



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 03 August 2020

EL (20)A/36

Our Ref: MDR 031-07/20

Dear Healthcare Professional,

Crescent Pharma Ltd

**SyreniRing 0.120 mg/0.015 mg per 24 hours, vaginal
delivery system**

PL 20416/0567

Batch Number	Expiry Date	Pack Size	First Distributed
LF18276AA	08/2021	3x1	March 2020
LF18894AA	11/2021	3x1	April 2020

Active Pharmaceutical Ingredients: etonogestrel/ethinylestradiol

Brief description of the problem

Crescent Pharma Ltd has informed us that the Patient Information Leaflet (PIL) within the packs for the above batches is missing important safety relevant text changes. The changes to the PIL include the addition of the following information:

- Warnings and precautions Psychiatric disorders: Some women using hormonal contraceptives including SyreniRing have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

It is important that any patients are provided with information on warnings and precautions whilst taking SyreniRing. Additionally, patients who notice the symptoms/side effects or mood effects should seek immediate medical advice.

Advice for healthcare professionals

When dispensing this product, please check the Marketing Authorisation Holder and the batch number; if any of the above batch numbers are being dispensed, ensure that patients are aware of any missing information.

The current PILs includes the special warning and precautions and should be issued when this product is dispensed. This can be obtained from the Crescent pharma web site (www.crescentpharma.com).

- [SyreniRing Vaginal Delivery System - PIL](#)



Further Information

For more information or medical information queries, please contact: Crescent Pharma Ltd. Medical Information Department on +00351 214643225, via email on tiago.barca@pharsolution.com or +44 (0) 1256 772740.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**