For users of **Vinelle**®

(desogestrel)

This is Vinelle

Vinelle is a contraceptive tablet which prevents you from becoming pregnant, provided you use it correctly. Vinelle contains small amounts of female sex hormone, the progestin desogestrel. Vinelle is therefore called a progestin-only contraceptive tablet. Unlike combined contraceptive tablets, Vinelle contains no oestrogen.

Vinelle prevents pregnancy as follows:

- Ovulation does not take place.
- The endometrium remains thin and does not fill with blood, which means that an egg is not able to attach.
- The secretion in the cervix thickens, making it difficult for sperm to penetrate.

Before using Vinelle:

- Carefully read the package leaflet in the packaging.
- · Contact your midwife or doctor if you have any questions.

Your normal menstrual cycle

In order to understand how Vinelle works, it is also important that you know how your normal menstrual cycle works. Once a month an egg is released from one of your ovaries. The endometrium prepares itself to receive the egg by filling with blood and becoming stronger in order for the egg, if fertilised, to get the nourishment it needs to grow into a foetus. If the egg is not fertilised, it will be ejected after 14 days together with the newly formed endometrium in the womb. The bleeding that arises is called a period. A normal period lasts 3-8 days. The entire menstrual cycle, from the beginning of the bleed to the next bleed, is usually 28 days, but varies among women from 21 up to 35 days. Ovulation can take place between days 9 and 20 in a 28-day cycle.

Note:

Contraceptive tablets do not provide protection against sexually transmitted diseases, so you should use condoms as extra protection if you meet a new partner.



The Vinelle packaging contains 3 or 6 blister packs with 28 tablets each. The days of the week are printed on each blister pack.

How to use Vinelle

- If you take the first tablet on the first day of your menstruation, you will be protected from pregnancy from day one. You can also begin taking Vinelle on day 2-5 of your menstrual cycle, but you will then have to use an extra contraceptive method (such as a condom) for the first 7 days.
- If you start taking Vinelle after giving birth or if you switch to Vinelle from another hormonal contraceptive, read the information on the package insert.
- To achieve full protection, you should take the tablets regularly at about the same time each day. Take the tablet together with a little liquid.
- On the front of the blister pack, there are arrows printed between the tablets. On the back, the days of the week are printed on the foil. Each tablet corresponds to a day of the week.



If you start on a Wednesday, for example, you should start with a tablet marked "O/K".

- Each time you start a new blister pack, you should take a tablet from the top row. If, for instance, you start on a Wednesday, you should take the tablet marked Wednesday (marked "O/K" on the blister pack).
- Continue taking one tablet daily until the pack is empty, following the direction of the arrows at all times. By checking on the back of the pack, you can always easily see whether you have already taken your tablet for the day.
- You may have bleeding when using Vinelle, but you should continue to take the tablets as usual.
- When the blister pack is empty, start on a new pack the following day, without waiting for bleeding. Begin the next blister pack on the same day of the week as the previous blister pack.

Speak to your midwife or doctor if you feel unsure about anything.



What if I forget to take a tablet?

Less than 12 hours late:

Take the missed tablet as soon as you remember to do so, and take the next tablet at the usual time. You are then protected against pregnancy.

More than 12 hours late:

If you are more than 12 hours late, i.e. more than 36 hours have passed since you took the last tablet, you may no longer be protected. Take the tablet as soon as you remember, and take the next dose at the usual time. Continue to take the tablets as usual, but you should also use an extra contraceptive, such as a condom, for the next 7 days.

If you have missed one or more tablets in the first week and you had intercourse the week before you forgot to take the tablets, you may be pregnant. Ask your midwife/doctor for advice.

What if I have irregular bleeding?

Irregular bleeding is normal. This can include spotting that does not require a liner, or bleeding that resembles light menstrual flow and requires protection. It may also be that there is no bleeding at all. Irregular bleeding is not a sign of reduced protection by Vinelle. Generally, you need not do anything but continue taking Vinelle. If the bleeds are heavy and long-lasting, contact your doctor/midwife.

What if I have vomited or had diarrhoea?

Follow the same instructions as for a forgotten tablet. If you have vomited within 3-4 hours after taking your tablet and/or had bad diarrhoea, it is possible that your body has not been able to absorb the hormone correctly. If this is the case you should use extra protection (such as a condom) for one week. You should also continue to take the tablets as normal.

What if I am taking other medication?

Always inform your midwife or doctor if you are taking any other medication. Taking Vinelle in combination with other medication can lead to reduced protection. Some antibiotics, medicine for epilepsy, charcoal tablets and the natural medicine St. John's wort are examples of this.

What if I want to become pregnant?

If you wish to become pregnant, stop taking Vinelle. In most women, ovulation returns immediately after they stop taking their contraceptive tablets. But it can also take some time, depending on the ovaries' own activity. Keep in mind that all women who wish to become pregnant should avoid tobacco and alcohol and take folic acid supplements, e.g. Natalben Gravid (additional reading on the next page).

What side effects might I experience?

Typical side effects that can occur include irregular bleeding, headache, acne and/or tenderness in the breasts. Mood swings, depression and weight gain can also occur. These complaints normally improve or disappear after a few months. There are also side effects which are rare yet serious. If you experience any side effects, especially if they are serious or prolonged, or if your health changes and you think that it might be due to Vinelle, contact a doctor or midwife.

Contact your doctor immediately if you experience any of the following symptoms:

Sudden bleeding from the genitals, sudden swelling or pain in your calves/legs, chest pain or difficulty in breathing, sudden or severe pain in the abdomen or lower abdomen, if you feel a lump in the breast or if you think you may be pregnant.

If you have any other questions or doubts, contact your midwife or doctor. For further information read the patient information leaflet in the packaging.

Start taking folic acid if you stop taking your contraceptive tablets and wish to become pregnant

Folic acid is necessary for normal cell division and development of the brain and nervous system in the foetus. Inadequate intake of folic acid can increase the risk of having a child with spina bifida. The Swedish National Food Administration and the National Board of Health and Welfare recommend a supplement of 400 micrograms of folic acid daily. To achieve the right effect, it is a good idea to begin approximately one month before conception.

Natalben Gravid is a nutrient tablet specially adapted for women who are or who plan to get pregnant. Natalben Gravid contains active folic acid that all women can benefit from, plus iron, iodine, vitamin D, omega-3 and another 14 carefully selected nutrients for pregnancy. Dietary supplements do not replace a healthy diet, but should be combined with a varied and balanced diet and a healthy lifestyle.

Speak to your midwife or read more at

www.natalben.se

Vinelle (75 micrograms desogestrel), tablets, progestin contraceptive tablets. Rx. F. ATC code G03AC09. Indication: Contraceptive.

Packaging: 3×28, 6×28. Packs with 28 tablets, each pack containing 28 active tablets.

Product summary updated 14 October 2015. For further information, see www.fass.se www.campuspharma.se

