

<date>

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 <National Competent 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 <date> (*market specific date for resolution*).
- Starting from <date> (*expected date of shortage*) until <date> (*market specific date for resolution*), 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 <insert the local NCA name> through <to be adapted locally depending on local regulations>.

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.

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.

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address >

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Cetrotide 0.25 mg powder and solvent for solution for injection
Marketing authorisation holder(s)	Merck Europe B.V.
Purpose of the communication	The purpose of the communication is to notify HCPs of possible patient level stock outs of Cetrotide (cetrotide acetate) 0.25 mg powder and solvent for solution for injection. This shortage has been caused by technical issue at the main manufacturing site. Merck is taking all the necessary proactive steps to resume the supply of Cetrotide as early as possible.
DHPC recipients	Healthcare Professionals who prescribe Cetrotide 0.25 mg The exact DHPC target group(s) should be discussed with the NCAs on a national level.
Member States where the DHPC will be distributed	Belgium*, Bulgaria, Cyprus, Czech Republic, France, Greece*, Hungary, Ireland, Latvia, Lithuania, Estonia, Luxemburg*, Malta, Netherlands, Poland*, Portugal, Romania, Slovakia*. *alternative pack size of Cetrotide might be available Potentially out of stock starting in May/June 2022, DHCP will be disseminated as required
Timetable	
DHPC and communication plan (in English) agreed by CHMP	23/06/2022
Submission of translated DHPCs to the national competent authorities for review	Within 10 days after receipt of the approved DHPC
Agreement of translations by national competent authorities	According to the timelines set by NCAs
Dissemination of DHPC	Within 2 weeks after respective NCA approval