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Direct Healthcare Professional Communication

<September, 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 "Scientific Center of Drug and Medical Technology Expertise after Academic E. Gabrielyan" Astellas Pharma Europe B.V. (the Netherlands) 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 Instruction for medicinal use.**

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, uterine fibrosis) and early puberty. In Armenia they are available as 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 Instruction for medicinal use 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.

In addition, Astellas Pharma Europe BV reminds that the above-mentioned information has been already included in the product information.

Contact details for adverse reactions reporting

We ask healthcare professionals to be aware of the need to continue reporting about suspected adverse reactions associated with the use of medicinal products and any handling errors, according to the applicable requirements for spontaneous reporting.
All suspected adverse reactions and any handling errors are to be reported in accordance with the national spontaneous reporting system to the Drug Safety Monitoring department of «SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELYAN» CJSC via following contacts: 49/4 Komitas av., 0051 Yerevan, Armenia, Phone: +37410231682 (ext: 123), Hot line for ADR reporting: + 3741020050; Email: vigilance@pharm.am;

Suspected adverse reaction reports and any handling errors for Eligard can also be sent to the Representative Office of Astellas Pharma Europe B.V. (the Netherlands) via e-mail or fax using the following contacts.

Company's contact details

Tel.: +38 044 490 68 25, fax: +38 044 490 68 26.
Email: pharmacovigilance.ua@astellas.com.