

More than a contraceptive pill*

Dienorette[®]

dienogest 2 mg/ethinyl estradiol 0,03 mg **21+7**

*) SPC

User guide

Dienorette®

– more than a contraceptive pill

You have been prescribed the combined contraceptive pill **Dienorette®** that is used for:

- **preventing pregnancy**
- **treating moderate acne** in women that have not benefited from applicable topical treatment or oral antibiotic treatment, and who choose an oral contraceptive product.

Dienorette® contains two hormones, estrogen (ethinyl estradiol 0,03 mg) and progestin (dienogest 2 mg).

In clinical trials **Dienorette®** has been shown to alleviate acne due to male hormones (androgens)

in a woman. Acne is alleviated ordinarily between 3 and 6 months from the start of treatment and recovery can continue six months afterwards, too.

Read this text carefully, and the package leaflet, before starting to use the product. If you have any questions, please get in touch with a public health care professional.

If no health risks arise, **Dienorette®** contraceptive pills can be used as long as a woman wants hormonal contraception.

Before you start

The **Dienorette®** package contains 3 blister sheets, each of which contains 28 film-coated tablets and 3 weekday sticker sheets, with the days of the week (Mon-Sun) marked on them.

The white tablets (21) contain the active ingredients and the green ones (7) are placebos that do not contain hormones.



How to start using **Dienorette**[®]

Use this drug exactly as it has been prescribed to you.

Start taking the tablets on the first day of your periods.

Choose the weekday sticker that starts from the day when you begin taking the tablets. Fix the suitable weekday sticker to “start” at the top of the blister sheet. **If you start, for example, on a Friday, choose the weekday sticker with FRI (=Friday) on the first day.** Now the day of the week can be seen above each tablet, enabling you to check whether you have taken a tablet daily.

Take all the tablets from the blister sheet by following the direction indicated by the arrow. Do not

mix the tablets; 1 white tablet once a day at roughly the same time, for the first 21 days and then one green tablet once a day for the final 7 days.

During those 7 days when you take the green placebos, menstrual bleeding should commence (known as withdrawal bleeding). It usually starts 2-3 days after the last white tablet is taken.

Contraceptive efficacy is maintained on those 7 days when you take the green placebos.

When you have taken the final green tablet, start the next blister sheet straightaway, regardless of whether bleeding has stopped or not.

When all the tablets on the blister sheet have been taken, go straight to the next blister sheet. **Do not take a break between the blister sheets.**

One **Dienorette**[®] tablet a day for 28 days.



Postponing menstrual bleeding (withdrawal bleeding)

If you want to postpone withdrawal bleeding, you should stop taking the green placebos and proceed straight to the white tablets on a new **Dienorette**[®] blister sheet, at “start”. Withdrawal bleeding can be postponed as long as you wish, but only until the end of the second blister sheet. In the meanwhile, breakthrough bleeding or spotting can occur.

Altering the starting date of menstrual bleeding

When you take the **Dienorette**[®] tablets according to the instructions, withdrawal bleeding starts every 4 weeks on roughly the same day. If you want to change this day, reduce the number of green placebos (never increase). If you usually start a new blister sheet on, for example, a Friday and want to change this day to Tuesday (3 days earlier) take only 4 green placebos and afterwards

take straightaway the first white tablet from a new blister sheet at “start”. If the placebo period is very short, bleeding does not necessarily occur at all during it. Afterwards breakthrough bleeding or spotting can occur.

Absence of menstrual bleeding during use of contraceptive pills

Some women do not necessarily experience withdrawal bleeding during the placebo period, or bleeding often becomes less frequent and may be completely absent. If the combination contraceptive pills have been used in accordance with the instructions, pregnancy is unlikely.

However, if the combination contraceptive pills have not been used in accordance with the instructions before the first absence of withdrawal bleeding or if two withdrawal bleedings are absent, carry out a pregnancy test before continuing to use the combination contraceptive pills.

Start with **Dienorette**[®]

In the table, you will find instructions on starting and switching from another contraceptive method.

No previous hormonal contraception	Switching from another hormonal combined contraceptive pill	Switching from a contraceptive ring or contraceptive patch	Switching from a minipill (containing only progestin)	Switching from an implant, injection or hormonal IUD
Dienorette [®] is started on the first day of the natural cycle (= first day of bleeding).	Dienorette [®] is started on the day following the taking of the final tablet containing active ingredients of the earlier combined contraceptive pills.	Dienorette [®] is started on the same day as the contraceptive ring or contraceptive patch is removed.	Dienorette [®] can be started at any time after tablets containing only progestin.	Dienorette [®] is started on the day of removal of the implant or hormonal IUD or on the next planned injection day.
You can start using the tablets also during the 2nd-5th days of the cycle, but then you must use additional contraception (e.g., a condom) for the first 7 tablet days.			N.B. additional contraception (e.g., a condom) for the first 7 Dienorette [®] tablet days.	

Follow your public health care professional's instructions if you start using contraceptive pills after use of an emergency contraceptive pill, abortion or birth, or in connection with a "quick start".



Did you forget a tablet?

If you forget to take one of the green placebos in row 4, it does not affect the contraceptive efficacy of the **Dienorette®** product. Dispose of the placebo that you forgot.

If you forget to take a white tablet containing the active ingredients on rows 1-3, proceed as follows:

If the tablet is **less than 12 hours late**, contraceptive efficacy has not weakened. Take the forgotten tablet as soon as you remember, and take the next tablets at the usual time.

If the tablet is **more than 12 hours late**, contraceptive efficacy may have weakened. The more tablets that you forget, the higher the risk of contraceptive efficacy weakening.

The risk is particularly high if you forget a tablet from the first or third row of the blister sheet. For that reason, follow the following instructions:

If you have forgotten one tablet on days 1-7 (first row of tablets):

Take the forgotten tablet as soon as you remember, even though it might mean taking two tablets at the same time. Continue taking the tablets at the usual time and employ additional contraception, e.g., a condom, during the next 7 days. If you have had intercourse in the week preceding forgetting the tablet, you can be pregnant. In this case, get in touch with the healthcare professional.

If you have forgotten one tablet on days 8-14 (second row of tablets):

Take the forgotten tablet as soon as you remember, even though it might mean taking two tablets at the same time. Continue taking the tablets at the usual time. Contraceptive efficacy is not weakened if the

tablets have been taken according to instructions during the 7 days preceding forgetting the tablet. Additional contraception does not need to be used. If you have forgotten more than one tablet, you must use additional contraception for 7 days.

If you have forgotten one tablet on days 15-21 (third row of tablets):

You can choose either of the following options. Additional contraception does not need to be used if the tablets have been taken according to instructions during the 7 days preceding forgetting the tablet.

1. Take the forgotten tablet as soon as you remember even though it might mean taking two tablets at the same time. Continue taking the tablets at the usual time. Instead of the green placebos, you should start taking the tablets from the next blister sheet. Menstruation will probably not occur until at the end of the second blister pack-

age. However, spotting or withdrawal bleeding can occur during use of the second blister package.

OR

2. You can alternatively stop taking the white active tablets from the blister sheet in use immediately and start taking the green placebos (starting from the day when you forgot to take a tablet). Proceed after the placebos to the white tablets on the next blister sheet. If you want to start a new blister sheet on the same day as usually, shorten the duration of the placebo period to fewer than 7 days.

If you have forgotten to take a tablet from the blister sheet and withdrawal bleeding does not start during the first placebo week (period for taking the green placebos), you may be pregnant. Get in touch with your physician or public health nurse before you start the next blister sheet.

What else should you take into account

If you vomit within 3-4 hours of taking a tablet or experience severe diarrhoea, the tablet's active ingredients are not necessarily absorbed properly into the body. The situation is almost the same as if you were to forget to take a tablet. If you vomit or experience diarrhoea, take a new tablet from the standby blister sheet as soon as possible.

If possible, take a new tablet within 12 hours of when you usually take a tablet. If this is not possible, or already more than 12 hours have passed, follow the instructions given in "Did you forget a tablet?".

Possible adverse effects

Like all contraceptive products, **Dienorette®** can also cause adverse effects. Not everyone, however, experiences them. The most common adverse effects are mood fluctuations, headache, nausea and tender breasts. If these adverse effects continue for long, please get in touch with the health care professional.

Combination contraceptive products and the risk of a blood clot

The overall risk of a blood clot associated with use of combination contraceptive products is low, lower than during e.g. pregnancy. It is very important for you to be able to identify situations when the risk of a blood clot may be greater than

usual, and for you to be aware of the kinds of symptoms to pay attention to and what to do if symptoms possibly occur.

The risk of a blood clot is at its highest:

- during the first year of use or when use is resumed after a break of at least 4 weeks
- if you are very overweight
- if you are over 35 and smoke
- if a close relative of yours has had a blood clot at a relatively young age (e.g., under the age of 50)
- if you have given birth in recent weeks

Observe possible symptoms of a blood clot, especially if

- you have just undergone surgery
- you have been bedridden for a long time
- you travel for long periods

Get in touch with the health care professional immediately if you notice one of the following symptoms:

- intense pain or swelling in one leg
- sudden unexplained shortness of breath or more frequent breathing, intense chest pain or a sudden cough
- chest pain that is often sudden
- weakening or numbness in the face, upper or lower extremities (especially if it occurs on only one side of the body), difficulties with speaking or understanding, sudden confusion, sudden loss or blurring of vision, intense and more severe headache/migraine
- If you end up, e.g., being treated in hospital, remember to mention that you use a contraceptive pill

The package leaflet contains more information on possible adverse effects.

This brochure can be ordered from
nordics@exeltis.com or
www.exeltis.fi



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