

SyreniRing 0.120mg/0.015mg per 24 hours**VAGINAL DELIVERY SYSTEM**

etotogestril/ethinylradriol

WHAT I NEED TO KNOW ON COMBINED HORMONAL CONTRACEPTIVES (CHCs)

Combined Hormonal Contraceptives (commonly named "pills") are not intended to treat any disease; its use is intended to prevent undesired pregnancies.

Contraceptive pills are one of the most reliable reversible methods of contraception if used correctly.

All combined hormonal contraceptives, including the one prescribed to you, increase the risk of the formation of a blood clot. The overall risk of developing a blood clot using combined hormonal contraceptive is low, however, blood clots can be serious and in very rare cases, even fatal. It is especially important that you recognise when you have a higher risk of a blood clot and what signs and symptoms you should look for, and what actions you need to take.

WHEN IS THE RISK OF DEVELOPING A BLOOD CLOT GREATEST?

- In the first year of use of a combined hormonal contraceptive, including if you are restarting after a 4 week or more break.

- Being overweight or obese.

- Being older than 35 years.

- If you smoke.

- When one of your relatives had a blood clot below the age of 50 years. Blood clots include Deep Vein Thrombosis (DVT), Lung / Pulmonary embolism (PE), heart attack or stroke.

- If you have given birth in the previous 6 weeks.

- If you smoke and are older than 35 year-old, you are strongly advised to quit smoking or use a non-hormonal contraceptive.

WHEN TO SEEK IMMEDIATE MEDICAL ADVICE

You should seek your doctor immediately if you notice any of the following symptoms, since you could be suffering from a deep vein thrombosis, a pulmonary embolism, a heart attack or a cerebrovascular attack (stroke).

Symptoms of Deep Vein Thrombosis:

- Soreness pain or swelling in either of your legs or feet that may be accompanied by pain on pressure, heat or change in the skin colour, such as turning pale, red or blue.

Symptoms of Pulmonary Embolism:

- Sudden cough without an obvious cause, which may produce bloody or blood-streaked sputum

- Severe pain in the chest, which may increase with deep breathing

- Sudden unexplained breathlessness, difficulty in breathing or rapid breathing that may occur whether you are active or at rest

Symptoms of a Heart Attack:

- Sudden chest pain or discomfort

- Upper body discomfort, pressure or heaviness radiating to one or both arms, the back, shoulders, neck, jaw, or upper part of the stomach (above the belly button).

- Feeling of fullness, indigestion or choking

- Cold sweat, nausea, vomiting or dizziness

Symptoms of a Cerebrovascular Attack (stroke):

- Sudden weakness or numbness of the face, arm or leg, especially on one side of the body

- Sudden confusion

- Trouble in speaking or understanding

- Sudden blurred or loss of vision in one or both eyes

- Severe or persistent headache/ migraine

- Loss of consciousness or fainting

Package leaflet: Information for the user**SyreniRing 0.120mg/0.015mg per 24 hours****VAGINAL DELIVERY SYSTEM**

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Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly.

- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.

- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots").

Read all of this leaflet carefully before you start using SyreniRing because it contains important information for you.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is available as the above name but will be referred to as SyreniRing throughout this leaflet.

What is this leaflet**1. What SyreniRing is and what it is used for****2. What you need to know before you use SyreniRing****2.1 When you should not use SyreniRing****2.2 Warnings and precautions****2.3 Blood clots****Cancer****2.3 Children and adolescents****2.4 Other medicines and SyreniRing****Laboratory tests****2.5 Pregnancy and breast-feeding****2.6 Driving and using machines****3. How to use SyreniRing****3.1 How to insert and remove SyreniRing****3.2 Three weeks in, one week out****3.3 When to start with the first ring****3.4 What to do if...****Your ring is accidentally expelled from the vagina****Your ring has temporarily been out of the vagina****Your ring breaks****You have inserted more than one ring****You have forgotten to insert a new ring after the ring-free interval****You have forgotten to remove the ring****You have missed a menstrual period****You have unexpected bleeding****You want to change the first day of your menstrual period****You want to delay your menstrual period****3.5 When you want to stop using SyreniRing****4. Possible side effects****5. How to store SyreniRing****6. Contents of the pack and other information****What SyreniRing contains****What SyreniRing looks like and contents of the pack****Manufacturer and Product License Holder****1. What SyreniRing is and what it is used for**

SyreniRing is a contraceptive vaginal ring used to prevent pregnancy. Each ring contains a small amount of two female sex hormones – oestrogen and ethinylestradiol. The ring slowly releases these hormones into the blood circulation. Because of the low amount of hormones that is released, SyreniRing is considered a low-dose hormonal contraceptive. Since SyreniRing releases two different types of hormones, it is a so-called combined hormonal contraceptive.

SyreniRing works just like a combined contraceptive pill (the Pill) but instead of taking a pill every day, the ring is used for 3 weeks in a row. SyreniRing works like two female sex hormones that prevent the release of an egg cell from the ovaries. If no egg cell is released you cannot become pregnant.

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