28/06/2022

Direct Healthcare Professional Communication (DHPC)

Cetrorelix acetate - Cetrotide® 0.25 mg Powder and solvent for injection: Temporary Shortage

Dear Healthcare Professional,

Merck Healthcare KGaA, in agreement with the European Medicines Agency and the Malta Medicine Authority, would like to inform you of the following:

Summary

- Technical problems at the main product manufacturing site for Cetrotide have led to a shortage which is expected to last until December 2022.

- Starting from 1 September until end of December 2022, we recommend that you do not initiate a cycle with Cetrotide. Please liaise with the Merck contact point listed below for further information if required. In the absence of Cetrotide, you might use any alternative available on the market.

Background on the shortage

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

Technical problems at the main product manufacturing site have led to a reduced and delayed supply of Cetrotide. The quality of the manufactured and released product batches is not affected by these technical problems.

Call for reporting

Please report any suspected adverse reactions to Cetrotide (cetrorelix acetate) 0.25 mg powder and solvent for injection to the Malta Medicine Authority through download report forms from www.medicinesauthority.gov.mt/adrportal and posted to ADR reporting/Post-Licensing Directorate/Medicines Authority, Sir Temi Zammit Buildings, Malta Life Science Parks, San Gwann, Malta or sent by email to postlicencing.medicinesauthority@gov.mt

Reporting suspected adverse reactions after authorization of the medicinal product is important to ensure patient safety. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Alternatively, suspected adverse drug reaction may be reported to the marketing authorisation holder, Merck Healthcare KGaA via the following email: GlobalDrugSafety@merckgroup.com or directly calling on +496151720.

Company contact point

Thank you for your patience and your continued support as we work to resolve this with as little disruption to you and your patients as possible. Please contact us directly via the contacts below with any queries and we will revert as soon as possible.

Company	**Email**	**Phone**
Merck Healthcare KGaA	GlobalDrugSafety@merckgroup.com	+49 6151 – 72 0

Local Contact Point

Vivian Corporation act as local distributor of Merck products in Malta on behalf of Merck Export GmbH.

Email: pv@viviancorp.com

Phone: 22588600