

Ornibel® contraceptive ring

This text contains useful and important information on the Ornibel® contraceptive ring. Study this text and package leaflet carefully before starting to use the Ornibel® product.

Ornibel® takes effect in the same way as a combined contraceptive pill. The advantage with Ornibel® is that the contraceptive ring is used continuously for 3 weeks and it does not need to be remembered daily.

Ornibel® releases steadily two female hormones that prevent ovulation, i.e., the release of an egg cell. A woman cannot become pregnant if an egg cell is not released.

If you have any questions, please contact a public health care professional.

A month's contraception with a single ring

What is the Ornibel® contraceptive ring?

Ornibel® is a flexible, soft, transparent and colourless ring that is inserted in the vagina to prevent pregnancy (diameter 54 mm and thickness 4 mm).

How does the contraceptive ring work?

The contraceptive ring is inserted in the vagina. When the ring is in place, it releases continuously hormones in small doses. Like other hormonal contraceptive methods, the ring prevents pregnancy by releasing hormones to prevent ovulation.

Starting with Ornibel®

In the table, you will find instructions on starting and switching from another contraceptive method.

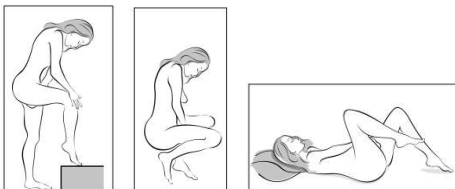
No previous hormonal contraception	Switch from another combined contraceptive product	Switch from a minipill, implant, injection or hormonal IUD
Ornibel® is started on the first day of the natural cycle (= first day of bleeding).	The Ornibel® ring is inserted at the latest on the final day of last tablet-free, patch-free or placebo-pill period (of earlier contraception).	<ul style="list-style-type: none"> From a minipill at any time From an implant and hormonal IUD on the day of their removal From an injection on the next planned injection day
		<p>N.B. Additional contraception (e.g., a condom) for the first seven days of use</p>

Please study the package leaflet in the Ornibel® package.

Ornibel® – practical information

Before inserting the ring

- Check that the date of the ring is valid.
- Wash your hands before inserting and removing the ring.
- Choose the most comfortable position for you for inserting. You can stand and raise one leg, crouch or lie on your back.



Ornibel® – reliable contraception

Ornibel® takes effect in the same way as combined contraceptive pills. Clinical studies have also demonstrated that its contraceptive efficacy is at least as good as that of oral contraceptive products. You can thus trust your contraception without thinking about it daily.

How Ornibel® prevents pregnancy

On average, the Ornibel® contraceptive ring releases 0.120 mg and 0.015 mg of etonogestrel (progestin) and ethinyl estradiol (estrogen) per day (24 hours) for 3 weeks, and so it is a low-hormone contraceptive product. These hormones are released steadily from the contraceptive ring and are absorbed continuously into the bloodstream through the wall of the vagina. The hormones take effect principally by preventing ovulation, i.e., release of an egg cell. They also alter the composition of the cervical mucus so that it is hard for sperm to penetrate, and make the mucous membrane of the cervix thinner. This is why periods also often become reduced.

The same hormones as in combination contraceptive pills

You receive a lower dose of hormones from Ornibel® than from combined contraceptive pills. Ornibel® releases only 15 micrograms of estrogen daily whereas, in the most common contraceptive pills, the daily estrogen dose is 20 or 30 micrograms. The hormones are released steadily. The daily hormone concentration does not fluctuate as with oral contraceptive products. Even though the amount of hormones released from Ornibel® is small, its contraceptive efficacy is good.

Efficacy is not weakened by diarrhoea/vomiting

Diarrhoea and vomiting have no effect on contraceptive efficacy because Ornibel's hormones are absorbed into the bloodstream directly from the mucous membrane of the vagina.

How Ornibel® is inserted and removed

- Remove the ring from the bag
- Hold the ring between your thumb and forefinger, press the opposite sides together and push the ring into your vagina.
- When the ring is in place, it cannot be felt at all.
- If the ring feels uncomfortable, push it carefully a little deeper into your vagina.
- Check regularly that the ring is still in place in your vagina (for example, before and after intercourse).



Three weeks in the vagina, one week out

- The ring must be in place continuously for 3 weeks from the date of insertion.
- You can remove the ring from your vagina by hooking your forefinger around the front edge of the ring or by gripping the edge of the ring and pulling it out.
- Remove the ring three weeks after its insertion, on the same day of the week and roughly at the same time as when you inserted it.

If for example you insert the Ornibel® ring on Wednesday at 20.00 h, remove it 3 weeks later on Wednesday at 20.00 h. Make a note to remind yourself. When you have removed the ring, take a break for 1 week. Your periods should start in the meantime.

- Start using a new ring exactly 1 week afterwards, even if your periods may not have stopped.

Dispose of the used ring with ordinary household waste preferably in the package bag. Do not flush the ring down the toilet.

Please study the package leaflet in the Ornibel® package.



Ornibel® – questions and answers

Is contraceptive efficacy retained throughout the month?

Used correctly, the ring protects against pregnancy for the entire month, also during the week without a ring.

How is the ring to be stored?

This product does not require cold storage. It should be stored out of direct light.

When should I start using the first ring?

Read the detailed instructions on starting to use the ring from this text or in the package leaflet.

What should I do if the ring feels uncomfortable?

If the ring feels uncomfortable, push it carefully a little deeper into your vagina.

What should I do if the ring has been used for too long?

If the ring has been in your vagina for over 3 weeks but a maximum of 4 weeks: Remove the ring immediately, have a break for a week, and then insert a new ring.

If the ring has been in your vagina for over 4 weeks its contraceptive efficacy may have weakened, and any pregnancy has to be ruled out before inserting a new Ornibel® ring.

Can I use tampons?

You can use tampons with the contraceptive ring. If the ring moves or slips out of your vagina, clean it with lukewarm water (not hot) and re-insert it.

What should I do if the ring slips out by mistake?

Rinse the ring with cold or lukewarm water and re-insert it immediately. If the ring has been outside your vagina for over 3 hours, its contraceptive efficacy may have weakened depending on the week. See the instructions in the package leaflet.

Is the ring noticeable during intercourse?

It is quite rare for the ring to be felt during intercourse. Check after intercourse whether the ring is still in place. If the ring bothers you, you can remove it for the duration of intercourse. It must, however, be re-inserted at the latest within three hours.

Can I alter the starting date of my periods?

If you use the ring according to the instructions, your periods (bleeding) start during the break week. You can change the starting date of your periods by shortening (never extending) the next break in use of the ring.

Can I postpone my periods?

If you want to postpone your periods, insert a new ring immediately in your vagina without a break week straight after removing the previous ring. You can use the new ring for a maximum of 3 weeks. When you want your periods to start, remove the ring and have a normal 7 days' break before inserting a new ring.

Can I use antifungal drugs and spermicides?

Antifungal drugs and spermicides administered in your vagina will probably not affect the contraceptive ring's contraceptive efficacy and safety.

Ornibel® - possible adverse effects

Like all drugs, Ornibel® can also cause adverse effects. Not everyone, however, gets them. The most common adverse effects can include mood fluctuations, headache, nausea, sensitive breasts, weight gain and depression. If these adverse effects continue for long, please get in touch with a public health care professional.

Combination contraceptive products and risk of a blood clot

All combined contraceptive products increase the risk of a blood clot. The overall risk is, however, small. It is very important for you to be able to recognise situations when the risk of a blood clot may be greater than usual, and for you to be aware of the kinds of symptoms to pay attention to.

The risk of a blood clot is at its greatest:

- if you are considerably overweight
- if you are over 35 and smoke
- if you have given birth in recent weeks
- if a close relative of yours has had a blood clot at a relatively young age (e.g., under 50)
- during the first year of use or when use begins after a break of at least 4 weeks.

Observe possible symptoms of a blood clot, especially if:

- you have just undergone surgery
- you have been bedridden for a long time
- you travel by flight for more than 4 h

Contact a physician immediately if you notice one of the following symptoms:

- intense pain or swelling in one leg.
- sudden unexplained shortness of breath or more frequent breathing, intense chest pain or a sudden cough.
- chest pain that is often sudden.
- Weakening or numbness in the face, upper or lower extremities (especially if it occurs on only one side of the body), difficulties with speaking or understanding, sudden confusion, sudden loss or blurring of vision, intense and more severe headache/migraine.
- If you end up, e.g., being treated in hospital, remember to mention that you use a contraceptive ring.

Read more about adverse effects in the package leaflet.