



Contraceptive pills

Dienorette[®]

dienogest 2 mg/ethinylestradiol 0.03 mg




Dienorette®

You have been prescribed **Dienorette®**, which is a combined contraceptive pill. This means that it contains two types of hormones: oestrogen (ethinylestradiol) and progestin (dienogest).

A combined contraceptive pill prevents pregnancy in different ways:

- The ovulation from the ovaries will not take place
- The uterine lining will remain thin, which prevents a fertilized egg from attaching
- The secretion in the cervix will become thick and difficult for the sperm to penetrate.

Dienorette® is used for:

- preventing pregnancy
 - the treatment of moderate acne when local treatment or antibiotics have not improved the skin condition, for women who choose to use contraceptive pills.
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Dienorette® packaging information

Each blister pack contains 28 pills. The first 21 white pills (rows 1–3) contain hormones, while the following 7 green pills (row 4) are hormone-free. It is important that you first take the 21 white pills, and thereafter the green hormone-free pills for 7 days.

Take a pill marked as the current day of the week (shown on the adhesive strip that you place on the blister pack yourself, according to the instructions). **For example, if you start taking the pill on a Friday, take a pill marked as FRE (for fredag, Friday in Swedish)** by pushing the pill through the aluminum foil. Take one pill every day, in the order shown on the adhesive strip on the blister pack.

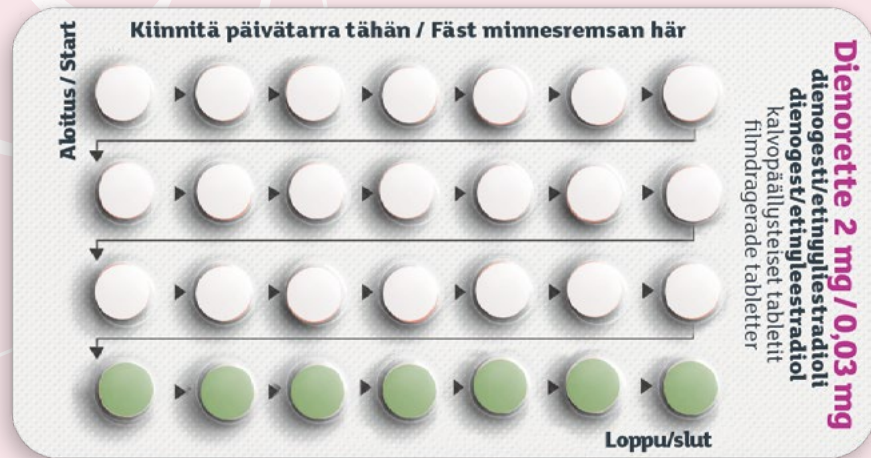


Start using Dienorette®

Dienorette® must be taken daily, at approximately the same time every day. The table below describes how to get started with **Dienorette®** from different starting points.

No previous hormonal contraceptives	Change from another hormonal combined contraceptive pill	Change from vaginal ring or contraceptive patch	Change from contraceptive pills that only contain progestin	Change from the implant, injections or hormonal IUD
Start using Dienorette® on the first day of your natural menstrual cycle (the first day of bleeding).	Start using Dienorette® on the day after you took the last active pill of your previous combined contraceptive pills.	Start using Dienorette® on the same day as you remove the vaginal ring or the contraceptive patch.	You can change from contraceptive pills that only contain progestin to Dienorette® at any time.	Start using Dienorette® on the same day as the implant or the hormonal IUD is removed, or when it is time for the next injection.
			NB! Use additional protection (e.g. a condom) during the first 7 days of using Dienorette®	NB! Use additional protection (e.g. a condom) during the first 7 days of using Dienorette®

Follow your doctor's/midwife's instructions if you start using contraceptive pills after using the emergency contraceptive pill, undergoing an abortion, giving birth, or for "quick start".



Bleeding

Intermittent bleeding

During the first months of using **Dienorette**[®], you may experience unplanned bleeding. These irregular bleedings will stop once your body adapts to the contraceptive pills (usually after 3 months). Contact your doctor/midwife if the bleeding becomes more severe (like your usual menstrual bleeding), or if it has persisted for several days.

Do you wish to postpone your menstrual bleeding?

You can postpone your menstrual bleeding by only taking the white active pills (not the green placebo pills in the fourth row), and then immediately starting a new blister pack of **Dienorette**[®] and completing the entire new blister pack. You may experience a light or menstrual-like bleeding while taking the second blister pack. Finish the second blister pack by taking the 7 green pills in the fourth row. Then start the next blister pack. Contact your doctor/midwife if you feel unsure.

Did you forget to take the pill?

If **less than 12 hours** have passed since you forgot the pill, Dienorette's contraceptive efficacy will not be affected. The pill should be taken as soon as possible, and the next pill should then be taken at the usual time.

If **more than 12 hours** have passed, the pills' contraceptive efficacy may be reduced. The impact on the contraceptive efficacy depends on where in the blister pack (which week) you forgot to take your pill. It does not matter if you forget to take one of the green placebo pills. In such a case, discard the forgotten pill.

Important! The risk of pregnancy is greater the more pills you have forgotten to take, and the closer you are to the end of the blister pack (the green pills) when you forget to take them. If you have forgotten 2 or more pills during your first week of use (the white pills), it is recommended that you contact your doctor/midwife for advice.

Did you forget to take the pill during the first week?

Take the forgotten pill as soon as you remember, even if this means taking two pills at the same time. Use additional protection (e.g. a condom) for the following 7 days. Continue with the pills in the blister pack. Use an emergency contraceptive pill if you have had intercourse within the last five days.

Did you forget to take the pill during the second week?

Take the forgotten pill as soon as you remember, even if this means taking two pills at the same time. Take the following pills at the usual time. The contraceptive pills will still have the desired effect, provided that you have taken the pills as intended during the 7 days prior to forgetting the pill, and you will not need to use additional protection. However, if you have missed taking more than one pill, you must use additional contraception (e.g. a condom) for 7 days.

Did you forget to take the pill during the third week?

You can choose between any of the following options. You do not need to use additional contraception, provided that you have taken the pills as intended for the 7 days prior to forgetting to take the pill:

1. Take the forgotten pill as soon as you remember, even if this means taking two pills at the same time. Take the following pills at the usual time. Rather than taking the green placebo pills in that blister pack, discard them and start the next blister pack.

Or

2. You can also stop your treatment of the active white pills and go directly to the green placebo pills (starting on the day that you forgot to take your pill). Thereafter, start using a new blister pack. If you wish to start a new blister pack on your fixed starting day, use the placebo pills for less than 7 days.

If you are experiencing diarrhea or severe vomiting

If you vomit within 3–4 hours after taking the pill, or if you experience severe diarrhea, the active substances of **Dienorette®** may not be absorbed completely. This situation is basically the same as having forgotten to take a pill. After vomiting or diarrhea, you must take a new pill from a reserve blister pack as soon as possible. If possible, take the pill within 12 hours of the time that you usually take your pill. If this is not possible, or if 12 hours have passed, you should follow the same recommendations provided in "Did you forget to take the pill?"

Important to consider!

Like other hormonal contraceptives, **Dienorette®** does not protect against HIV (AIDS) or other sexually transmittable diseases. Therefore, you should use a condom as additional protection if you are having intercourse with a new partner.

Side effects:

Like other contraceptive pills, **Dienorette®** can cause side effects, but not all users may experience them. The most commonly reported side effects are headache and chest pain. Less common side effects are e.g. irregular, heavy or missed menstrual bleeding, and mood swings. For other side effects, please read the packaging leaflet. Side effects will often subside, but if they don't, it is recommended that you contact your doctor/midwife.

Combined contraceptives and the risk of blood clots

The risk of having a blood clot increases with the use of all combined contraceptive pills, even if the risk is generally low. It is important that you are acquainted with which situations increase the risk of having a blood clot, which symptoms you will experience, and what to do should you get a blood clot.

The risk of having a blood clot is greatest:

- during the first year of using contraceptive pills, or when you start using the pills again after a break of at least 4 weeks
- if you are significantly overweight
- if you are above the age of 35
- if a close relative has had a blood clot
- if you have given birth within the last few weeks
- in connection with surgical procedures
- in the event of immobilization (long-term bed rest, plastered broken limbs)

If you are a smoker and over the age of 35, there are extra reasons to speak to your doctor for advice about smoking cessation or alternative contraception.

Immediately consult your doctor if you have any of the following symptoms:

- severe pain or swelling in an arm or a leg
- acute and unexplained respiratory distress or increased respiratory rhythm, severe chest pain or acute coughing
- chest pain, often abrupt
- muscle weakness or sensitivity in the face, an arm, or a leg (especially if this is on one side), difficulty speaking or understanding, acute confusion, acute loss of sight or blurry sight, severe headache/migraine that is more painful than usual

See FASS for complete information about **Dienorette®**: www.fass.se

Read the packaging leaflet carefully before using Dienorette®. It contains important information for you.

Dienorette® Dienogest/ethinylestradiol, 2 mg/0.03 mg, coated pills. Prescription medication with reimbursement. **Indication:** Contraception and moderate acne. **Dose:** One pill every day. **Warnings/caution:** Do not use Dienorette® if you have, or are suspected of having, cancer that is sensitive to sex hormones, a blood clot in a blood vessel or the lungs, impaired liver function, migraines with visual disturbances/loss of vision, or unexplained vaginal bleeding. Contact your doctor or midwife immediately if you experience any unusual symptoms, such as unexplained pain in your chest, abdomen or legs. The packaging leaflet contains information about risk factors and symptoms of blood clots, and information about situations in which you should stop using Dienorette®, or if the reliability of Dienorette® may be reduced. **Side effects:** Headache and breast pain. Some women who use hormonal contraception, including **Dienorette®**, have reported experiencing depression or malaise. If you notice that your mood changes, or if you experience symptoms of depression, you must immediately contact a doctor/midwife for medical advice. Other side effects: see the packaging leaflet and www.fass.se. Dienorette® contains lactose. Abbreviated information based on the packaging leaflet dated 16/08/2022.

If you experience any side effects, please speak to your doctor or midwife. This also applies to side effects not mentioned in this information.

Please note: This user guide is a translation into English of material initially produced in Swedish. It is aimed at supporting the counselling of non-Swedish-speaking patients. In case of doubts, please contact your prescriber.

Fact checked by Kristina Gemzell Danielsson, Professor of obstetrics and gynecology, April 2018.

