets from the next blister right away. In this case, you will most probably not experience proper withdrawal bleeding until you have finished this second blister, but spotting and bleeding between periods may occur whilst you are taking tablets from the second blister.
2. You can also stop taking tablets from your current blister immediately and, after a tablet-free interval of no more than 7 days (including the day when the tablet was missed), start taking tablets from the next blister right away. If you would like to start taking tablets from the new blister on your usual day of the week, you can insert a tablet-free interval of less than 7 days.
- If you have forgotten to take your tablet more than once and, after finishing a blister, no bleeding occurs in the first normal tablet-free interval, you may have become pregnant. In this case, you must consult your doctor before starting a new blister.



**What to consider**

**... if you suffer vomiting or diarrhoea**

In the event of severe gastrointestinal disorders, the active substance may not be completely absorbed and extra contraceptive measures should be used.

If you experience vomiting within 3-4 hours of taking a tablet, the same instructions as for missing a tablet apply. If you do not wish to change your dosing schedule, you must take the replacement tablet from another blister.

**..... if unexpected bleeding occurs**

Especially in the first few months, unexpected bleeding may occur (spotting or bleeding between periods). However, you should continue to take your tablets as normal. This irregular bleeding generally wears off after about three cycle packs, as soon as your body has become used to Diane-35. However, you must consult your doctor if bleeding persists, becomes heavier or returns.

**..... if you fail to have a period**

If you have taken all your tablets correctly, have not vomited or had severe diarrhoea and if you have taken no other medicines, pregnancy is very unlikely. However, you should consult your doctor and stop taking the tablets until your doctor has conclusively ruled out pregnancy.

**If you stop taking Diane-35**

If you want to stop taking Diane-35, ask your doctor or pharmacist for advice.

**Use in children and adolescents**

Do not use Diane-35 if you have not yet started your periods (menstruation).

**Use in elderly women**

Diane-35 should not be used during or after the menopause.

**Use in women with liver dysfunction**

Do not take Diane-35 if you have liver disease. See also sections 2.1 "Do not take Diane-35" and 2.2 "Take special care with Diane-35".

**Use in women with impaired kidney function**

Talk to your doctor before you start taking Diane-35.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Diane-35 can cause side effects, although not everybody gets them.

For all women who use Diane-35, there is an increased risk of venous and arterial thromboembolism (e.g. venous thromboembolism, pulmonary embolism, stroke, heart attack). For further information, see also "Take special care with Diane-35" in the section "What you need to know before you take Diane-35".

This risk can be further increased by additional factors (smoking, high blood pressure, disorders of blood clotting or fat metabolism, considerable obesity, varicose veins, history of vein inflammation and thrombosis); see "What you need to know before you take Diane-35".

For other serious side effects such as liver tumours, breast cancer or cervical cancer, see "Take special care with Diane-35".

The following frequency statements are used for evaluating side effects:

<b>Very common:</b>	more than 1 in 10 patients treated
<b>Common:</b>	less than 1 in 10, but more than 1 in 100 patients treated
<b>Uncommon:</b>	less than 1 in 100, but more than 1 in 1,000 patients treated
<b>Rare:</b>	less than 1 in 1,000, but more than 1 in 10,000 patients treated
<b>Very rare:</b>	less than 1 in 10,000 patients treated, including isolated cases

The most common side effects (> 10%) associated with taking pills that contain ethinylestradiol and levonorgestrel as active substances are headaches (including migraines), spotting and bleeding between periods.

Organ system	Frequency of side effects		
	Common	Uncommon	Rare
Eye disorders			Intolerance to contact lenses (dry eyes)
Vascular disorders			Blood clot in a vein
Gastrointestinal disorders	Nausea, abdominal pain	Vomiting, Diarrhoea	
Immune system disorders			Hypersensitivity reactions
Investigations	Weight gain	Increase in blood pressure	Weight loss
Metabolism and nutrition disorders		Fluid retention in body tissues	
Nervous system disorders	Headache	Migraine	
Psychiatric disorders	Depressed mood, mood swings	Effect on sex drive	
Reproductive system and breast disorders	Breast tenderness, breast pain, bleeding between periods	Breast enlargement	Breast secretion, change in vaginal secretion (e.g. increased discharge)
Skin and subcutaneous tissue disorders		Skin rash, hives, yellowish-brown patches on the skin (chloasma)	Red lumps beneath the skin (erythema nodosum), severe skin rash (erythema multiforme)

Furthermore, the following side effects have been reported with use of the pill:

- vascular occlusion (blockage) in the arteries due to blood clots,
- vascular occlusion (blockage) in the veins due to blood clots,
- stroke,
- high blood pressure,
- fat metabolism disorders (hypertriglyceridaemia),
- changes in glucose tolerance, effect on glucose and insulin balance, liver tumours (non-cancerous or cancerous), liver dysfunction,
- pigment disorders (chloasma)
- onset and worsening of the following disorders associated with taking the pill, but whose causes have not been definitely proven:
  - jaundice and/or itching due to bile accumulation,
  - galstones,
  - metabolic disorder with impaired haemoglobin production (porphyria),
  - a certain disease of the immune system (butterfly rash, systemic lupus erythematosus),
  - a certain blood disorder leading to kidney damage (haemolytic-uraemic syndrome),
  - Sydenham's chorea (chorea minor),
  - blistery rash that also occurs during pregnancy (herpes gestationis),
  - middle ear deafness caused by bone formation,
  - chronic inflammatory bowel disease (Crohn's disease and ulcerative colitis),
  - cervical cancer.
- If you suffer from hereditary angioedema, medicines that contain oestrogens can trigger or worsen symptoms of angioedema.

The frequency of breast cancer diagnoses is slightly increased in users of the pill. As breast cancer rarely occurs in women under 40 years of age, the number of additional breast cancer diagnoses is small in relation to the overall risk of developing breast cancer. For more information, see the section "The pill and cancer".

Sex hormones have an effect on breast tissue and potentially increase its sensitivity to other cancer-promoting factors. However, sex hormones are only one among several other possible risk factors not associated with taking hormonal contraceptives. Epidemiological studies that have investigated the possibility of a link between hormonal contraceptives and breast cancer are incon