26.02.2018

Eligard (leuprorelin acetate) – Medication errors associated with leakage due to overtightening of the safety needle

Dear Healthcare Professional,

In agreement with «Scientific Center of Drug and Medical Technology Expertise after Academic E. Gabrielyan» MoH of the Republic of Armenia, Astellas would like to inform you of important new safety information:

Summary

- **There have been reports of medication errors associated with leakage of the medicine from the syringe. Overtightening of the safety needle hub at reconstitution can cause cracking, resulting in leakage of the product during injection with a potential risk of lack of efficacy due to underdosing.**
- **It is important to secure the safety needle to Syringe B by holding the syringe and gently turning the needle clockwise with approximately a three-quarter turn until the needle is secure (see Annex I, approved changes of the section "Posology and method of administration", step 11 of the preparation of the product in Patient Information leaflet).**
- **If the needle hub is cracked or appears to be damaged, or is leaking, the product should not be used. The product should be disposed of securely. A new product should be reconstituted and injected.**
- **Testosterone levels should be evaluated in suspected cases of incorrect handling of Eligard.**
- **It is important that the reconstitution steps as described in the product information are carefully followed.**

Background information on the safety concern

ELIGARD is indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy. It is available in six-month (45mg), three-month (22.5mg) and one-month (7.5mg) formulations.

In 2013 a new safety needle was introduced in the EU for ELIGARD. Since then, there have been 295 cases of medication errors associated with needle leakage due to overtightening of the safety needle.

The safety needle has a different depth of attachment to the syringe compared to the previous conventional needle. The safety needle is to be secured to Syringe B by gently turning the needle clockwise with approximately a three-quarter turn until the needle is secure.

If the safety needle is turned completely to the luer lock connection on the syringe, this may cause cracking of the needle hub resulting in leakage of the product during injection and an incomplete injection of the product.

In view of the viscosity of the reconstituted product, the appropriate needle needs to be used to ensure that all of the product is injected into the patient. The standard needle used in clinical practice differs from the safety needles provided for Eligard. For the 7.5 mg and 22.5 mg dosages a 20 gauge needle is provided in the package, and for the 45 mg dosage an 18 gauge needle is provided in the package.

If the needle hub is cracked, appears to be damaged, or is leaking, the safety needle should not be replaced and ELIGARD should not be used. The entire product should be disposed of securely and a new product should be reconstituted and injected.

Lack of clinical efficacy may occur due to incorrect reconstitution of the product. See section "Posology and method of administration" and section "Special warnings and special precautions for use" of the PIL for the instructions for preparation and administration of the product and for evaluation of testosterone levels in cases of suspected or known handling errors.

On January 30, 2018 Product information leaflet was updated with more detailed instructions for preparation (see Annex I).

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions as well as product quality complaints and medication errors associated with this product in accordance with the national spontaneous reporting system.

All suspected adverse reactions associated with ELIGARD should be reported in accordance with "Guidelines on good PV practice in Eurasian Economic Union, dated 03.11.2016.

Suspected adverse reactions to ELIGARD may also be reported to Astellas via phone, email or by fax to the Astellas affiliate in Ukraine using the contact details below.

Company contact point

For any questions concerning the method for the preparation of ELIGARD please contact
the Representative Office of Astellas Pharma Europe B.V. in Ukraine, 04050, Kyiv, Pimonenko Str. 13, bld. 7-B, office 41 at tel.+38 044-490-68-25, +38-050-418-37-07; fax: +38 044-490-68-26
or by email to: Pharmacovigilance.UA@astellas.com.

Annexes

The approved changes of the section "Posology and method of administration", step 11 in Patient information leaflet (PIL)

ANNEX I

Previous PIL text for section "Posology and method of administration", Step 11	**Approved PIL text for section "Posology and method of administration", Step 11**
Step 11: Hold Syringe B upright. Open pack of the safety needle by peeling back paper tab and take out safety needle. Secure the safety needle to Syringe B by holding the syringe and twisting the needle clockwise to fully seat the needle (Figure 11). Do not over tighten	Step 11: • Hold Syringe B upright and hold back the white plunger to prevent loss of the product. • Open pack of the safety needle by peeling back paper tab and take out the safety needle. • Secure the safety needle to Syringe B by holding the syringe and gently turning the needle clockwise with approximately a three-quarter turn until the needle is secure (Figure 11). **Do not over tighten** as this may cause cracking of the needle hub resulting in leakage of the product during injection. Should the needle hub crack, appear to be damaged, or have any leakage, the product should not be used. The damaged needle should not be substituted/replaced and the product should not be injected. The entire product should be disposed of securely. In the event of damage to the needle hub, a new replacement product should be used".