09-05-2017

## Direct Health Care Professional Communication

**Eligard (leuprorelin acetate depot injection) – Risk of lack of efficacy due to incorrect reconstitution and administration process**

Dear Healthcare Professional,

In agreement with Saudi Food and Drug Authority (SFDA), Astellas Pharma Europe Ltd would like to inform you of the following:


*Summary*

- **Lack of clinical efficacy may occur due to incorrect reconstitution of the product.**
- **There are reports of medication errors related to storage, preparation, and reconstitution of Eligard.**
- **Appropriate reconstitution of Eligard is a critical step in the administration of the product to ensure the safe and effective treatment of prostate cancer patients.**
- **It is important to be familiar with and adhere to the instructions for appropriate methods of reconstitution and administration before using the product.**
- **The device will be modified to simplify reconstitution and administration and the room storage temperature will be changed. Until approval of these changes the current instructions in section 6.6 of the SmPC and section 7 of the PL should be followed.**
- **The reconstitution can only be performed when the product is at room temperature.**
- **Testosterone levels should be evaluated in suspected cases of maladministration of Eligard.**


### *Further information on the safety concern and the recommendations*

The recommendations above follow reports of inappropriate technique in Eligard administration process, some of them associated with a lack of clinical efficacy in patients diagnosed with advanced prostate cancer.

A number of case reports indicated a lack of efficacy, as they include analytical data of an increase of testosterone levels above the castrate level (≤50 ng/dl) and/or an increase of PSA (prostate-specific antigen) levels.

A cumulative review of known cases of medication error events reported revealed a variety of errors during the preparation, mixing and administration of the product.

It is very important to review and understand the detailed instructions for appropriate reconstitution and administration of Eligard that are provided in Section 6.6 'Special precautions for disposal and other handling' of the Summary of Product Characteristics and Section 7 'Information for Healthcare Professionals' of the Package Leaflet. These instructions should be read before reconstituting and administering Eligard *(please refer to the latest approved SPC and PIL).*

***Background***

Eligard is indicated for the treatment of hormone dependent advanced prostate cancer.

It is available in 6 monthly (45mg), three monthly (22.5mg) and one-monthly (7.5mg) formulations.

In most patients, androgen deprivation therapy (ADT) with Eligard results in testosterone levels below the standard castration threshold (< 50 ng/dL; < 1.7 nmol/L); in most cases, patients reach testosterone levels below < 20 ng/dL. Testosterone levels should be evaluated in suspected cases of maladministration of Eligard.

***Reporting Adverse Events***

All cases of incorrect storage, preparation, reconstitution, and administration of Eligard or any other adverse reactions should be reported in accordance with your national reporting system:

The National Pharmacovigilance and Drug Safety Centre (NPC)
o Fax: +966-11-205-7662
o Toll free phone: 8002490000
o E-mail: npc.drug@sfda.gov.sa
o Website: www.sfda.gov.sa/npc

Reports can be sent by email to Astellas. (Please refer to "Company Contact Point" here below)

astellas

***Company Contact Point***

For questions regarding the appropriate methods for preparation of Eligard, please contact:

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**Sincerely,**

Tatiana Kolganova
Regulatory Affairs manager
MENA/SSA on behalf of
Astellas Pharma Europe B.V.

Ph. Salman Al-Murdhi
Pharmacovigilance Representative
(QPPV)
Salehiya Trading Establishment

on Behalf of Ph. Salman (QPPV)

Muthammed Waqas
PV-Supervisor and Deputy (QPPV)
9.05.2017

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**Annex 1**

Currently approved SPC and PL