



**Patient
information**

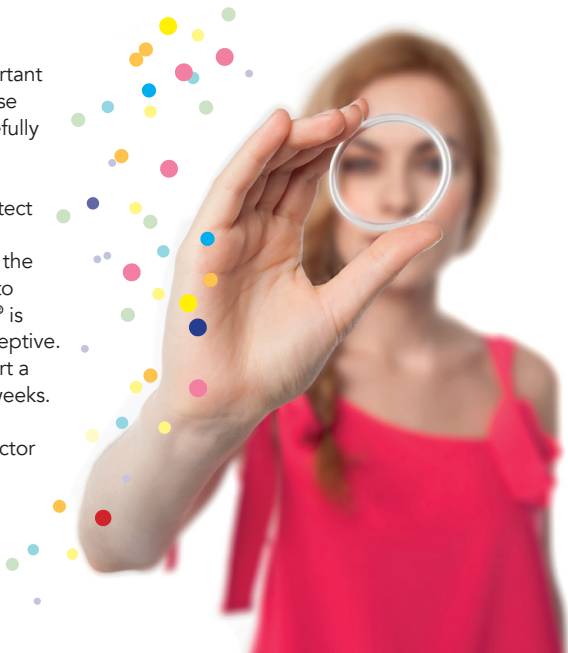
Ornibel[®]
vaginal ring



This patient information contains useful and important information about the vaginal ring **Ornibel®**. Please read this information and the package leaflet carefully before using **Ornibel®**.

Ornibel® is a flexible plastic ring, intended to protect you from becoming pregnant. It contains the two hormones oestrogen and progestin, and works in the same way as a combined contraceptive pill. Due to the small amount of hormones released, **Ornibel®** is considered to be a low dosage hormonal contraceptive. You insert **Ornibel®** in the same way that you insert a tampon, and then you leave it in place for three weeks.

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

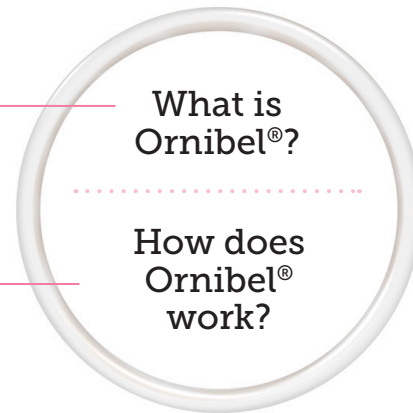


Ornibel® is a flexible and transparent ring (diameter 54 mm and cross-sectional diameter 4 mm) that is inserted into the vagina to prevent pregnancy.

Ornibel® is inserted into the vagina. When the ring is in place, **it emits a low and even dose of hormones.**

What is Ornibel®?

How does Ornibel® work?



Ornibel® – a combined contraceptive

How does Ornibel® prevent pregnancy?

Ornibel® works in the same way as a combined contraceptive pill, and protects you in three ways:

You will not ovulate, as the signal that initiates ovulation will not occur.

The secretion in the cervix (the entrance to the uterus) will become thick and difficult for the sperm to penetrate.

The mucous membrane inside the uterus will change, so that an egg cannot attach and develop.

The efficacy is not reduced in the event of diarrhea/vomiting

As the hormones from Ornibel® are absorbed into the bloodstream directly from the mucous membrane of the vagina, diarrhea and vomiting will not impact the efficacy of protection.

Ornibel® – change or start your method of contraception

The following table contains instructions for how to start using Ornibel® or how to change from another contraception.

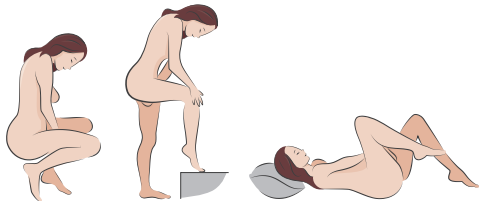
No hormonal contraception for the last month	Changing from another combined contraceptive	Changing from progestin-only pills, implant, injection or hormonal IUD
Start using Ornibel® on the first day of your natural menstrual cycle (i.e. the first day of bleeding).	Ornibel® must be inserted no later than the day after your last day without a contraceptive pill or patch (the "resting" days), or the day after the placebo pill period (from your previous contraception).	<ul style="list-style-type: none">• From progestin-only pills: at any time• From an implant or a hormonal IUD: the day it is removed• From an injection: on the day of your planned injection
You can also start using Ornibel® during days 2-5 of your menstrual cycle, but remember to use additional protection (e.g. a condom) if you have intercourse during your first 7 days of using Ornibel®.		NB! Use additional protection (e.g. a condom) during your first 7 days of using Ornibel®.

Read the package leaflet in the Ornibel® pack.

How to use Ornibel®?

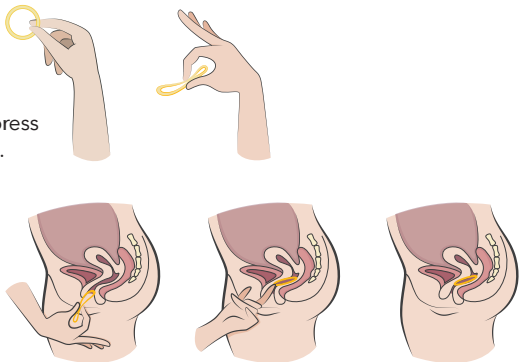
Before inserting the ring

- Please check that the ring's expiry date has not passed.
- Wash your hands before inserting or removing the ring.
- Choose the position that feels most comfortable to you. For example, you can stand with one leg up, squat, or lie down.



To insert the ring

- Remove the ring from the packaging.
- Hold the ring between your thumb and index finger, press the sides together and insert the ring into your vagina.
- You should feel nothing when the ring is in place.
- If you feel any discomfort, carefully push the ring a little further into your vagina.
- Regularly make sure that the ring is in place inside your vagina (e.g. before and after intercourse).



Three weeks with the ring, one week without

Removing the ring

- The ring should remain in the vagina for 3 weeks continuously from the time of insertion.
- You can remove the ring by hooking your index finger on the bottom of the ring, or by holding the side of the ring, and pulling it out.
- Remove the ring 3 weeks after inserting it, on the same day of the week and at approximately the same time.



For example, if you insert Ornibel® on a Wednesday at 8pm, you should remove it after three weeks on Wednesday at 8pm. Set a reminder for yourself. When you have removed the ring, you need a week's break. During this week, you should experience bleeding.

- Start using a new ring after exactly one week, even if the bleeding has not stopped.

Read the package leaflet in the **Ornibel®** packaging.

Discard the used ring together with your household garbage, preferably in its packaging. Do not flush the ring down the toilet.

Does the protective efficacy last for the entire month?



If the ring is used correctly, it will **protect you from getting pregnant for the entire month**, including the week in which you do not wear the ring.

When should I insert the first ring?



For more detailed information about how to start using **Ornibel®**, read page 5 or the packaging leaflet.

How should Ornibel® be stored?



Ornibel® should be kept **out of direct light**. In terms of **temperature** there are **no specific instructions**.

What should I do if the ring feels uncomfortable?



If you feel discomfort, **carefully push the ring a little further inside** the vagina.

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



If the ring has been inside your vagina for more than 3 weeks, **but no more than 4 weeks**: Remove the ring at once. Resume the usual interval of one week and then insert a new ring. If the ring has been inside your vagina for **more than 4 weeks**, the contraceptive efficacy may be reduced and you must confirm you are not pregnant before inserting a new ring.

What should I do, if the ring is accidentally expelled?



Rinse the ring with cold or lukewarm water and immediately re-insert it. If the ring has been outside of the vagina for more than **3 hours**, the contraceptive efficacy may be reduced depending on which week of the cycle you are in. **See the packaging leaflet for instructions**.

Can I use tampons?



You can use a tampon while using Ornibel®. If the ring is accidentally expelled from the vagina, wash the ring with cold or lukewarm (not hot) water and re-insert it.

Can the ring be felt during intercourse?

It is unusual to feel the ring during intercourse. Make sure that **the ring is in place after intercourse**. If the ring is in the way, it may be removed during intercourse. However, it must be re-inserted **within 3 hours** so that the contraceptive efficacy is not affected.

*See further information in the packaging leaflet.

Can I change the first day of my menstrual bleeding?



If you use the ring according to the instructions, you will experience your menstrual bleeding (period) during the ring-free interval. If you wish to change the day that your bleeding begins, you can **shorten** (but never prolong) **your next ring-free interval**.

Can I postpone my menstrual bleeding?



If you wish to postpone your menstrual bleeding, **insert a new ring into your vagina immediately** after removing the previous ring, without starting a ring-free period*. The new ring may be left in place for **no more than 3 weeks**. When you want the menstrual bleeding to start, simply remove the ring. Follow the normal **ring-free interval of one week**, then insert a new ring.

Can I use antifungal medicine and spermicides?

Antifungal medicine and spermicides (spermicidal substances) used in the vagina **will probably not affect Ornibel's® contraceptive efficacy and safety**.



*Even though this is not a recommended routine, it is possible to postpone your menstrual bleeding.

Ornibel® may cause side effects, but not all users may experience them. Some of the most common side effects (may occur in up to 1 of 10 women) include depression, tender breasts, headaches, nausea and increased discharge. If you experience any side effects, please contact your doctor/midwife.

Combined contraceptives and the risk of blood clots

All combined contraceptives increase the risk of having a blood clot. However, the total risk is small, smaller than e.g. during a pregnancy. It is important that you are acquainted with which situations increase the risk of having a blood clot, which symptoms you will experience, and what to do should you get a blood clot.

The risk of having a blood clot is greatest:

- if you are significantly overweight
- if you are above the age of 35 and a smoker
- if you have given birth within the last few weeks
- if a close relative has had a blood clot at a relatively young age (i.e. younger than 50 years of age)
- during the first year of using a contraceptive pill/ring, or when you start using the pills/rings again after a break of at least 4 weeks

Keep aware of symptoms of a blood clot, especially if you:

- have recently undergone surgery
- have been bedridden for a long period of time
- will be travelling by air for more than 4 hours

Immediately consult your doctor if you have any of the following symptoms:

- severe pain or swelling in an arm or a leg
- sudden, unexplained breathlessness or increased respiratory rhythm, severe chest pain or a sudden cough
- severe instability or dizziness, fast or irregular heartbeats, severe stomach pain
- weakness or numbness of the face, arms or legs (especially if it happens on one side of the body), difficulties speaking or understanding things, sudden confusion, sudden loss of vision or blurred vision, severe headache/migraine which is worse than usual

Read more about the side effects in the packaging leaflet.

Abbreviated product information

Ornibel® (etonogestrel/ethinylestradiol), 0.120 mg/0.015 mg per 24 hours, vaginal insert. Prescription medication without reimbursement. **Indication:** Ornibel is a contraceptive in the form of a vaginal ring and is used to prevent pregnancy. **Warnings/caution:** Do not use Ornibel if you have, or are suspected of having, cancer that is sensitive to sex hormones, a blood clot in a blood vessel or the lungs, impaired liver function, migraines with visual disturbances/loss of vision, or unexplained vaginal bleeding. Contact your doctor or midwife immediately if you experience any unusual symptoms, such as unexplained pain in your chest, abdomen or legs. The packaging leaflet also contains information about risk factors and information about situations in which women should stop using Ornibel, or if the reliability of Ornibel may be reduced. **Common side effects:** Abdomen pain, nausea, vaginal fungal infection (e.g. "candida"), vaginal ring discomfort in the vagina, genital itch, discharge from the vagina, headache or migraine, malaise, reduced libido, tender breasts, pelvic pain, painful menstruation, acne, weight gain, and ejection of vaginal ring. Contact: Exeltis Sverige AB, Strandvägen 7A, 114 56 Stockholm, Sweden. Telephone: +46 (0)8-586 335 10. E-mail: nordics@exeltis.com. Abbreviated information based on packaging leaflet dated 15/12/2021.

Please read the packaging leaflet carefully before using Ornibel®.
It contains important information for you.

Please note: This user guide is a translation into English of material initially produced in Swedish. It is aimed at supporting the counselling of non-Swedish-speaking patients. In case of doubts, please contact your prescriber.