SyreniRing 0.120 mg/0.015mg per 24 hours,
vaginal delivery system, Etonogestrel/ Ethinylestradiol (POM)

CHECKLIST FOR PRESCRIBERS

Please use this checklist in conjunction with the relevant technical information of the product when prescribing any combined hormonal contraceptives (CHCs).

Ever since the introduction or oral contraceptives, their use has been associated with an increased risk of both venous thromboembolism (VTE) and arterial thromboembolism (ATE).
The individual risk associated to the use of CHCs depends on each user's baseline risk of thromboembolism. In order to decide if the use of CHCs is suitable for the user, the contraindications and the risk factors of the user should be taken into account, in particular the risk factors for thromboembolic events. For this, please use the following checklist of risk factors to determine the individual's risk of ATE and VTE.

When using a CHC, the risk of thromboembolism increases:
- During the first year of application
- When restarting the treatment after a 4 weeks (or longer) break

It is known that among the CHCs, combinations of ethinylestradiol with levonorgestrel, norgestimate or norethindrone, have the lowest risk of VTE. The decision to use a different CHC to the one with the lowest risk for VTE should be made only after informing the user.
Please ensure that the user understands the following:
- The risk of VTE or ATE when using CHCs
- The influence of her own personal risk factors on the thrombosis risk
- She should pay attention to the signs and symptoms of thrombosis

Don't prescribe a CHC if one of the boxes in this section is ticked:	
	Has the woman an existing thromboembolism or history of thromboembolism? E.g. deep vein thrombosis, pulmonary embolism, heart attack or stroke, transient ischemic attack, angina pectoris
	Has the woman any blood clotting disorder?
	Has the woman migraine with focal neurological symptoms (aura)?
	Has the woman had diabetes mellitus with vascular complications in the past?
	Has the woman very high blood pressure, i.e. systolic at ≥160 mmHg or diastolic at ≥100 mmHg?
	Has the woman hyperlipidemia?
	Is a major surgery or a long immobilisation planned? If so, the intake should be interrupted and a non-hormonal method of contraception should be used for at least 4 weeks before surgery and 2 weeks after the remobilisation. (Note increased risk of VTE when restarting CHC after break of 4 weeks or more.)

Discuss the suitability of CHC with the woman, if you tick one of the boxes in this section:	
	Is her BMI over 30kg/m^2?
	Is she older than 35 years?
	Does she smoke? If so, and if she is also older than 35 year-old, she should be strongly recommended to quit smoking or to use a non-hormonal contraceptive method
	Does she have high blood pressure, i.e. systolic at 140-159 mmHg or diastolic at 90-99 mmHg?
	Has any close relative (i.e. parent or sibling) of the woman had a thromboembolic event (see list above) at a young age (i.e. younger than 50 years)?
	Does she or a close relative have high blood lipids?
	Does she have migraines?
	Does she suffer from a cardiovascular disease, i.e. atrial fibrillation, arrhythmias, coronary artery disease, valvular heart disease?
	Does she suffer from diabetes mellitus?
	Has she given birth in the last 6 weeks?
	Will she regularly take long flights (over 4 hours) or drive for more than 4 hours per day?
	Has she any other disease that may increase her risk of thrombosis (e.g. cancer, systemic lupus erythematosus, sickle cell anaemia, Crohn's disease, ulcerative colitis, hemolytic uremic syndrome)?
	Is she taking other medicines that may increase the risk of thrombosis (i.e. corticosteroids, neuroleptics, antipsychotics, antidepressants, chemotherapeutics and others)?
If more than one risk factor is ticked, a CHC should not be prescribed. Do not forget that the individual risk factors may change over time. It is important to regularly use this checklist during the consultation.	

Ensure that the woman understands that she must inform a health professional that she is using a CHC, if she:

- **Requires surgery**
- **Will be immobilised for a long time period (eg due to an injury or disease or if her leg is in a cast)**

- In these situations, it would be best to discuss whether a non-hormonal method of contraception should be used until the temporary increased risk is no longer present

Please tell the user of the CHC that her risk for a blood clot is increased if:

- **She travels for a long time (e.g. flights over 4 hours)**
- **She develops one of the contraindications or risk factor for VTE**
- **She has given birth in the last 6 weeks**

- In these situations, your patient should pay particular attention to signs and symptoms of thromboembolism

Please advise the users, to inform you of any changes or deterioration of the situations listed above. Please encourage users to read the leaflet that comes with each package of CHC. This includes the symptoms of a blood clot which they should be alert to.

Please report all adverse drug reactions of a combined oral contraceptive to the marketing authorization holder or to the National Health Authority.

MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited, 3 & 4 Quidhampton Business Units, Polhampton Lane, Overton, RG25 3ED, UK.
PL 20416/0567