

Package leaflet: Information for users

GinoRing®

0.120 mg/0.015 mg per 24 hours vaginal drug delivery system Etonogestrel/Ethinylestradiol

Important information about combined hormonal contraceptives (CHC):

- In correct application count them to the most reliable reversible contraceptive methods.
- They cause a slight increase of the risk for a blood clot in the veins and arteries, especially in the first year of use or upon resumption of use of a combined hormonal contraceptive after one interruption of 4 or more weeks.
- Pay attention please carefully to symptoms of a blood clot and contact yourself with your doctor, if you suspect, to have these (see section 2 "Blood clots").

You must read the entire package leaflet carefully through, before you start with the use of this medication, because it contains important information.

- Keep the package leaflet for. You may want to read it again.
- If you have further questions, contact your doctor or pharmacist. This medication was prescribed to you personally. Do not give it to others. It can harm other people.
- If you notice side effects, contact your doctor or your physician or pharmacist. This also applies to side effects, which are not listed in this package leaflet. See section 4.

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1. What is GinoRing and what is it used for

? GinoRing is a contraceptive Vaginal ring, which for contraception is used .. ring contains two female sex hormones Sexual hormone etonogestrel and ethinylestradiol. The ring releases slowly small amounts small amounts this hormones in the bloodstream off. Due to the low amount of hormones that released are, is GinoRing as low dose hormonal Contraceptive considered. As GinoRing two different types of hormones releases, it is called a so-called combined hormonal contraceptive hormonal Contraceptive.

GinoRing acts like a combined contraceptive pill (the "pill"), but instead of every day a pill taking , the ring three weeks continuously applied.

GinoRing releases two female sex hormones that prevent , that an egg cell from the ovaries Ovaries released is. If no egg cell released is, can you not pregnant become.

2. What should you before the use from GinoRing note?

General Notes

Please read you the information about blood clots in section 2, before you start the Application of GinoRing start. It is particularly important to read the symptoms of a blood clot to read – see section 2 "Blood Clots".

In this package leaflet are various situations described, in which you must discontinue the use of GinoRing or have to in which GinoRing less reliable be can. In these situations should you no sexual intercourse have or additionally non-hormonal contraceptive methods such as a condom or a other barrier method apply. Use do not the calendar or temperature method. These methods can unreliable be, as GinoRing the monthly temperature fluctuations and changes of the cervical mucus affects.

Like other hormonal contraceptives provides GinoRing no protection against HIV-infections (AIDS) or other sexually transmitted Diseases.

2.1 GinoRing may not be used ,

GinoRing may not be used , if one of the following listed items applies to you applies. If one of the following listed points applies to you, you must inform this your doctor .. Your Doctor will then with you discuss, which other form of contraception for you better suitable is.

- if you a blood clot in a blood vessel of the legs (deep vein thrombosis, DVT), the lungs (pulmonary embolism, PE) or another organ have (or in the past Past had);
- if you known is, that you suffer from a disorder of blood coagulation for example for exampleprotein -C deficiency,protein Antithrombin-III deficiency, Factor-V Leiden or antiphospholipid antibodies;
- if you need to be operated on or are bedridden for an extended period (see Section "Blood clot");
- if you ever had a heart attack or stroke had;
- if you have angina pectoris (a disease, which severe chest pain caused and a first sign of a heart attack can be) or a transient ischemic attack (TIA – temporary Symptoms of a stroke) have (or in the past had);
- if you suffer from one of the following diseases that increase the risk for a blood clot in an artery increase can:
 - o severe diabetes with damage of the blood vessels
 - o very high blood pressure
 - o very high Blood lipid levels (Cholesterol or Triglycerides)
 - o a disease, known as Hyperhomocysteinemia known is
- if you suffer from a certain form of Migraine (sog. "Migraine with aura") suffer or in the past have suffered ;if
- you have pancreatitis Pancreatitis pancreatitisPancreatitisassociated connected with high blood lipid levels have (had);
- if you a severe liver disease have (had) and your liver function still restricted is;
- if you have a benign or malignant liver tumor have (had);
- if you breast cancer or a cancer in the genital organs have (had) or a corresponding suspicion exists;
- if in you not unexplained bleeding from the Vagina occur;
- if you allergic to Ethinylestradiol or Etonogestrel or any of the in section 6. mentioned other ingredients of this medicinal product are.

Should a the listed conditions first during the use of GinoRing occur, remove immediately the ring and and contact your doctor . Until clarification you should use a non-hormonal contraceptive method . GinoRing must not.

GinoRing may not applied are if you Hepatitis C have and medicines, which Ombitasvir/Paritaprevir/Ritonavir, Dasabuvir, Glecaprevir/Pibrentasvir or Sofosbuvir/Velpatasvir/Voxilaprevir contain, take (see section 2.4 "Use of GinoRing together with other medicines").

2.2 Warnings and Precautions

When should you contact your doctor ? Seek medical help immediately if you experience

- possible You possible Signs of a blood clot notice, which could mean, that you have a blood clot in the leg (i.e., deep vein thrombosis), a blood clot in the lung (i.e., pulmonary embolism), a heart attack or a stroke have (see the section "blood clots" below).

For a description of the Symptoms of serious side effects see the section "How to recognize a blood clot Blood clot..

your doctor , Doctor, if one of the following points applies to you.

If the disease breaks out or worsens during the use of GinoRing worsens, should you also your doctor inform.

- if a close relative breast cancer has or had;
- if you Epilepsy have (see section 2.4 "Use of GinoRing together with other medicines");
- if you a liver disease (e.g. Jaundice) or a gallbladder disease (e.g. gallstones) have;
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease) have;
- if you systemic Lupus erythematosus (SLE – a disease, that your natural immune system affects) have;
- if you a hemolytic-uremic syndrome (HUS – a disorder of blood coagulation, which leads to kidney failure results) have;
- if you sickle cell anemia (a hereditary disease of the red blood cells) have;
- if you elevated blood lipid levels (hypertriglyceridemia) have or this disease in your Family occurred is. Hypertriglyceridemia was associated with an increased risk for pancreatitis (inflammation of the pancreas) associated;
- if you are operated will must or longer time bedridden are (see section 2 "Blood clots");
- if you recently had delivered have, is your risk for blood clots increased. Ask your doctor , howsoon after the delivery you You with the application of GinoRing begin can;
- if you in the veins under the skin an inflammation have (superficial thrombophlebitis);
- if you varicose veins (varices) have;
- if the following symptoms during a pregnancy or the previous use of Sex hormones for the first time in you occurred or worsened deteriorated: hearing disorder ,porphyria (a blood disease), herpesgestationis gestationis duringduring the pregnancy occurring skin rash with blister formation), Sydenham-Chorea (a disease of the nerves with involuntarily occurring movements);
- if you chloasma (yellowish-brown pigment spots, so called "pregnancy spots", mainly on the face) have (or had). If yes, then should you excessive sunlight or UV-radiation avoid;
- if it for medical reasons for you difficult is, GinoRing to use; You have e.g. constipation, a uterine prolapse or pain during sexual intercourse;
- if you frequently, urgently urinate must and in doing so a burning and/or pain feel and not locate the ring in the vagina locate can. These symptoms can a Signs for be, that GinoRing accidentally into the bladder inserted was;

- if you symptoms of angioedema on yourself notice, such as swelling from face, tongue and/or throat and/or difficulty swallowing or rash possibly together with breathing difficulties, should You immediately your doctor consult. Medicinescontaining estrogens contain, can the symptoms of a hereditary and acquired angioedema trigger or worsen.

BLOOD CLOT

During the use of a combined hormonal contraceptive like GinoRing is your risk for the formation of a blood clot higher, as if you none apply. In rare cases can a blood clot blood vessels block and serious problems cause.

Blood clots can occur

- in veins (so-called. "venous thrombosis", "venous thromboembolism" or VTE)
- in the arteries (so-called. "arterial thrombosis", „arterial thromboembolism“ or ATE).

The healing of a blood clot is not always complete. Rarely can it lead to serious persistent complaints come and very rarely progress blood clots fatal.

It is important not to forget, that the overall risk of a harmful to health Blood clots due to of GinoRing low is.

HOW TO RECOGNIZE A BLOOD CLOT

Seek medical urgently assistance immediately ifyou experience any of the following following Signs or symptoms notice.

Does occur to you one of these signs ?	What could you suffer from?
Swelling of a leg or along a vein in the leg or foot, especially if the following occurs simultaneously: <ul style="list-style-type: none"> - Pain or tenderness in the leg, which may only when standing or walking is noticed; - Warming of the affected leg; - Change in skin color of the leg, e.g., emerging paleness, red- or blue discoloration. 	Deep vein thrombosis
sudden unexplained shortness of breath or rapid breathing; sudden cough without obvious cause, where blood may be coughed up; sharp chest pain, that increases with deep breathing; severe dizziness or lightheadedness; faster or irregular heartbeat; severe stomach pain. <p>If you are not sure, talk to a doctor, as some of these symptoms like cough or shortness of breath with a doctor, as some of these symptoms such as cough or shortness of</p>	symptoms,

breath milder illness lighter Disease like e.g. a inflammation of the respiratory tract (e.g. a cold infection) can be mistaken for. Pulmonary embolism	
which mostly in one eye Eye occur: immediate loss of vision or painless blurred vision, which can progress to a loss of vision. Thrombosis of a retinal vein (blood clot	Thrombosis of a retinal vein (blood clot a vein in the eye)
chest pain, malaise, Pressure, Heaviness;	Heart attack
Tightness- or Fullness in chest, arm or below the breastbone; Fullness, Indigestion or Choking sensation; in the back, jaw, neck, arm and stomach radiating discomfort in the upper body; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety or shortness of breath; rapid or irregular heartbeats.	
sudden weakness or Numbness of the face, arm, or leg, particularly pronounced on one side of the body; sudden confusion, speech or understanding difficulties; sudden visual disturbances in one or both eyes; sudden walking difficulties, dizziness, loss of balance or coordination disorders; sudden severe or longer persistent headaches of unknown cause; loss of consciousness or fainting with or without seizure. In some cases, the symptoms of a stroke can be temporary and accompanied by an almost immediate and complete recovery. accompany. should still urgently seek medical treatment, as you suffer another stroke again. could.	Stroke
Swelling and mild bluish discoloration of an extremity; severe stomach pain (acute abdomen).	Blood clots that block other blood vessels obstruct

BLOOD CLOT IN A VEIN

What can happen, when itself in a vein a blood clot forms?

- The use of combined hormonal contraceptives has been associated with a higher risk Blood clot in a vein (venous thrombosis) in association with. These side effects occur however only rarely .. they occur in the first year of use a combined hormonal contraceptive on.

- If it in a vein in leg or foot to a Blood clot comes, can this a deep vein thrombosis (DVT) cause.
- If a blood clot from the leg into the lung travels and lodges there settles, can it a pulmonary embolism cause.
- Very rarely can a blood clot in a vein of another others Organs such as e.g. the eye (thrombosis of a retinal vein) form.

When is the risk of the formation of a blood clot in in a vein at greatest?

The risk of the formation of a blood clot in a vein is in the first year of the first-time application of a combined hormonal contraceptive at the greatest. The risk may also be increased if you use the application of a combined hormonal contraceptive (same or another medication) after an interruption of 4 or more weeks resume ..

After the first year decreases the risk, it remains but always slightly higher, than if no combined hormonal contraceptive was used would.

When you the use of GinoRing stop, returns the risk of a blood clot in a few weeks to the normal level back.

How large is the risk for the formation of a blood clot?

The risk is dependent on your natural Risk for VTE and the type of of you used combined hormonal contraceptive.

The overall risk for a blood clot in leg or lung (DVT or LE) with GinoRing is low.

- Approximately 2 out of 10,000 women, who are neither pregnant nor a combined hormonal contraceptive Contraceptive apply, suffer in the course of a year a blood clot.
- Approximately 5 to 7 out of 10,000 women, who a Levonorgestrel, Norethisterone or a Norgestimate containing combined hormonal contraceptive use, suffer in the course of a year a blood clot.
- Approximately 6 to 12 out of 10,000 Women, who a norelgestromin or etonogestrel containing combined hormonal contraceptive such as GinoRing use, experience in the course of a year a Blood clot.
- The risk of the formation of a blood clot is according to your personal medical history variously high (see following Section "Factors, that risk for a blood clot in a vein increase").

	Risk for the formation of a blood clot per year
Women who do not combined hormonal preparation in the form of a pill/a patch/a ring use and are not pregnant are	Approximately 2 out of 10,000 women
Women, who a Levonorgestrel, Norethisterone or Norgestimate containing combined hormonal pill use	Approximately 5 – 7 out of 10,000 women

Women, who use GinoRing use	Approximately 6 – 12 out of 10,000 women
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Factors, which risk for a blood clot in a vein increase

The risk for a blood clot with GinoRing is low, but is increased by certain conditions and risk factors. The risk is increased:

- if you are severely overweight are (Body Mass Index or BMI over 30 kg/m²);
- if in one of your close relatives at a young age (i.e. younger than 50 years) a blood clot in the leg, in the lung or in another organ occurred is .. this case Case have you possibly a hereditary blood coagulation disorder;
- if you need to be operated must or due to an injury or illness for a longer time bedridden are or a leg in a cast is. It is possible, that the application of GinoRing several weeks before a Operation or in case of restricted mobility terminated must be. If you discontinue use of GinoRing you must discontinue, ask you Your doctor, when you the application resume can;
- if you older become (especially from an age of approximately 35 years);
- if you a few weeks ago gave birth ..

risk of the formation of a blood clot increases with with the Number of existing diseases and risk factors.

Air travel (> 4 hours) can your risk for a blood clot temporarily increase, especially if in you additional of the listed factors are present.

It is important that you your doctor inform, if one of these points applies to you, even if you are not sure .. doctor can then then decide, GinoRing to discontinue.

Inform your doctor about ,if it occurs in one of the above mentioned points during the the Application of GinoRing to a change occurs, e.g. if in a close relative from unknown cause a thrombosis occurs or if you gain a lot of weight.

BLOOD CLOT IN AN ARTERY

What can happen, if a blood clot forms in an artery ??

Exactly like a blood clot in a vein can also a clot in an artery serious problems cause. It can lead to Example a heart attack or stroke cause.

Factors, that risk for a blood clot in an artery increase

It is important, to note, that the risk of a heart attack or stroke due to the use of GinoRing is very low, however increase can:

- with increasing age (older than 35 years);
- if you smoke. When using a combined hormonal contraceptive Contraceptive how GinoRing is advised, to quit smoking .. you cannot quit smoking and older than 35 years old than 35 years are, may your doctor advise you to use another type of contraceptive ;if
- you are overweight overweight are;
- if you have high blood pressure ;if

- one of your close relatives in young years (younger than 50 years) a heart attack or stroke had. In this case could you also a increased risk for a heart attack or stroke have;
- if you or one of your close relatives have a high blood lipid level (cholesterol or triglycerides) have;
- if you migraine and in particular migraine with aura have;
- if you suffer from heart problems (heart valve disease, arrhythmia called atrial fibrillation);
- if you have diabetes have.

If more than one of these points applies to you or one of these conditions is particularly severe, your doctor Risk for the development of a blood clot additionally increased be.

Inform your doctor about ,if there is a of the above above mentioned points during the application of GinoRing a change occurs, e.g. if you start smoking , with the start of close relatives from unknown cause a thrombosis occurs or if you gain weight.

cancer

The following information was received by from studies, which with combined contraceptives, which for oral use are (oral contraceptives, pill), conducted were. They could also for GinoRing apply. Information about the use of contraceptive hormones, which are used in the vagina applied (as in GinoRing), are not available.

Breast cancer was in women who combined pills take, slightly more frequently found. It is however not known, whether this is due to the intake of the pill attributable is. This can for example also due to be, that women , who take the pill take ,more often medically examine have let and thereby more often tumors found will be. After discontinuation of the combined pill the increased frequency of breast cancer cases gradually decreases again ..

It is important, that you regularly examine your breasts. You should consult your doctor, if you find Lump feel. Report your doctor also ,if a close relative breast cancer has or ever had (see section Section 2.2 "Warnings and Precautions").

In pill users rarely reported benign liver tumors and even less frequently reported malignant liver tumors .. Search your doctor if unusually severe abdominal pain occurs . It has.

reported , that in, that at Users of combined pills less frequently cancer of the endometrium (uterine lining) and the ovaries occurs. This could also apply to GinoRing apply, it was however not yet confirmed.

Psychiatric disorders

Some women, who use hormonal contraceptives like GinoRing use, report about depression or depressive mood. Depressions can severe be and occasionally lead Suicidal thoughts suicidal thoughts. If you experience mood swings and depressive symptoms occur, let you be as quickly as possible by your doctor medically advise.

2.3 Children and Adolescents

The safety and efficacy from GinoRing in adolescents under 18 years were not studied.

2.4 Use of GinoRing together with other medicines

Inform you always your doctor, which other medications or herbal preparations you take or use. Inform you also any other Doctor or dentist, who you a different medication prescribes, (or. pharmacist), that you GinoRing use .. You can you also tell you if you additional methods for contraception (e.g. a condom for the man) use must and, if yes, how long, or whether with the application of a further medication, that you need, something changed must be.

Some medications can

- have an influence on the blood levels of GinoRing have;
- its contraceptive effect reduce;
- unexpected bleeding trigger.

These include medications for Treatment of:

- o epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate);
 - o tuberculosis (e.g. rifampicin);
 - o HIVinfections (e.g., Ritonavir, Nelfinavir, Nevirapine, Efavirenz);
 - o Hepatitis C virusinfections (e.g., Boceprevir, Telaprevir);
 - o other infectious diseases (e.g., Griseofulvin);
 - o High blood pressure in the blood vessels of the lungs (Bosentan);
 - o depressive moods (the herbal medicinal product St. John's Wort).
- If you are taking medicinal products or herbal preparations , which could reduce the effectiveness of GinoRing could, should additionally a contraceptive barrier method (for example a condom for the man) used be. Other medications can the effectiveness from GinoRing to to 28 days, after you the application ended have, affect. Therefore is it necessary, the additional contraceptive barrier method also long to use. Note: Do not use GinoRing with together with a diaphragm ,a cervical cap Cervical cap or a condom for women.
 - GinoRing can the effectiveness of other medicines influence, e.g.
 - medicines containing ciclosporin contain
 - of the antiepileptic lamotrigine (this could to an increased incidence lead).
 - GinoRing must not be used if you have Hepatitis C and take medications ,which which Ombitasvir/Paritaprevir/Ritonavir, Dasabuvir, Glecaprevir/Pibrentasvir or Sofosbuvir/Velpatasvir/Voxilaprevir contain, as these the results of a liver function blood test increase can (Increase of ALT liver enzymes).
Your doctor will give you another contraceptive before starting the treatment with this medication prescribe.
Two weeks after completion of the treatment can with GinoRing be started again.
See section 2.1 "GinoRing must not be used ".

Questions Ask your doctor or pharmacist, before you take a medication ..

the application of GinoRing you can use Use tampons. Insert you first GinoRing before you insert a tampon . Be. when you remove the tampon . the tampon remove, and pay attention you to, that GinoRing is not accidentally pulled out with removed. If this does happen, then rinse You the ring simply with cold to lukewarm water off and place it immediately back in.

The ring can break, if in the vagina simultaneously other preparations, such as lubricants or medications for treatment of infections are used (see section 3.4 "What is to do if ... your ring breaks").

The use of spermicides or agents against fungal infections for application in the Vagina affects not the contraceptive effect of GinoRing.

Laboratory tests

GinoRing can the result of some laboratory tests influence. Inform you please therefore the medical staff about, that you GinoRing use, when at you a blood or urine test performed is.

2.5 Pregnancy and lactation

GinoRing must not by pregnant women or by women, who suspect, they might be pregnant be, used be. If you during the use of GinoRing become pregnant , you should remove the ring and consult your doctor ..

If You the application of GinoRing want to stop, because you are pregnant want to become, note please the information in section 3.5 " If If You the application of GinoRing end want to".

The application of GinoRing during the lactation is usually not recommended. If you during the breastfeeding GinoRing use want, then discuss you this please with your doctor.

2.6 Driving ability and ability to Operating of machines

It is unlikely, that GinoRing your ability to drive and your ability to operate machines is impaired impaired.

3. How is GinoRing to use?

You can insert GinoRing yourself and remove. If you are using GinoRing for the first time, will you your doctor tell you, when you GinoRing insert should. The vaginal ring must on the correct day of your menstrual cycle into the vagina inserted are (see Section 3.3 "When is the first GinoRing inserted") and remains there for three consecutive weeks Weeks. You should regularly check, whether the the GinoRing is still in your vagina is located (e.g. before and after the Intercourse), to ensure that you are protected from a pregnancy Pregnancy After the. week remove third Week remove You GinoRing. Now follows a 1-week ring-free period. Usually you will you during this ring free period your menstrual bleeding have.

Use you GinoRing not together with certain barrier methods for women, such as a diaphragm for use in the vagina, one cervical cap or a condom for the woman. These barrier methods for contraception must not be used as additional contraceptive method applied because GinoRing for the correct insertion and position of a diaphragm, a cervical cap or a condom for the woman obstructive be can. However can a condom for the man as additional barrier method applied be.

3.1 How is GinoRing inserted and removed

1. Before you insert the ring insert, check You, whether perhaps the expiry date exceeded was (see section 5 "How to store GinoRing to store?").
2. Wash you your your Hands, before you insert the ring insert or remove.
3. Choose the for the insertion the most comfortable position for you, such as a bent leg, squatting or lying.
4. Remove the GinoRing from the pouch. Keep the pouch for later use Use on.
5. Hold you GinoRing between thumb and index finger firmly, press you the opposite sides together and place you GinoRing into the vagina insert (see figures 1 – 4). If GinoRing is correctly inserted ,you should not feel anything. Do You the feeling, that GinoRing not correctly positioned, then gently push it carefully a bit deeper into the vagina. It is not important, that the ring in a specific place in the vagina lies.
6. After three weeks remove you GinoRing from the vagina, by You with the index finger in the ring hook or the edge with two fingers grasp and the ring pull out (see figure 5). If you the position of the ring in the vagina have felt ,it however not remove can ,then should you your doctor Doctor consult.
7. The used ring can, preferably in the bag, with the household waste disposed of be. Please dispose of GinoRing not over the toilet.

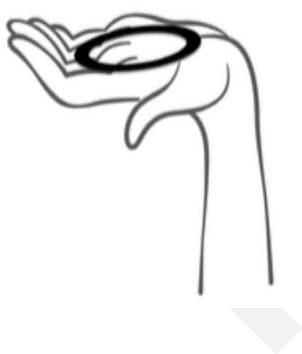


Figure 1
Take you GinoRing out of the pouch



Figure 2
Press you the ring together

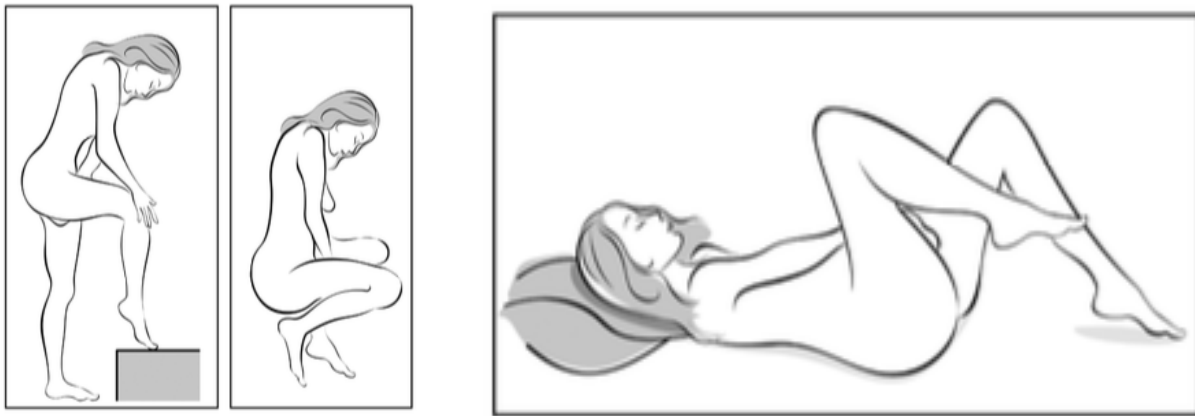


Figure 3
Take you for the Insert of the ring a comfortable position a



Figure 4A Figure 4B Figure 4C
Insert you the ring with one hand into the vagina a (Figure 4A); if necessary, can the labia with the other hand spread be. Insert the ring into the vagina, until it feels comfortably fitted . (Figure 4B). Leave you the ring for 3 weeks in this position (Figure 4C).



Figure 5

GinoRing can be inserted by hooking of index finger or Grasp with the index- and middle finger from the vagina removed be.

3.2 Three weeks application, a Week Break

1. With Start the insertion must the vaginal ring for three consecutive following weeks continuously inserted remain.
2. After three weeks remove you the ring on the same day of the week and approximately at the same time, at the you the ring inserted . Example:Example: You have GinoRing on a Wednesday, approximately at 22:00 o'clock, inserted. Then should you the ring three weeks later, on Wednesday, approximately at 22:00 o'clock, remove.
3. After you remove the ring have removed , apply you a a Week long no ring on. During this week you should get your menstrual period .. usually begins two to three three Days, after you GinoRing removed have.
4. After exactly one week (again on the same weekday, approximately at the same Time) insert you a new ring in. Even then, if your menstrual bleeding still continues.

If the new Ring more than three hours too late inserted is, can the contraceptive effect be impaired be. Follow the instructions Instructions in section 3.4 "What is to do if forgot to insert after the ring- free period a new ring Ring insert".

If you the above described instructions follow, you will your menstrual period every month approximately at the same time get.

3.3 When will the first ring inserted

- If you in the previous month no hormonal contraceptives used have Insert you the first GinoRing on first day of your menstrual cycle (i.e. on first day of the menstrual bleeding) insert. GinoRing begins immediately to act. You do not need contraceptive methods use.
- You can GinoRing also on the days 2 – 5 of your menstrual cycle insert. However should you then during the first seven days of GinoRing use additionally a different

contraceptive (such as a condom) apply, when you have sexual intercourse . This applies however only ,when you GinoRing for the first time use ..

- If You in previous month a combined pill taken have
- Insert you GinoRing at the latest on the first day after the pill-free period Your Pill a. Contains Your pill pack also Tablets without active ingredient, insert you GinoRing at the latest on the Day after the Intake the last placebo tablet a. If you are not sure ,which tablet this is ,ask your doctor Your doctor or pharmacist. Never extend the prescribed hormone- freeperiod of the pill. If
- you take the pill regularly and correctly taken taken have and you are sure are, that you not pregnant are, can you on any day start the pill intake end and immediately with the application of GinoRing start.
- If you in the previous month a contraceptive patch used have
- Insert you GinoRing at the latest on the first day after the patch-free period a. Never extend the prescribed patch- freeperiod. If
- If You the contraceptive patch regularly and correctly applied have and you are sure ,that you are not pregnant are ,, can you on any given day stop the contraceptive patch and immediately start with the use of GinoRing .
- If you in previous month a minipill (pure progestogen-pill) taken have You can the intake of the minipill on any chosen day end and on the next day at the usual time of administration GinoRing insert. Use you but during the first seven days of application of the ring additional contraceptive methods (such as a condom), if you have sexual intercourse ..
- you in the previous month a hormonal injection Hormone injection, a implant or a hormone-containing coil (an IUD – intrauterine progestogen-releasing system) used have Insert you GinoRing on the Day a, on which your next hormone injection due would be, or on which day, on which your implant or the hormone-containing coil removed is. Use you during the first seven days of application of the ring additional contraceptive methods (such as a condom), when you have intercourse ..
- a birth After
- a birth you will be advised by your doctor to that You Your first normal menstrual period wait, before you start the use of GinoRing begin. Sometimes is it also possible, earlier to begin. Your doctor will advise you. If you are breastfeeding and GinoRing use want, should you this first with your doctor discuss.
- After a miscarriage or an abortion
- Your doctor will advise you accordingly.

3.4 What is to do, if ...

Your ring accidentally out of your vagina expelled

was GinoRing can accidentally out of the expelled will be, for example if it is not correctly inserted was, during the removal of a tampon, during sexual intercourse, in case of constipation or in a uterine prolapse. Therefore should you regularly check, whether the ring is still in your vagina located (e.g. before and after the Sexual intercourse).

Your Ring temporarily outside the vagina was

GinoRing can you possibly still before a pregnancy protect, this is however of it dependent, how long the ring outside your vagina was.

If the ring

- less than three hours outside the vagina was, protects it you still before a pregnancy. Rinse the ring with cold to lukewarm (not hot) water off and place it him as soon as possible again a, however only then, if the ring was not longer than three hours outside the vagina was.
- during the first or second week of use more than three hours outside the vagina was, it may not possibly be effective before a pregnancy protect. Rinse the ring with cold to lukewarm (not hot) water off and place the ring back into the Vagina a, as soon as you think about it. The ring must at least the next seven days without interruption remain inserted. If you during this seven days sexual intercourse have, then use you additionally a condom for the man. Are you in the first first Week of use and you had during the previous seven days sexual intercourse, you could be pregnant have become. In this case contact please Your doctor.
- during the third week of use more than three hours outside the vagina was, it may you possibly not anymore before a pregnancy protect. You should this Ring dispose and one of the following options choose:
 - 1) Place you immediately a new ring a. This starts you the next three weeks of use. Your monthly bleeding may be absent, there could however breakthrough bleeding or spotting occur.
 - 2) Insert you no ring in. Wait you your menstrual bleeding for and insert you then within of seven days, after the previous ring expelled or removed was, a new ring insert. From this possibility should you only use make, if you GinoRing in the previous seven days continuously used had.
- If itself GinoRing for an unknown period outside the vagina was, you are possibly not protected against Pregnancy pregnancy. You should a pregnancy test perform and your doctor consult, before you a new ring insert.

Your ring breaks

GinoRing can break. In connection with a ring break was reported injuries in the vagina reported. If you notice, that GinoRing broken is, so use you this not further, but start you as soon as possible with a new Ring. Use you during the next seven days additional contraceptive methods (such as a condom for the man). Did you have intercourse, before You noticed, that the ring is broken is, so contact you please your doctor.

You more than one ring inserted have

There are no reports about serious effects of an overdose of the hormones in GinoRing contained hormones available. If you accidentally more than a ring inserted have, may nausea, vomiting or spotting occur. Remove the excess rings and seek search You your doctor consult, if these symptoms persist.

You forgotten have, after the ring-free period a new Ring to insert

If your ring-free time longer than seven days lasted: As soon as you notice this, insert you a new ring into the Vagina a. Use you additional contraceptive methods (such as a condom for the man), if you within the next seven days sexual intercourse have. Had you during the ring-free period sexual intercourse, then there is the possibility, that you became pregnant are. In this case contact your doctor immediately . Thelonger the ring- freeperiod lasted ,the greater is the risk Risk, that you pregnant become are.

You forgot to remove the ringto remove If

- your ring between three to four weeks Weeks inserted was, is the contraceptive effect not impaired. Continue you with a ring-free week continue and insert you then a new Ring one.
- If your Ring more than four weeks inserted was, there is the possibility pregnant to become. Contact your doctor ,before you insert a new ring ..

menstrual bleeding has not occurred is You

- have the application instructions Instructions for use for GinoRing exactly followed If your menstrual bleeding has not occurred is, you however the instructions for use for GinoRing exactly followed and no other Medicinal product taken/applied have, so is it very unlikely, that you pregnant are. Continue you with the Application of GinoRing as usual continue. If your menstrual bleeding however twice in a row misses, then there is the possibility, that You pregnant are. Discuss this immediately with your doctor . Do notuse the next GinoRing until then ,if you Your doctor a pregnancy excluded has.
- You have the instructions for use for GinoRing not followed If your menstrual bleeding has not occurred is, You the instructions for use for GinoRing not followed have and the expected monthly bleeding in the first ring- freeperiod does not occur ,, could it be, that you are pregnant ?. Consult your doctor before inserting a new GinoRing . a new GinoRing insert.

You unexpected bleeding have

During the use of GinoRing occur in some women between the normal menstrual bleeding unexpected bleeding from the Vagina on. It could be that you appropriate hygiene products use must. Leave you GinoRing in any case in the vagina and continue you the application as usual continue. Persist the irregular bleeding persist, become they stronger or repeat themselves these, so search you please your doctor consult.

you the first day your menstruation postpone want

If you GinoRing like prescribed apply, will Your menstrual period (withdrawal bleeding) in the ring-free week begin. If you the first day of the menstrual period change want, so shorten (but never extend!) You the ring-free period.

For example: Does your menstrual bleeding usually on a Friday, so can you this from the next month to the Tuesday (three days earlier) postpone. You must the ring only three days earlier than usual insert.

If you the ring-free period very shorten (e.g. three days or less), so it may be that your usual monthly bleeding does not occur .. the use of the next ring however may occur Spotting (Blood drops or Blood spots) or Breakthrough bleeding occur.

Consult your doctor for advice, if you feel not not sure are, how you proceed should.

you your menstrual period delay want

Although this is not the recommended usage instructions corresponds, can you your Menstrual bleeding (withdrawal bleeding) delay, by you the ring-free period skip and immediately after the used ring a new Ring insert.

The new ring can up to three weeks in the vagina remain. During the application of the new Ring can spotting (blood drops or blood stains) or breakthrough bleeding occur. If you want, that your menstrual bleeding starts, remove you the ring simply. Hold you the normal one-week ring-free period in and place you then a new ring a.

You can ask your doctor for advice, before you decide to delayyour monthly period . delay.

3.5 If you the use of GinoRing want to stop

You can the use of GinoRing, whenever you want, stop. If If You not pregnant become want, so ask your doctor about other contraceptive methods Contraceptive methods.

you the use of from GinoRing due to a desire to have children discontinue, then you should wait for a normal menstrual bleeding beforeyou try to becomepregnant. pregnant to become. This helps, to calculate the due date to calculate.

4. What side effects are possible?

Like all medicines can this medicine have side effects , which, the but not in every occur must. If you side effects experience, especially, if these severe and persistent are, or if your health condition changes and you attribute this to GinoRing, talk to your doctor . Doctor.

All womenwho combined hormonal contraceptives use, have an increased risk for blood clots in the veins (venous thromboembolism [VTE]) or arteries (arterial thromboembolism [ATE]). Further details on the various risks associated with the use of combined hormonal contraceptives see section Section 2 "What should you before the use of GinoRing consider?".

You should immediately consult your doctor, if you one of the following symptoms of an angioedema on yourself notice: swelling of face, tongue and/or throat and/or difficulty swallowing or skin rash possibly together with breathing difficulties (see also section "Warnings and Precautions").

Users of GinoRing have about the following side effects reported:

Common: may up to 11 10 10 affect abdominal pain

- Abdominal pain/feeling unwell Feeling of illness (nausea)
- Infections the vagina by yeast (such as "thrush"); discomfort in the vagina due to the ring; itching in the genital area; discharge from the vagina
- Headaches or migraine; depressive mood; reduced libido
- Breast pain; Pain in the pelvis; painful menstruation
- Acne
- Weight gain
- The ring is expelled

Occasionally: can up to 1 in 100 women affect

- Visual disturbances; Dizziness
- Bloating abdomen; Vomiting; Diarrhea or Constipation
- Fatigue, Malaise, Irritability; Mood changes; Mood swings
- Fluid retention in the body (Edema)
- Cystitis or Inflammation of the urinary tract
- Difficulties or pain during urination; increased urge to urinate, increased urination
- Problems during sexual intercourse such as pain, Bleeding or the sexual partner feels the ring
- Increased blood pressure
- Increased appetite
- Back pain; Muscle cramps; Pain in the legs or arms
- Reduced sensation of the skin
- Chest pain or Enlargement of the breasts; fibrocystic mastopathy (cysts in the breasts, which swell or painful become can)
- Inflammation of the cervix; formation of polyps in the cervix (tumors in the cervix); protrusion of the cervix (ectropion)
- Changes of the bleeding behavior (it can e.g. lead to heavy, prolonged or irregular menstrual bleeding occur or these can completely cease); complaints in the pelvic area; premenstrual syndrome; uterine cramp
- vaginitis (caused by bacteria or fungi); burning, odor, pain, Complaints or dryness in the vagina or the external genitalia
- hair loss, eczema, itching, skin rash or hot flashes
- hives

Rarely: can to up to 1 in 1,000 women affect

- Harmful blood clots in a vein or artery, for example:
 - o in a leg or foot (i.e. DVT)
 - o in a lung (i.e. PE)

- o heart attack
- o stroke
- o mini-stroke or transient, a stroke like symptoms, which are referred to as transient ischemic attack (TIA) referred to are
- o blood clot in the liver, the stomach/intestines, the kidneys or the eye.

The probability of a blood clot can increased be, if you have a different condition suffer, which this risk increases (further information on the conditions, which the risk for a blood clot increase, and the symptoms of a blood clot see section 2).

- Milky discharge from the mammary gland

Not known (Frequency based on the available data not estimable)

- Chloasma (yellowish-brown pigment spots in the skin, predominantly on the face)
- Penile complaints at the sexual partner (such as skin irritation, skin rash, itching)
- the ring cannot without medical assistance be removed (e.g. because the ring at the septum adheres)
- Injuries in the vagina caused by ring breakage

Among users of combined hormonal contraceptives there has been reports of breast cancer and liver tumors reported. Further information on this see section 2.2 "Warnings and precautions, cancer".

GinoRing can break. Further information on this see section 3.4 "What to do if your ring ...". Reportingof.

Report from Side effects

If you notice side effects, contact your doctor or your physician or pharmacist. This also applies to side effects not listed in this package leaflet. Package leaflet specified are. You can side effects also directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de report.

By you Side effects report, can you contribute to that more information about the safety of this medication available provided be. How be.

5. How is GinoRing to store?

Keep this medicine out of reach of children ..

you notice, that a child with with the in GinoRing contained hormones in contact come is, so ask your doctor for advice. For

this medication are regarding regarding the Temperature no special storage conditions required. In the original packaging store, to protect the contents from light to protect.

GinoRing must at the latest a month before expiry of the on the carton after "usable until" stated expiration date inserted be. The expiration date refers to the last day of the specified month.

Do not use GinoRing if you notice any discoloration or visible signs of damage one Damage notice.

This medication can a risk for the environment represent. After removal should GinoRing be placed back in the pouch returned and this properly sealed be. The sealed bag should with the regular household waste or to the pharmacy for proper disposal according to local requirements returned be.

Dispose of medicines never via the wastewater (e.g. not via the toilet or the sink). Ask your pharmacist Your pharmacy, how to medication to dispose is, when you no longer use . You contribute to the protection of the environment at. Further information can be found at www.bfarm.de/arzneimittelentsorgung. Contents

6. of the package and further information What GinoRing contains The

active ingredients are :: Etonogestrel and Ethinylestradiol

GinoRing contains 11.0 mg Etonogestrel and 3.474 mg Ethinylestradiol. Over a period of 3 weeks releases the ring on average each 0.120 mg Etonogestrel and 0.015 mg ethinylestradiol in 24 hours free.

The other components are: Poly(ethylene-co-vinyl acetate) (72:28) 28% vinyl acetate and polyurethane (a plastic, which is not from body absorbed is).

How GinoRing looks and Contents of the package

GinoRing is a flexible, transparent, colorless to almost colorless ring, with a outer diameter of 54 mm and a cross-sectional diameter of 4 mm.

Each ring is in a Aluminum pouch packed. The pouch is together with this package insert and adhesive labels for your appointment calendar in a folding box packed. The adhesive labels help you to remember when you need to insert GinoRing and remove it..

carton contains 1 ring 3

3 6

6 Rings

There may be possibly not all pack sizes placed on the market .

Pharmaceutical entrepreneur and manufacturer

Pharmaceutical entrepreneur Exeltis Germany GmbH Adalperostraße 84

85737 Ismaning www.exeltis.de

Phone: 089 4520529 – 0

Fax: 089 4520529 – 99

Manufacturer

Laboratorios León Farma, S.A.

Polígono Industrial Navatejera;

La Vallina s/n;

24008-Villaquilambre, León

Spain

This medication is in the Member States of the European Economic Area (EEA) under the following designation approved:

Denmark: Ornibel 120/15 microg./24 hours, vaginal delivery system
Germany: GinoRing 0.120 mg/0.015 mg per 24 hours vaginal drug delivery system
Estonia: Ornique
Finland: Ornibel 0.120 mg / 0.015 mg per 24 hours, depot preparation, vaginally
Austria: GinoRing vaginal ring 0.120 mg/0.015 mg per 24 hours vaginal active ingredient release system
Lithuania: Ornique 120/15 micrograms/24 hours use into vagina system
Latvia: Ornique 120/15 micrograms/24 hours vaginal administration system
Netherlands: Ornibel 0.120/0.015 mg per 24 hours, vaginal use device
Norway: Ornibel
Poland: Ginoring
Sweden: Ornibel
Slovakia: Ornibel 0.120/0.015 mg per 24 hours vaginal insert
Czech Republic: Ornibel 0.120 mg/0.015 mg per 24 hours
Hungary: Ladeering 0.120/0.015 mg per 24 hours, vaginal delivery system

This package leaflet was last revised in September 2022.