Direct Healthcare Professional Communication (DHPC)

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,

Astellas Pharma Europe B.V., Central Procurement & Supplies Unit, Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd in agreement with the European Medicines Agency and the Malta Medicines Authority 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

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are reminded to continue to report suspected adverse reactions associated with Leuprorelin-containing depot medicinal products, in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.

Company contact point

Company	Product Name	Email	Phone
Astellas Pharma Europe B.V	ELIGARD 7.5mg powder and solvent for solution for injection	GreeceDrugSafety@astellas.com	+30 210 8189900
	ELIGARD 22.5mg powder and solvent for solution for injection		
	ELIGARD 45mg powder and solvent for solution for injection		
Central Procurement & Supplies Unit	Prostap SR DCS 3.75mg Powder and Solvent for Prolonged-release Suspension for Injection	Info.cpsu@gov.mt	+356 23439150
	Lutrate 1 month Depot 3.75mg Powder & Solvent for prolonged-release Suspension for Injection		
Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Prostap SR DCS 3.75mg Pdr & solv for prolonged-release susp for injection in pre-filled syringee	contact@healthhouse.co.uk	+44 1 420487501

Yours faithfully,

Post Licensing Directorate

Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Astellas Pharma Europe B.V., Central Procurement & Supplies Unit, Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd

Annexes

The following measures shall be implemented by the Marketing Authorisation Holders:

Eligard	• The product information will be updated with warnings to strictly follow the instructions for preparation and administration and to monitor patients if a handling error occurs • The company marketing Eligard will replace the current device used to administer the medicine with one that is easier to handle
Lutrate Depot	• Instructions for handling the medicine will be revised to make them easier to follow • The packaging will be changed so the instructions are easier to find