Direct Healthcare Professional Communication

30th July 2020

Leuprorelin-containing depot products: need to strictly follow instructions for reconstitution and administration to reduce the risk of handling errors that may result in lack of efficacy

Dear Healthcare Professional,

In agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA), the Marketing Authorisation Holders of leuprorelin-containing depot medicinal products would like to inform you of the following:

Summary

- **Handling errors have been reported with leuprorelin-containing depot medicinal products, potentially resulting in lack of efficacy.**
- **The risk of handling errors is increased when there are multiple steps in the product reconstitution and administration process.**
- **Leuprorelin-containing depot products should be prepared, reconstituted and administered only by healthcare professionals who are familiar with these procedures.**
- **It is important to strictly follow instructions for reconstitution and administration provided in the product information.**

Background on the safety concern

Leuprorelin-containing medicines are used to treat prostate cancer, breast cancer and conditions that affect the female reproductive system (endometriosis, symptomatic uterus myomatosus, uterine fibrosis) and early puberty. They are available as daily injections or depot formulation (implants and powders and solvents for the preparation of injections). Cases of handling errors potentially resulting in lack of efficacy have been reported with depot formulations.

The present recommendations are made following an EU-wide review of this issue which concluded that the risk for handling errors is increased when there are multiple steps in the product reconstitution and administration process. To minimise the risk of handling errors, measures will be introduced, including updates to the SmPC and package leaflet to strengthen the importance that the instructions for reconstitution and administration need to be strictly followed and to recommend that these products should be only prepared and administered by healthcare professionals, who are familiar with these procedures. In case of suspected or known handling error with the medicine, patients should be monitored appropriately. In addition, the company that markets Eligard has been asked to modify the device to reduce the high number of preparation steps.

Call for reporting

Suspected adverse reactions and **any handling errors** should be reported in accordance with the national spontaneous reporting system, via HPRA Pharmacovigilance, website: www.hpra.ie.

Company contacts

This letter concerns all Leuprorelin containing depot medicinal products and has been agreed by the below listed companies.

Overview of Local Marketing Authorisation Holders

Marketing Authorisation Holder	**Registered Product Name**	**Contact details**
Takeda Products Ireland Ltd	Prostap SR DCS Prostap 3 DCS Prostap 6 DCS	Takeda UK Ltd 1 Kingdom Street London W2 6BD Tel: +44 (0) 3333 000181 medinfoemea@takeda.com
Astellas Pharma Co. Ltd	Eligard 7.5 mg Eligard 22.5 mg Eligard 45 mg	Astellas Pharma Co. Ltd. 5 Waterside, Citywest Business Campus, Citywest, Dublin 24, Ireland Tel: +353 1467 1555 irishdrugsafety@astellas.com
Rowex Ltd	Leuprex 3, 5mg Implant	Rowex Ltd., Newtown, Bantry, Co. Cork, P75 V009, Ireland Tel: +353(0)27 50077 PV@rowa-pharma.ie
Gp-Pharm S.A.	Lutrate 1 month Depot 3.75 mg Lutrate 3 month Depot 22.5 mg These products are not currently marketed in Ireland.	GP-Pharm S.A Plaza Europa 9-11, Planta 13 08908 L'Hospitalet de Llobregat Barcelona Spain Tel: +34 936 649 018 Ext. 1410 farmacovigilancia@gp-pharm.com

Signed on behalf of the above MA holders

Dr Simon Meadowcroft
Medical Director, Takeda