Information about Prionelle® and Prionelle 28®

Prionelle is a contraceptive pill which prevents you from becoming pregnant, provided you use it in the correct way. It is a so-called combined contraceptive pill, which means that it contains two types of hormone, estrogen (ethinyl estradiol) and progesterone (levonorgest-rel). Before you begin using Prionelle you should read this information leaflet carefully, and if you have any other questions speak to your midwife or your gynaecologist. For additional information, please read the package leaflet in the pack.

Your normala menstrual cycle

In order to understand how Prionelle 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 fertilized, to get the nourishment it needs to grow into a foetus. If this is the case then no bleeding occurs. However, if the egg is not fertilized it will break off and be shed along with the newly formed endometrium after 14 days. The bleeding which occurs is called a period. A normal period lasts between 3–8 days. The entire menstrual cycle, from the beginning of the bleeding to the next bleeding period, is usually 28 days but varies among women from 21 up to 35 days.

How Prionelle works

There are several different factors which combine in Prionelle to prevent pregnancy;

- 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 becomes thick and difficult for sperm to penetrate.

Prionelle 21

Each blister pack contains 21 pills. You should take the first pill on the first day of your period. If you follow this advice then you are protected against pregnancy from the very first day.

How to use Prionelle 21

Start with a pill which has the current day's weekly marking. For example, if you start on a Tuesday, take a pill which has a Ti marking. After this, follow the direction of the arrows and take a pill each day for 21 days. You should take the pills at about the same time each day.

After these 21 days you take a break from the pills for 7 days. You will typically experience bleeding that resembles a period (withdrawal bleeding) 2 to 3 days after taking your final Prionelle pill. You are protected against pregnancy throughout the entire break period.

On day 8 you start again with a new blister pack. You should take your pill even if you are still bleeding. This means that you always begin a new blister pack on the same day of the week and will therefore have your withdrawal bleeding on roughly the same day each month.

Do you want to postpone your period?

If you want to postpone your period you can begin a new blister pack immediately after the previous pack is finished, in which case you do not have any break from taking the pills. Continue to take your contraceptive pills for as long as you want to prevent your period. If you are unsure, speak to your midwife.

Do you want to change the day on which your period starts?

Your withdrawal bleeding starts on roughly the same day every fourth week. If you want to change the start day you can shorten the break period. For example, if you usually start bleeding on a Friday and you want it to start on a Tuesday instead, shorten your break period by 3 days. *Ensure you never allow your break period to last longer than 7 days.*

Prionelle 28

Each blister pack contains 28 pills. The first 21 white pills (rows 1-3) contain hormones, while the following 7 yellow pills (row 4) are hormone-free. You therefore take a pill every day at roughly the same time without a break.

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

How to use Prionelle 28

You should take the first pill on the first day of your period. If you follow this advice you will be protected against pregnancy from the very first day, because you are starting with the pills which contain hormones.

Follow the direction of the arrows until all 28 pills have been taken. It is important that you take the 21 white pills first, and then take the yellow hormone-free pills for 7 days. During the 7 days that you take the hormone-free pills, you will usually experience bleeding that resembles a period (withdrawal bleeding) 2 to 3 days after the final white hormone pill has been taken. When the pack is finished, immediately start taking the first pill from row 1 in a new pack, i.e. you do not take a break from the pills.

Do you want to postpone your period?

You can postpone your period by skipping the yellow hormonefree pills and instead immediately starting with a new blister ampusPharma

pack at row 1 once you have taken the last pill in row 3. Continue to take your white hormone pills for as long as you want to avoid having a period. Speak to your midwife if you feel unsure about anything.

Do you want to change the day on which your period starts?

Your withdrawal bleeding starts on roughly the same day every fourth week. If you want to change the start day, you can refrain from taking all pills in row 4 before you begin the next pack of pills. 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 blister pack 3 days earlier than normal. Throw the excess pills from the first pack away. If you are unsure, speak to your midwife.

Positive effects of contraceptive pills

When you use combined contraceptive pills, your period will often become lighter and also less painful than it perhaps was previously.

Contraceptive pills also provide a certain amount of protection against ovarian cancer and cancer of the mucous membrane in the womb. The risk of inflammation in the Fallopian tubes is also reduced.

Frequently asked questions

What if I forget to take a pill?

If **less than 12 hours** have passed since you were meant to take your pill then you are still protected against pregnancy. Take the pill as soon as you remember to do so, and take the next pill at the usual time.

If **more than 12 hours** have passed the effects of the contraceptive pill can be reduced. How much the protection has been affected will depend on where in the pack (which week) you forgot to take your pill.

Forgotten 1 pill during week 1

- Take the pill that you forgot.
- Use extra protection (condoms) for 7 days.
- Continue taking the pills in the blister.
- If you had sex the week before, contact your midwife/doctor as soon as possible to get advice!

Forgotten 1 pill during week 2

Take the pill that you forgot.

• Continue taking the pills in the pack.

Forgotten 1 pill during week 3

- Take the pill that you forgot.
- Continue with the pills.
- Prionelle 21: Do not take a break, instead continue immediately with a new pack.
- Prionelle 28: Skip the 7 hormone-free pills (placebo) in row 4. Continue immediately with a new pack at row 1 instead.

Or do as follows

Prionelle 21:

- Immediately stop using the current pack.
- Take a break from the pills of no longer than 7 days including

- the day you forgot the pill.
- Continue with a new pack.

Prionelle 28:

Immediately stop taking the active pills in row 3

ampusPharma

- Start taking the hormone-free pills. The number of hormonefree days should not exceed 7, including the day you forgot the pill.
- Continue with row 1 of a new pack.

What if I have forgotten more than one pill?

Contact your midwife/doctor for advice as soon as possible!

What if I have irregular bleeding?

Light bleedings can occur and are most common when you start taking contraceptive pills. The risk of irregular bleeding increases if you do not take your contraceptive pills regularly. If the bleeding becomes an issue or occur not until after a couple of months, then contact your midwife/doctor.

What if I have vomited or have diarrhoea?

If you have vomited within 3–4 hours from taking a white pill and/or suffer from severe diarrhoea, it is possible that your body has not been able to absorb the hormones in the correct way. After vomiting or diarrhoea you must take a new white pill from another blister pack (backup blister) as soon as possible. If this is not possible, or if more than 12 hours have passed since you were ment to take your pill, follow the advice under "What if I forget to take a pill".

What if I am taking other medications?

Always inform your midwife or doctor if you are taking any other medicines. Contraceptive pills combined with other medicines 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 want to become pregnant you should complete the blister you are taking but not begin a new one. In most women the period will return immediately after finishing the contraceptive pills, but it can also take a while.

What side effects might I experience?

Common side effects which can occur include tenderness in the breasts, feeling sick, headache, irregular bleeding or mood swings. These side effects are usually mild and usually disappear within a few months. There are side effects which are rare yet serious. These include an increased risk of blood clots. The risk of blood clots also increases if you have a major operation or are bedridden for a prolonged period of time. In these situations you should take a break from your contraceptive pills.

Important to remember!

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

If you experience a side effect, especially if it is serious or persistent, or if your health changes and you suspect that this can be due to Prionelle, contact a doctor or a midwife.

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

- Sudden swelling or pain in the calf
- Change in the skin colour (e.g. pale, red or blue) of the legs
- Sudden changes in vision
- Migraine-type headache which you have not experienced before
- Stitch in the chest area or difficulty breathing
- Severe stomach pain
- Dizziness or loss of balance
- Intense itching or skin rash.

If you have any other questions or thoughts, contact your midwife or doctor.

For additional information, please read the package leaflet in the pack.

EN CampPrionelle 2015 01

CampusPharma