

DRETINE 28 0.03 mg/3 mg FILM-COATED TABLETS

Ethinylestradiol/Drospirenone

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

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The risk of a **venous blood clot** in users of combination pills increases:

- with increasing age
- if you are overweight
- if one of your close relatives has ever had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
- if you have to have surgery, if you have had a serious accident or if you are immobilized for a long time. It is important to tell your doctor that you are using Dretine as you may have to stop taking it. Your doctor will tell you when to start again. This is usually about two weeks after you are back on your feet.

Your chances of having a blood clot are increased by taking the Pill.

- Of 100,000 women who are not on the Pill and not pregnant, about 5-10 may have a blood clot in a year.
- Of 100,000 women taking a Pill like Dretine, 30-40 may have a blood clot in a year, the exact number is unknown.
- Of 100,000 women who are pregnant, around 60 may have a blood clot in a year.

A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2 % of cases.

The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options.

The use of combination pills has been connected with an increase of the risk of an **arterial blood clot (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of an **arterial blood clot** in users of combination pills increases:

- **if you smoke. You are strongly advised to stop smoking when you use Dretine 28, especially if you are older than 35 years**
- if the fat content of your blood is increased (cholesterol or triglycerides)
- if you are overweight
- if one of your close relatives ever had a heart attack or stroke at a young age
- if you have high blood pressure
- if you suffer from migraine
- if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm).

Q WHAT DRETINE 28 IS AND WHAT IT IS USED FOR

- Dretine 28 is a contraceptive pill and is used to prevent pregnancy.

- Each of the 21 yellow tablets contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.
- The 7 white tablets contain no active substances and are also called placebo tablets.
- Contraceptive pills that contain two hormones are called "combination" pills.



BEFORE YOU TAKE DRETINE 28

General notes

Before you can begin taking Dretine 28 your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Dretine 28, or where the reliability of Dretine 28 may be decreased. In such situations you should either not have sex or you should take extra non hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Dretine 28 alters the monthly changes of body temperature and of the cervical mucus.

Dretine 28, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

When you should not use Dretine 28 Do not take Dretine 28:

- if you have (or have ever had) a blood clot in a blood vessel of the leg (thrombosis), lung (pulmonary embolism) or other organs
- if you have (or have ever had) a heart attack or stroke
- if you have (or have ever had) a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects)

- if you have a disease that may increase the risk of a blood clot in the arteries. This applies to the following diseases:
- diabetes with damaged blood vessels
- very high blood pressure
- a very high level of fat in the blood (cholesterol or triglycerides)
- if you have a disturbance of blood clotting (for example, protein C deficiency)
- if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms)
- if you have (or have ever had) an inflammation of the pancreas (pancreatitis)
- if you have (or have ever had) a liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of Dretine 28. This may cause itching, rash or swelling.

When to take special care with Dretine 28

In some situations you need to take special care while using Dretine 28 or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, tell your doctor before starting to use Dretine 28. Also, if any of the following applies or if any of the conditions develops or worsens while you are using Dretine 28 consult your doctor if:

- a close relative has or has ever had breast cancer
- you have a disease of the liver or the gallbladder
- you have diabetes
- you have depression
- you have Crohn's disease or inflammatory bowel disease (ulcerative colitis)

- you have a blood disease called HUS (haemolytic uraemic syndrome) which causes kidney damage
- you have a blood disease called sickle cell anaemia
- you have epilepsy (see "Dretine 28 and using other medicines")
- you have a disease of the immune system, called SLE (systemic lupus erythematosus)
- you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a disease of the nerves in which sudden movements of the body occur (Sydenham's chorea))
- you have or have ever had chloasma (a discolouration of the skin especially of the face or neck known as "pregnancy patches"). If so, avoid direct sunlight or ultraviolet light
- you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing, or hives together with difficulty breathing.

Dretine 28 and venous and arterial blood clots

The use of any combination pill, including Dretine, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women who do not take any contraceptive pill.

Stop taking Dretine 28 and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak

- giddiness or fainting
- weakness, strange feeling, or numbness in any part of the body.

Dretine 28 and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Bleeding between periods

During the first few months that you are taking Dretine 28, you may have unexpected bleeding (bleeding outside the week when you are taking the white tablets). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What to do if no bleeding occurs during the placebo days

If you have taken all the yellow active tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

Dretine 28 and using other medicines

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Dretine 28. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can make Dretine less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

- medicines used for the treatment of:
- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)

- tuberculosis (e.g. rifampicin)
- HIV infections (ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
- high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort.

Dretine 28 may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

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

Taking Dretine 28 with food and drink

Dretine 28 may be taken with or without food, if necessary with a small amount of water.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormone contraceptives can affect the results of some tests.

Pregnancy

If you are pregnant, do not take Dretine 28. If you become pregnant while taking Dretine 28 stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Dretine 28 at any time (see also "If you want to stop taking Dretine 28").

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

Use of Dretine 28 is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast-feeding you should contact your doctor. **Ask your doctor or pharmacist for advice before taking any medicine.**

Driving and using machines

There is no information suggesting that use of Dretine 28 affects driving or use of machines.

Important information about some of the ingredients of Dretine 28

Dretine 28 contains **lactose**.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Q HOWTO TAKE DRETINE 28

Each blister contains 21 active yellow tablets and 7 white placebo tablets. The 7 white placebo tablets are enclosed by a box printed on the blister.

The two differently coloured tablets of Dretine 28 are arranged in order. A strip contains 28 tablets.

Take one tablet of Dretine 28 every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

One strip contains 28 tablets, each marked with a day of the week. Start by taking a yellow active tablet from the 1st row marked with the correct day of the week. If, for example, you start on Wednesday, you should take a yellow tablet from the first row, labelled "WED7". Continue by taking one yellow tablet marked with the correct day of the week each day until you have taken all 21 yellow tablets. Then move on to the boxed area of the blister and take one white placebo tablet each day for the last 7 days, following the correct days of the week. **Do not confuse the tablets:** take a yellow tablet once per day for the first 21 days, and then one white tablet per day for the last 7 days. When you have taken all 28 tablets you should start a new strip (21 yellow tablets and 7 white tablets). Consequently there is no drug-free interval between strips.

During the 7 days when you are taking the white placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last yellow active tablet of Dretine 28. Once you have taken the last white tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.

If you use Dretine 28 in this manner, you are protected against pregnancy also during the 7 days when you are taking a placebo tablet.

When can you start with the first strip?

- **If you have not used a contraceptive with hormones in the previous month**

Begin with Dretine 28 on the first day of the cycle (that is, the first day of your period). If you start Dretine 28 on the first day of your period you are

immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

- **Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch**

You can start Dretine 28 preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.

- **Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)**

You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

- **After a miscarriage**

Follow the advice of your doctor.

- **After having a baby**

You can start Dretine 28 between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Dretine 28 use.

If, after having a baby you have had sex before starting Dretine 28 (again), be sure that you are not pregnant or wait until your next period.

- **If you are breast-feeding and want to start Dretine 28 (again) after having a baby** Read the section on "Breast-feeding"

Ask your doctor what to do if you are not sure when to start.

If you take more Dretine 28 than you should

There are no reports of serious harmful results of taking too many Dretine 28 tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

If you have taken too many Dretine 28 tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Dretine 28

The white tablets in the 4th row of the strip are the placebo tablets. These are enclosed by a box which is printed on the blister. If you forget one of these tablets, this has no effect on the reliability of Dretine 28. Throw away the forgotten placebo tablet. If you miss a yellow, active tablet from the **1st, 2nd or 3rd row**, do as follows:

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced.

The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see the diagram below):

- **More than one tablet forgotten in this strip.**

Contact your doctor.

- **One tablet forgotten in week 1.**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use **extra precautions** for the next **7** days, for example, a condom. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.

- **One tablet forgotten in week 2.**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

- **One tablet forgotten in week 3.**

You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away, and start the next strip.

Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.

2. You can also stop the active yellow tablets and go directly to the 7 white placebo tablets (**before taking the placebo tablets, record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, take the placebo tablets for **less than 7 days**.

If you follow one of these two recommendations, you will remain protected against pregnancy.

- If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the normal placebo days, you may be pregnant. Contact your doctor before you start the next strip.

What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking an active yellow tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another yellow tablet from a reserve strip as soon as possible. If possible, **take it within 12 hours** of when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Dretine 287

Delaying your period: what you need to know

Even though it is not recommended, you can delay your period by not taking the white placebo tablets from the 4th row and going straight to a new strip of Dretine 28 and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 7 white tablets from the 4th row. Then start your next strip.

You might ask your doctor for advice before deciding to delay your menstrual period.

Changing the first day of your period: what you need to know

If you take the tablets according to the instructions, then your period will begin **during the placebo week**. If you have to change this day, reduce the number of placebo days (**but never increase them - 7 is the maximum!**). For example, if you normally start taking the placebo tablets on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the placebo interval very short (for example, 3 days or less) you may not have any bleeding during these days. You may then experience light or menstruation-like bleeding.

If you are not sure what to do, consult your doctor.

If you want to stop taking Dretine 28

You can stop taking Dretine 28 whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Dretine 28 and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Q POSSIBLE SIDE EFFECTS

Like all medicines, Dretine 28 can cause side effects, although not everybody gets them.

The following is a list of the side effects that have been linked with the use of Dretine 28:

Common side effects (between 1 and 10 in every 100 users may be affected):

- menstrual disorders, bleeding between periods, breast pain, breast tenderness
- headache, depressive mood
- migraine
- nausea
- thick, whitish vaginal discharge and vaginal yeast infection.

Uncommon side effects (between 1 and 10 in every 1,000 users may be affected):

- changes in interest in sex
- high blood pressure, low blood pressure
- vomiting
- acne, skin rash, severe itching
- infection of the vagina
- fluid retention and body weight changes.

Rare side effects (between 1 and 10 in every 10,000 users may be affected):

- allergic reactions (hypersensitivity), asthma
- breast secretion
- hearing impairment

- blockage of a blood vessel by a clot formed elsewhere in the body
- the skin conditions erythema nodosum (characterized by painful reddish skin nodules) or erythema multiforme (characterized by rash with target-shaped reddening or sores).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet or if you think that this may be the case, please tell your doctor or pharmacist.



HOWTO STORE DRETINE 28

Keep Dretine 28 out of the reach and sight of children.

This medicinal product does not require any special storage conditions. **Expiry date**

Do not use Dretine 28 after the expiry date which is stated on the blister and package after the phrase "Do not use after:" or "EXP:"

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



FURTHER INFORMATION

What Dretine 28 contains

A strip of Dretine 28 contains 21 yellow active tablets in the 1st, 2nd and 3rd rows of the strip and 7 white placebo tablets in row 4. The 7 white placebo tablets in row 4 are enclosed by a box printed on the blister.

Active tablets

The active ingredients are ethinylestradiol 0.03 mg and drospirenone 3 mg. The other ingredients are:

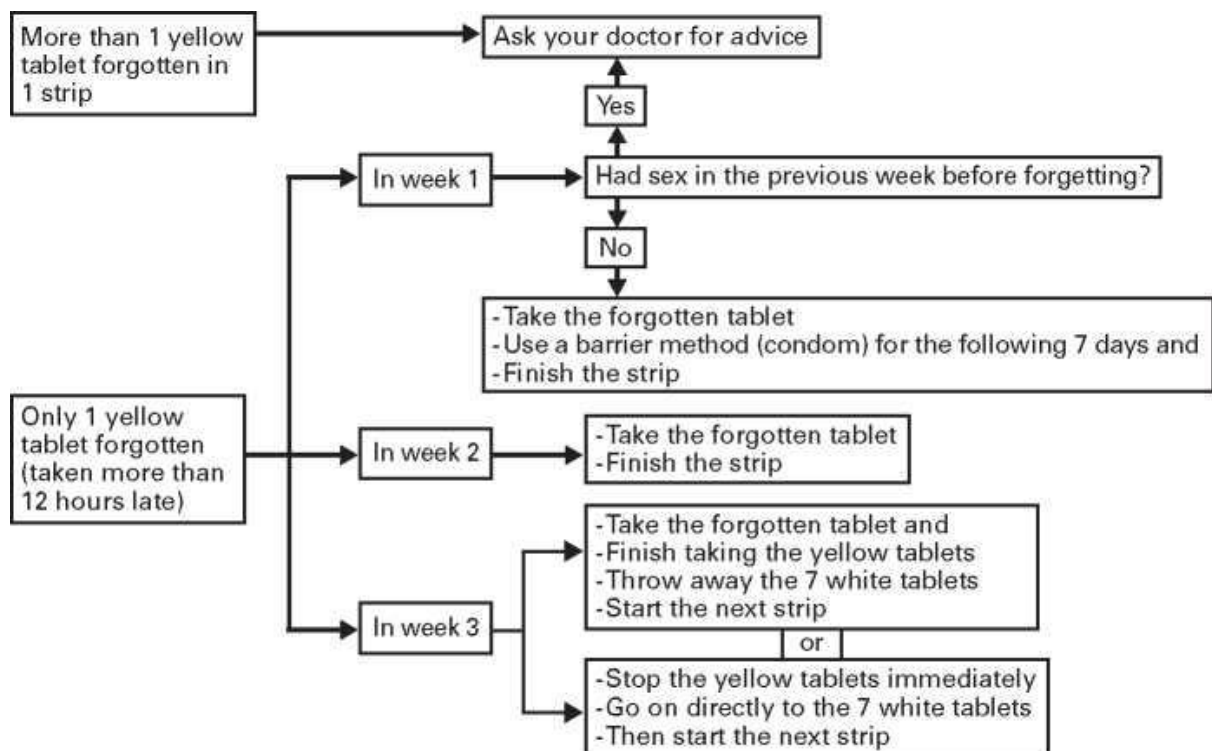
Tablet core: lactose monohydrate, maize starch, pregelatinised starch (maize), crospovidone, povidone, polysorbate 80, magnesium stearate.

Coating: Polyvinyl alcohol partial hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172).

Placebo tablets

Tablet core: lactose anhydrous, povidone, magnesium stearate.

Coating: Polyvinyl alcohol partial hydrolyzed, titanium dioxide (E171), macrogol 3350, talc.



What Dretine 28 look like and contents of the pack

Active tablets are yellow, round film-coated tablets.

Placebo tablets are white, round film-coated tablets.

Dretine 28 is available in boxes of 1, 2, 3, 6 and 13 blisters, each one containing 28 tablets (21 active plus 7 placebo tablets).

Not all package sizes may be marketed!

Marketing Authorisation Holder

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