

Package leaflet: Information for the user
Vinelle 75 micrograms 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, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Vinelle is and what it is used for

Vinelle is used to prevent pregnancy. Vinelle contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason Vinelle 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 but they do not always prevent the egg cell from ripening, which is a difference from the combined pills.

Vinelle 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, Vinelle provides high contraceptive efficacy.

In contrast to the combined pill, Vinelle tablets 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 Vinelle. You also may not have any bleeding at all.

2. What you need to know before you take Vinelle

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

Do not take Vinelle

- 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) or the lungs (pulmonary embolism)).
- if you have or have had jaundice (yellowing of the skin) or severe liver disease and your liver function is still not working normal.
- if you have or if you are suspected of having 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 Vinelle 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 Vinelle.

Warnings and precautions

Talk to your doctor before you start to use Vinelle, if:

- you have ever had breast cancer.
- you have liver cancer, since a possible effect of Vinelle cannot be excluded.
- you have ever had a thrombosis.
- you have diabetes.
- you suffer from epilepsy (See section 'Other medicines and Vinelle').
- you suffer from tuberculosis (See section 'Other medicines and Vinelle').
- you have high blood pressure.
- 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.

When you use Vinelle in the presence of any of these conditions, you may need to be kept under close observation by your doctor. Your doctor can explain what to do.

Breast cancer

- It is important to regularly check your breasts and you should 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, so that 10 years after stopping the Pill, 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. 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 Vinelle is believed to be similar to that in women who use the Pill, 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 was noticed earlier.

Thrombosis

See your doctor immediately if you notice any possible signs of a thrombosis (see also 'Regular check-ups').

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, causing a so-called “pulmonary embolism”. As a result, fatal situations may occur. 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 is higher in Pill-users than in non-users. The risk with progestogen-only pills like Vinelle tablets is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

Psychiatric disorders

Some women using hormonal contraceptives including Vinelle have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Children and adolescents

No clinical data on efficacy and safety are available in adolescents below 18 years.

Other medicines and Vinelle

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take Vinelle. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Some medicines:

- can have an influence on the blood levels of Vinelle
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

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 infection (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)
- Hepatitis C virus infection (e.g. boceprevir, telaprevir)
- other infectious diseases (e.g. griseofulvin)
- high blood pressure in the blood vessels of the lungs (bosentan) depressive moods (the herbal remedy St. John's Wort)
- certain bacterial infections (e.g. clarithromycin, erythromycin)
- fungal infections (e.g. ketoconazole, itraconazole, fluconazole)
- high blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem).

If you are taking medicines or herbal products that might make Vinelle less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Vinelle may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

Vinelle may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing ciclosporine) or a decrease in effect (e.g. lamotrigine).

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

Pregnancy and breast-feeding

Pregnancy

Do not use Vinelle if you are pregnant, or think you may be pregnant.

Breast-feeding

Vinelle may be used while you are breast-feeding. Vinelle does not appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using Vinelle. A small amount of the active substance of Vinelle passes over into the milk.

The health of children who were breast-fed for 7 months while their mothers were using another desogestrel-only pill has been studied up to 2.5 years of age. No effects on the growth and development of the children were observed.

If you are breast feeding and want to use Vinelle, please contact your doctor.

Driving and using machines

There are no indications of any effect of the use of Vinelle on alertness and concentration.

Vinelle contain 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.

Regular check-ups

When you are using Vinelle, your doctor will 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 pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a **thrombosis**);
- you have a sudden, severe stomach ache or jaundice (possibly indicating **liver problems**);
- you feel a lump in your breast; (possibly indicating **breast cancer**)
- 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);
- you are to be immobilised or are about to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are **pregnant**.

3. How to take Vinelle

When and how to take the tablets?

Each blister pack of Vinelle contains 28 tablets. This is 4 weeks supply.

Take your tablet each day at about the same hour. Swallow the tablet whole, with water.

Arrows are printed on the front of the blister pack, between the tablets. The days of the week are printed on the back of the blister pack. Each day corresponds with one tablet.

Every time you start a new blister pack of Vinelle, 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 (on the back) with WED. Continue to take one tablet every day until the pack is empty, always following 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.

You may have some bleeding during the use of Vinelle, but you must continue to take your tablets as normal. When a blister pack is empty, you must start with a new blister pack of Vinelle on the next day - without interruption and without waiting for a bleed.

Starting your first pack of Vinelle

- **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 Vinelle tablet. You do not need to take additional contraceptive precautions.

You may also take your first tablet on days 2 to 5 of your cycle. In this case use an additional barrier method of contraception (such as condom) for the first 7 days of tablet-taking.

- **When changing from a combined pill (COC), vaginal ring, or transdermal patch**

You can start using Vinelle 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 break). If your present Pill pack also contains inactive tablets you can start Vinelle 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 the day following the tablet-, ring-, patch-free break, or placebo tablet interval, of your present contraceptive. If you follow these instructions, make sure you use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

- **When changing from another progestogen-only pill (mini-pill)**

Switch on any day from another mini pill. Additional contraceptive precautions are not necessary.

- **When changing from an injection, implant or a hormonal Intrauterine device (IUS)**

Start using Vinelle when your next injection is due or on the day that your implant or you IUS is removed. Additional contraceptive precautions are not necessary.

- **After having a baby**

You can start taking Vinelle between 21 to 28 days after the birth of your baby.

If you start later, make sure that during the first cycle you use an additional barrier method of contraception (such as condom) for the first 7 days of tablet-taking. However, if you have already had intercourse, you should make sure that you are not pregnant before you start using Vinelle.

Information for breast-feeding women can be found in section 2 “What you need to know before you take Vinelle” in the paragraph “Pregnancy and breast-feeding”. Your doctor can also advise you.

- **After having a miscarriage or an abortion**

Your doctor will advise you.

If you forget to take Vinelle

- **If you are less than 12 hours late:**

Take the missed tablet as soon as you remember and take the next one at the usual time. Vinelle will still protect you from pregnancy.

- **If you are more than 12 hours late:**

If you are more than 12 hours late in taking any tablet, you may not be completely protected against pregnancy. The more consecutive tablets you have missed, the higher the risk that you might fall pregnant. Take the tablet as soon as you remember and take the next one at the usual time. This may mean taking two tablets in one day. Continue to take your tablets as usual but you must also use an extra contraceptive method, such as a condom, for the next 7 days. If you missed one or more tablets in the very first week of tablet-intake and had intercourse in the week before missing the tablets, you may fall pregnant. Ask your doctor for advice.

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

Follow the advice for forgotten tablets in the section above. If you vomit within 3-4 hours after taking your Vinelle tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed.

If you take more Vinelle than you should

There have been no reports of serious harmful effects from taking too many Vinelle 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 stop taking Vinelle

You can stop taking Vinelle 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor if you notice any unwanted effect, especially if severe or persistent.

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

You should see your doctor immediately if you experience allergic reactions (hypersensitivity), including swelling of the face, lips, tongue, and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis).

Vaginal bleeding may occur at irregular intervals during the use of Vinelle. This may be just slight staining which might 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. Irregular bleeding is not a sign that the contraceptive protection of Vinelle is decreased. In general, you do not need to not take any action; just continue to take Vinelle.

If, however, bleeding is heavy or prolonged you should consult your doctor.

Other side effects

Common (may affect up to 1 in 10 women)

- mood altered
- depressed mood
- decreased sexual drive (libido)
- headache
- nausea
- acne
- breast pain
- irregular or no menstruation
- weight increase.

Uncommon (may affect up to 1 in 100 women)

- infection of the vagina
- difficulties in wearing contact lenses
- vomiting
- hair loss
- painful menstruation
- ovarian cysts
- tiredness.

Rare (may affect up to 1 in 1000 women) skin conditions such as

- rash
- hives
- painful blue-red skin lumps (*erythema nodosum*).

Not known (cannot be estimated from the available data)

- allergic reaction

Apart from these side effects, breast secretion may occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Vinelle

Keep this medicine out of the sight and reach of children.

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

Vinelle does not require any special storage conditions.

The active substance shows an environmental risk to fish.

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 Vinelle contains

The active substance is desogestrel. Each tablet contains 75 micrograms of desogestrel.

The other ingredients are: Lactose anhydrous, all-rac- α -tocopherol, Povidone, Potato starch, Silica colloidal anhydrous, Stearic acid.

(See also 'Vinelle contain lactose' in section 2).

What Vinelle look like and contents of the pack

Each tablet is round, uncoated, biconvex, debossed with '152' on one side and other side plain. Each box of Vinelle contains 1, 3, 6 or 13 blisters pack of 28 tablets each.

Each carton contains blisters packed separately in an aluminium laminated sachet.

Packs may be marketed with or without a desiccant. Not all pack sizes may be marketed.

Marketing Authorization Holder

<To be completed nationally.>

Manufacturer

<To be completed nationally.>

This leaflet was last revised in 2021-01-21

Detailed information on this medicine is available on the website of {name of MS Agency (link)}.