

For users of

Prionelle® and Prionelle 28®

(levonorgestrel + ethinylestradiol)



This is Prionelle/Prionelle 28

Prionelle/Prionelle 28 is a contraceptive tablet which prevents you from becoming pregnant, provided you use it correctly. It is a so-called combined contraceptive tablet, which means that it contains two types of hormone, oestrogen (ethinylestradiol) and progesterone (levonorgestrel).

Prionelle/Prionelle 28 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 Prionelle/Prionelle 28:

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

Your normal menstrual cycle

In order to understand how Prionelle/Prionelle 28 works, it is also important that you know how your normal menstrual cycle works. Once a month, one of the ovaries releases an egg. 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 which occurs 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.

Positive effects of contraceptive tablets

When you use combined contraceptive tablets, menstrual flow is reduced compared to your usual menstruation. Menstrual cramping and ovulation pain are also reduced. The thickened secretion in the cervix can make it harder for bacteria to pass through. Women who use contraceptive tablets have fewer instances of salpingitis. On the other hand, contraceptive tablets do not give protection against sexually transmitted diseases.

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.

Prionelle



If you begin on a Tuesday, for example, you should start with a tablet marked "Tis".

Read more on the package leaflet about how to start using Prionelle/Prionelle 28 after childbirth or if you previously used a different hormonal contraceptive.

The Prionelle packaging contains 3 or 13 blister packs with 21 tablets each. The days of the week are printed on each blister pack.

How to use Prionelle

- If you take the first tablet on the first day of your menstruation, you will be immediately protected from pregnancy. You can also begin taking Prionelle 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.
- You should take the tablets with a little liquid at about the same time each day.
- Start with a tablet which has the current day's weekly marking. After that, follow the direction of the arrows and take a tablet each day for 21 days.
- After these 21 days, take a break from the tablets for 7 days. You will typically experience withdrawal bleeding 2 to 3 days after taking the last tablet. You are protected against pregnancy throughout the entire break period.
- On day 8, start with a new blister pack. You should take your tablet even if you are still bleeding. This means that you always begin a new blister pack on the same day of the week and that you will have your period on about the same days each month.

Prionelle 28



The box contains adhesive labels that you can stick to the top of the pack to mark the first tablet with the correct day of the week. The first tablet in each row is always the same day of the week as the starting day.

The Prionelle 28 packaging contains 3 or 13 blister packs with 28 tablets each. The first 21 white tablets (rows 1-3) contain hormones, while the 7 yellow tablets (row 4) are free of hormones.

How to use Prionelle 28

- If you take the first white tablet on the first day of your menstruation, you will be immediately protected from pregnancy. You can also begin taking Prionelle 28 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.
- You should take the tablets with a little liquid at about the same time each day.
- Start with a tablet from the top row with the current day's weekly marking. For example, if you start on a Tuesday, take a tablet that has a TIS marking. Mark the starting day with an adhesive label at the top of the pack.
- Follow the direction of the arrows until you have taken all 28 tablets. You will typically experience withdrawal bleeding 2 to 3 days after taking the last white tablet.
- The day after emptying a blister pack, begin a new one, even if you are still bleeding. This means that you always begin a new blister pack on the same day of the week and that you will have your period on about the same days each month.

Frequently asked questions

What if I forget to take Prionelle/Prionelle 28?

The risk of pregnancy is greatest if you forget a tablet in connection with the hormone-free period, i.e. if the hormone-free period is longer than 7 days.

- If **less than 12 hours** have passed since you should have taken your tablet, you are still protected against pregnancy. Take the tablet as soon as you remember to do so, and take the next tablet at the usual time.
- If **more than 12 hours** have passed, the effects of the contraceptive tablet may be reduced. Follow the instructions below:

You have forgotten more than 1 tablet from the blister pack:
Contact your doctor/midwife for advice.

You have forgotten 1 tablet in week 1:

Take the missed tablet as soon as you remember, even if it means taking two tablets at the same time. Take the next tablets at the usual time, but do not forget to use extra contraceptive protection (such as a condom) for the next 7 days. If you had intercourse in the week prior to forgetting the tablet, there is a risk that you may be pregnant. Tell your doctor/midwife immediately.

You have forgotten 1 tablet in week 2:

Take the missed tablet as soon as you remember, even if it means taking two tablets at the same time. Take the next tablets at the usual time. The contraceptive tablet still has the desired effect and you do not need any extra contraceptive protection. If you forget more than 1 tablet, supplementary contraception should be used for 7 days.

You have forgotten 1 tablet in week 3:

If you choose one of the following two options, you do not need extra contraceptive protection:

1. Take the forgotten tablet as soon as you remember, even if it means taking two tablets at the same time. Take the remaining tablets at the usual time. When the blister pack is empty, start the next pack immediately without a break from tablets (if you use Prionelle). If you use Prionelle 28, skip the 7 yellow tablets and start immediately on the next blister pack.

You will probably not have any real withdrawal bleeding until the end of the second blister pack. However, you may have spotting and breakthrough bleeding on the days when you take tablets.

2. *Prionelle:* Finish the current blister pack and stop taking tablets for a maximum of 7 days, including the day you forgot to take a tablet. Then continue with a new blister pack.

Prionelle 28: Immediately stop taking the active tablets in row 3 and begin taking the hormone-free (yellow) tablets in the last row. Then continue with a new blister pack.

1 tablet forgotten in week 4:

If you use Prionelle 28, forgetting to take a yellow hormone-free tablet does not affect the contraceptive effect. Throw away the forgotten yellow tablet and take the next tablet at the usual time.

Note: If you have forgotten to take tablets from a blister pack and do not experience withdrawal bleeding during the hormone-free period, you may be pregnant. Consult your doctor/midwife before starting on the next blister pack.

What if I want to switch the starting day of my period?

Prionelle: For example, if your bleeding usually starts on a Friday and you want to have it on a Tuesday instead, you can shorten the break period by 3 days. Ensure that you never allow your break from tablets to last longer than 7 days.

Prionelle 28: Do not take all of the tablets in row 4 before starting on the next blister pack. For example, if your bleeding usually starts on a Friday and you want to have it on a Tuesday instead, you can begin a new tablet pack 3 days earlier than normal. Begin on the top row with the white tablets.

What if I want to delay my period?

Prionelle: Start a new blister pack immediately when the old pack is empty – i.e. no break between tablets. Continue to take your contraceptive tablets for as long as you want to prevent your period.

Prionelle 28: When you have taken the last tablet in row 3, skip the yellow hormone-free tablets and instead start immediately on a new blister pack at row 1. Continue to take your white hormone tablets for as long as you want to avoid bleeding.

What if I experience small bleeds?

Small bleeds can occur and are most common when you start taking contraceptive tablets. The risk of irregular bleeding increases if you do not take your contraceptive tablets regularly or if you take your tablets for a long stretch of time. If the bleeding becomes uncomfortable, or only appears after a couple of months, contact your midwife/doctor.

What if I have vomited or had diarrhoea?

If you have vomited within 3-4 hours after taking a white tablet and/or had bad diarrhoea, it is possible that your body has not been able to absorb the hormones correctly. After vomiting or diarrhoea, you must take a new white tablet from another blister pack (spare pack) as soon as possible. If this is not possible, or if 12 hours have already passed from when you normally take your tablet, follow the advice under "What if I forget to take a tablet?"

What if I am taking other medication?

Always inform your midwife or doctor if you are taking any other medication. Using contraceptive tablets 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. You should also avoid drinking grapefruit juice, as it can diminish the effect of the contraceptive tablet.

What if I want to become pregnant?

If you want to become pregnant you should complete the pack you are taking but not begin a new one. In most women, ovulation resumes 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 (read more on the next page).

What side effects might I experience?

Typical side effects which can occur include tenderness in the breasts, feeling sick, headache, breakthrough bleeding or mood swings. These side effects are usually mild and normally disappear within a few months.

There are side effects which are rare yet serious. Among other things, there is a slightly higher risk of blood clots in veins or arteries, particularly in the first year or when combined contraceptive tablets are used following a break of 4 or more weeks. The risk of blood clots also increases if you have a major operation or are bedridden for a prolonged period. In these instances, you should take a break from your contraceptive tablets.

Frequently asked questions

Be alert and contact a doctor immediately if you experience any of the following symptoms:

Sudden swelling or pain in your calves, skin discolouration on the legs (e.g. pale, red or blue), sudden change in vision, migraine-like headaches that you have not had before, pain in the chest or difficulty breathing, severe pain in the abdomen, dizziness or impaired balance, severe itching or rash.

Important to remember:

- 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 Prionelle/Prionelle 28, contact a doctor or midwife.

Can I avoid my period?

There are general recommendations that you can take your contraceptive tablets without any break, but these do not specifically concern Prionelle/Prionelle 28. There is no contraceptive that can guarantee that you will be entirely free of bleeding. However, if you take your active tablets continuously, without any break, your bleeding episodes may be fewer. You can continue with the active tablets until you bleed (breakthrough bleeding). Then you take a break for no more than 7 days and start again with the active (white) tablets.

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 that is 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

Prionelle, Prionelle 28 (150 micrograms levonorgestrel, 30 micrograms ethinylestradiol), tablets, combined contraceptive tablets. Rx. F. ATC code G03AA07.

Indication: Contraceptive.

Warnings and restrictions: When deciding on the prescription of Prionelle/Prionelle 28, the individual woman's risk factors must be taken into consideration, in particular venous thromboembolism (VTE) with Prionelle/Prionelle 28 compared to other combined hormonal contraceptives.

Packaging Prionelle: 3x21, 13x21. Packs with 21 tablets, each pack containing 21 active white tablets.

Packaging Prionelle 28: 3x28, 13x28. Packs with 28 tablets, each pack containing 21 active white tablets and 7 yellow placebo tablets.

Product summary updated 31 July 2017. For further information, see www.fass.se www.campuspharma.se

