

Direct Healthcare Professional Communication

12 June 2018

Cetrotide® (cetrotirelix acetate) 0.25 mg powder and solvent for injection: Risk of pulling out the plunger with the new syringe when drawing up medication resulting in loss of product sterility

Dear Healthcare professional,

Merck Serono Ltd, in agreement with the European Medicines Agency and the MHRA would like to inform you of the following:

Summary

- **When using Cetrotide with the newly introduced syringe (Becton Dickinson Hypak) there is a risk of completely pulling out the plunger with the attached rubber stopper when drawing up medication. If this happens, the sterility of the product is lost and therefore the dose should be discarded.**
- **Healthcare professionals should advise patients of the following:**
 - **When drawing the medication from the vial, patients should pull out the plunger slowly and carefully, in order to draw the medicine from the vial back into the syringe. Patients should be careful not to pull out the plunger with the attached rubber stopper completely.**
 - **If patients pull out the plunger with the attached rubber stopper completely, they should discard the dose, as sterility of the medicine will be lost.**
 - **Patients should contact their doctor or pharmacist and request a replacement dose as soon as possible if this occurs.**
- **The Product Information will be updated as soon as possible with instructions on how to avoid the plunger from pulling out completely when using the new Becton Dickinson Hypak syringe.**
- **Merck is working to resolve this problem with the plunger.**

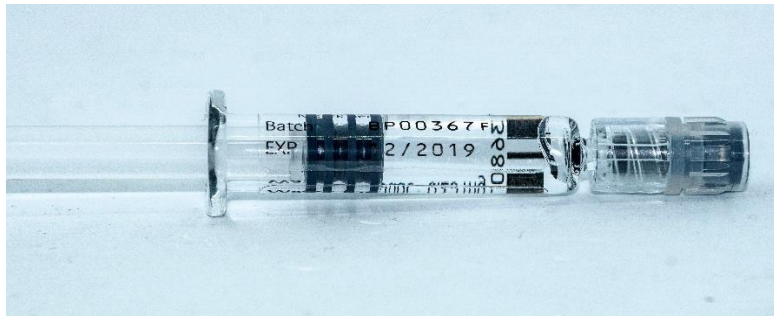
Background of safety considerations

Cetrotide® is indicated for the prevention of premature ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.

Recently, a new syringe (Becton Dickinson Hypak) has been introduced for Cetrotide.

Since the introduction of this new syringe in 2017, complaints were received from patients using Cetrotide that the plunger with the attached rubber stopper can accidentally be pulled out completely when drawing up medication as shown in the pictures below:

Picture 1. BD Hypak Syringe as packed in Cetrotide pack



Picture 2. Syringe plunger can be pulled to this position



Picture 3. Plunger pulled out completely, sterility is lost



When this happens the sterility of the dose is lost, thereby introducing a safety risk.

Merck is evaluating options to resolve this problem with the plunger.

Call for reporting

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>.

Adverse events should also be reported to Merck (0208 818 7373) / medinfo.uk@merckgroup.com

Company contact point

Health care providers and patients are encouraged to report any incidents with the Becton Dickinson Hypak syringe using the following contact details via Merck medical information. Should you have any questions or require additional information regarding the use of Cetrotide® please contact the Merck Medical Information department on 0208 818 7373 or by email via: Medinfo.uk@merckgroup.com.

Yours faithfully,

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Cetrotide® 0.25 mg (cetorelix acetate) Powder and solvent for solution for injection
Marketing authorisation holder(s)	Merck Serono Europe Ltd
Safety concern and purpose of the communication	To inform about design difference with the new Becton Dickinson Hypak syringe and potential risk of loss of sterility when using new syringe.
DHPC recipients	Pharmacies <ul style="list-style-type: none">• National Homecare pharmacies• Community pharmacies Fertility specialist HCPs: <ul style="list-style-type: none">• Fertility HCPs, fertility specialists, fertility nurses
Method of Dissemination	Physical letter to be disseminated via mailing house to Fertility Specialists Email letter with read receipts to Fertility Clinic primary contact list Email letter with read receipts to pharmacies