



Package leaflet: Information for the user

NACREZ
75 micrograms FILM-COATED TABLETS
Desogestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Nacrez is and what it is used for
2. What you need to know before you take Nacrez
3. How to take Nacrez
4. Possible side effects
5. How to store Nacrez
6. Contents of the pack and other information

1. What Nacrez is and what it is used for

Nacrez is used to **prevent pregnancy**. It contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason Nacrez is called a progestogen-only-pill (POP), or a **mini-pill**. Contrary to the combined pill, the POP or mini-pill does not contain an oestrogen hormone next to the progestogen.

Most POPs or mini-pills work primarily by preventing the sperm cells from entering the womb. They do not always prevent the egg cell from ripening, which is the primary action of combined pills. Nacrez is distinct from other mini-pills in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, Nacrez provides high contraceptive efficacy.

In contrast to the combined pill, Nacrez can be used by women who do not tolerate oestrogens and by women who are breast-feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Nacrez. You also may not have any bleeding at all.

2. What you need to know before you take Nacrez

Do not take Nacrez

- if you are **allergic** to desogestrel or any of the other ingredients of this medicine (listed in section 6)
- if you have a **thrombosis**. Thrombosis is the formation of a blood clot in a blood vessel (e.g. of the legs (deep venous thrombosis) that can among others migrate into the lungs and cause a pulmonary embolism)
- if you have or have had **jaundice** (yellowing of the skin) or **severe liver disease** and your liver function is still not normal
- if you have or are suspected to have a **cancer** that is sensitive to sex-steroids, such as certain types of breast cancer
- if you have any **unexplained vaginal bleeding**.

Tell your doctor before you start to use Nacrez if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of birth control. Consult your doctor immediately if any of these conditions appear for the first time while using Nacrez.

Take special care with Nacrez

- if you have ever had **breast cancer**
- if you have **liver cancer**, since a possible effect of Nacrez on liver cancer cannot be excluded
- if you have a **reduced liver function**
- if you have ever had a **thrombosis**
- if you have **diabetes**
- if you suffer from **epilepsy** (see section 2 "Other medicines and Nacrez")
- if you suffer from **tuberculosis** (see section 2 "Other medicines and Nacrez")
- if you have **high blood pressure** or your blood pressure increases significantly
- if you have or have had **chloasma** (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation.

Please tell your doctor if one of these conditions applies to you.

When Nacrez is used in the presence of any of these conditions, you may need to be kept under close observation. Your doctor can explain what to do.

Regular Check-ups

When you are using Nacrez, your doctor may tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible

- if you have **severe pain or swelling in either of your legs**, unexplained **pain in the chest**, **breathlessness**, an unusual cough, especially when you **cough up blood** (possibly indicating a thrombosis or an embolism respectively)
- if you have a sudden, **severe stomach ache** or **look jaundiced** (possibly indicating liver problems)
- if you feel a **lump in your breast** (possibly indicating breast cancer)
- if you have a sudden or **severe pain in the lower abdomen or stomach area** (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb)
- if you are to be **immobilised** or are to have **surgery** (consult your doctor at least four weeks in advance)
- if you have **unusual, heavy vaginal bleeding**
- if you suspect that you are **pregnant**.

Breast cancer

Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.



Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill, the risk gradually decreases. 10 years after stopping the risk is the same as for women who have never taken the Pill. Breast cancer is rare under 40 years of age but the risk increases as the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if the age until which the woman continues to take the Pill is higher. How long she takes the Pill is less important.

In every 10,000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group. Likewise, in 10,000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed. In 10,000 women who take the Pill for up to 5 years but stop taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.

The risk of breast cancer in users of progestogen-only pills like Nacrez is believed to be similar to that in women who use pills that also contain oestrogens (combined pills), but the evidence is less conclusive. Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill. It is not known whether the difference in breast cancer risk is caused by the Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

Thrombosis

See your doctor immediately, if you notice possible signs of a thrombosis. For signs, see "Contact your doctor as soon as possible," first bullet.

Thrombosis is the **formation of a blood clot, which may block a blood vessel**. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs. This causes a so-called "pulmonary embolism". As a result, life-threatening situations can occur, which may lead to death. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.

The risk of getting a thrombosis is higher in Pill-users than in non-users. The difference in the risk of getting a thrombosis with progestogen-only pills like Nacrez compared to Pills that also contain oestrogens (combined Pills) is unknown.

Children and adolescents under 18 years

There is not enough information about the use of Desogestrel in children and adolescents under 18 years.

Other medicines and Nacrez

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may stop Nacrez from working properly and may lead to unexpected bleeding or being less effective in preventing pregnancy. These include medicines used for the treatment of -

- **epilepsy** (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate and phenobarbital)
- **tuberculosis** (e.g. rifampicin, rifabutin)
- **HIV infections** (e.g. ritonavir, nelfinavir)
- or **other infectious diseases** (e.g. griseofulvin), **stomach upset** (medical charcoal), **depressive moods** (the herbal remedy St. John's wort)
- in case of transplantations (e.g. ciclosporin).

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 Nacrez. They can tell you if you need to take **additional contraceptive precautions** (for example condoms) and if so, for how long. Nacrez may also affect the mode of action of certain medicines in the body, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

Nacrez with food and drink

You can take Nacrez with or without food and drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do **not** use Nacrez if you are pregnant, or think you might be pregnant.

Breast-feeding

Nacrez may be used while you are breast-feeding. If you are breast-feeding and want to use Nacrez, please contact your doctor.

Driving and using machines

Nacrez has no influence on your ability to drive or using machines.

Nacrez contains lactose

Nacrez contains **lactose (milk sugar)**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Original Artwork Scale = 1:1 (100%)
50mm

3. How to take Nacrez

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

- the Nacrez pack contains **28 tablets**
- take **one tablet daily**
- **swallow the tablet whole** with a sufficient amount of water.

Arrows are printed on the front side of the pack between the tablets. If you turn over your pack and look at the back side, you will see the days of the week printed on the foil. Each day corresponds with one tablet. Every time you start a new pack of Nacrez, take a tablet from the top row. **Don't start with just any tablet.** For example if you start on a Wednesday, you must take the tablet from the top row marked (at the back) with "Wed". Continue to take one tablet a day until the pack is empty. **Always follow the direction indicated by the arrows.** By looking at the back of your pack you can easily check if you have already taken your tablet on a particular day.

Take your tablet each day at about the same time so that **the interval between two tablets is always 24 hours.** You may have some bleeding during the use of Nacrez, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of Nacrez on the next day - thus without interruption and without waiting for a bleed.

Starting your first pack of Nacrez

• When no hormonal contraceptive has been used in the past month

Wait for your period to begin. On the first day of your period take the first Nacrez tablet. You need not take extra contraceptive precautions. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method, for example a condom) for the first 7 days of tablet-taking.

• When changing from a combined pill, vaginal ring, or transdermal patch

You can start taking Nacrez on the day after you take the last tablet from the present Pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free interval). If your present Pill pack also contains inactive tablets you can start Nacrez on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, you need not take extra contraceptive precautions. You can also start at the latest on the day following the tablet-, ring-, patch-free interval, or after the intake of the inactive tablets of your present contraceptive. If you follow these instructions, make sure you use an additional contraceptive method (barrier method, for example a condom) for the first 7 days of tablet-taking.

• When changing from another progesteron-only containing pill (mini pill) to Nacrez

You may stop taking it any day and start taking Nacrez right away. You need not take extra contraceptive precautions.

• When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD) to Nacrez

Start using Nacrez when your next injection is due or on the day that your implant or your IUD is removed. You need not take extra contraceptive precautions.

• After having a baby

After delivery you can start taking Nacrez before your menstrual bleeding returns. If you start later than 21 days after delivery, make sure you use during the first cycle an additional contraceptive method (barrier method, for example a condom) for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy must be excluded before starting Nacrez use.

• After a miscarriage or an abortion

Your doctor will advise you.

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

If you take more Nacrez than you should

There have been no reports of serious harmful effects from taking too many desogestrel-containing tablets at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For more information ask your doctor for advice.

If you forget to take Nacrez

If you are **less than 12 hours late** in taking a tablet, the reliability of Nacrez is maintained. Take the missed tablet as soon as you remember and take the next tablet at the usual time.

If you are **more than 12 hours late** in taking any tablet, the reliability of Nacrez may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. Take the last missed tablet as soon as you remember and take the next tablets at the usual times. This means that you possibly take 2 tablets on one day. Use an **additional contraceptive method (such as condoms)** too for the next 7 days of tablet-taking.

If you missed one or more tablets in the first week of tablet-intake and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

If you suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea)

If you **vomit** or have **severe diarrhoea** or if you use **medical charcoal** within 3-4 hours after taking your Nacrez tablet, the active ingredient may not have been completely absorbed and the reliability of Nacrez may be reduced. In such a case you need **additional contraceptive methods (such as condoms)** for the next 7 days. Take the next tablet at the usual time.

If you stop taking Nacrez

You can stop taking Nacrez whenever you want. From the day you stop you are **no longer protected against pregnancy.**

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious undesirable effects associated with the use of Nacrez are described in the paragraphs "Breast cancer" and "Thrombosis" in section 2 "What you need to know before you take Nacrez". Please read this section for additional information and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals during the use of Nacrez. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Nacrez is decreased. In general, you need not take any action. Just continue to take Nacrez. If, however, bleeding is heavy or prolonged you should consult your doctor.

The side effects rating was based on the following frequency data:

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people
Not known:	frequency cannot be estimated from the available data

Users of desogestrel have reported the following side effects:

Common	Mood altered, decreased sexual drive (libido) , depressed mood (feeling sad more than usual) Headache Nausea Acne Breast pain, irregular or no menstruation Increased body weight
Uncommon	Infection of the vagina Difficulties in wearing contact lenses Vomiting Hair loss Painful menstruation, ovarian cyst Tiredness
Rare	Rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin conditions)

Apart from these side effects, breast secretion may occur.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Nacrez

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nacrez contains

- The active substance is desogestrel. Each film-coated tablet contains 75 micrograms of desogestrel.
- The other ingredients are: lactose monohydrate (see also "Nacrez contains lactose" in section 2), maize starch, povidone K30, stearic acid, all-rac-alpha-tocopherol, silica, colloidal anhydrous, hypromellose, macrogol 400, talc, titanium dioxide.

What Nacrez looks like and contents of the pack

Nacrez tablets are white to off white, circular, biconvex film-coated tablets of 5.4-5.8 mm diameter without embossing.

One blister pack of Nacrez contains 28 film-coated tablets. Each carton contains 1, 3 or 6 blister packs, each blister pack may or may not be separately packed in a pouch.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

TEVA UK Limited, Eastbourne, BN22 9AG, UK.

Manufacturer:

Cemelog-BRS Ltd., Vasut u. 13., 2040 Budaörs, Hungary.

This leaflet was last revised in 07/2012

PL 00289/1706



21226-B
212074.01-GB
APPDG22
01