HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

Following identification of a signal of administration errors with Eligard and concerns that such errors may impact on clinical efficacy, this issue was reviewed at EU level by the Pharmacovigilance Risk Assessment Committee (PRAC). A cumulative review of reported global cases identified errors related to storage, preparation and reconstitution of Eligard. Appropriate reconstitution is a critical step in the administration of the product to ensure the effective and safe treatment of patients with prostate cancer. Lack of efficacy may occur due to incorrect reconstitution of Eligard.

Eligard is indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy. It is available in six-monthly (45mg), three-monthly (22.5mg) and one-monthly (7.5mg) formulations. In the majority of patients, androgen deprivation therapy (ADT) with Eligard results in testosterone levels below the standard castration threshold (<50ng/dL; <1.7 nmol/L); and in most cases, patients reach testosterone levels below <20ng/dL.

Advice to Healthcare Professionals

- Appropriate reconstitution of Eligard is a critical step in the administration of the product.
- It is important that all staff involved in the reconstitution and administration of Eligard are familiar with and adhere to the instructions for appropriate methods of reconstitution and administration before using the product.
- Testosterone levels should be measured in suspected cases of maladministration of Eligard.
- The storage conditions for the product have been updated and the product information reflecting this update is available on the HPRA website (www.hpra.ie). The syringe will be modified to simplify reconstitution and administration. The modified syringe (the blue plunger rod design is changing) will be made available as soon as possible.
- A Direct Healthcare Professional Communication (DHPC) was circulated to relevant healthcare professionals in December 2014 and is available on the HPRA website.
- All cases of incorrect storage, reconstitution and administration of Eligard should be reported to the HPRA.

Key messages

- There have been global reports of medication errors related to storage, preparation and reconstitution of Eligard.
- Lack of clinical efficacy may occur due to incorrect reconstitution of Eligard.
- Reconstitution instructions in section 6.6 of the SmPC for Eligard must be followed exactly.

**Further details on Eligard are available at www.hpra.ie*

This section has been supplied by the HPRA (formerly called IMB) for use in MIMS Ireland. However, the HPRA is independent and impartial to any other information contained in this directory.