Handling errors with depot formulations of leuprorelin medicines: PRAC starts a review

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Information on depot formulations of leuprorelin

- Depot formulations of leuprorelin are used to treat prostate cancer, breast cancer and conditions that affect the female reproductive system such as endometriosis, symptomatic uterus myomatosus, uterine fibrosis and early puberty
- Depot formulations of leuprorelin include implants, powders and solvents for the preparation of injections to release the active substance gradually.

In Malta the following products are authorised through national procedures

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/licen se holder
Leuprorelin acetate	ELIGARD 7.5mg powder and solvent for solution for injection	Powder and solvent for solution for injection	POM	AA067/01101	Astellas Pharma Europe B.V.
Leuprorelin acetate	ELIGARD 22.5mg powder and solvent for solution for injection	Powder and solvent for solution for injection	POM	AA067/01102	Astellas Pharma Europe B.V.
Leuprorelin acetate	ELIGARD 45mg powder and solvent for solution for injection	Powder and solvent for solution for injection	POM	AA067/01103	Astellas Pharma Europe B.V.
Leuprorelin acetate	Prostap SR DCS 3.75mg Powder and Solvent for Prolonged-release Suspension for Injection	Powder	POM	AA565/27501	Central Procureme nt & Supplies Unit
Leuprorelin acetate	Lutrate 1 month Depot 3.75mg Powder & Solvent for prolonged-release Suspension for Injection	Powder	POM	AA565/42901	Central Procureme nt & Supplies Unit

Information from the EMA about Leuprorelin-containing depot medicines

In June 2019, the Pharmacovigilance Risk Assessment Committee (PRAC) started a review on leuprorelin depot medicines under Article 31 of Directive 2001/83/EC, following the request of Germany. The review was started after receiving reports of handling errors with the depot formulations (formulations given by injection under the skin or into a muscle and release the active substance gradually over 1 to 6 months) of leuprorelin preparation and administration. These errors can result in some patients receiving insufficient amount of medicine, therefore they might have reduced benefit of treatment.

- Depot formulations have a complex procedure to prepare the injection. Handling errors with these formulations have been reported to lead to problems such as leakages from the syringe or failure to deliver implants from the applicator
- The PRAC will now evaluate all available data and determine whether measures are needed to ensure that leuprorelin depot formulations are appropriately prepared and administered
- While the review is ongoing, healthcare professionals are advised to follow the handling instructions for leuprorelin medicines
- Patients prescribed leuprorelin medicines who have any concerns should discuss them with their doctor.

PRAC's recommendation will be forwarded to the CMDh which will adopt a position.

For more information please see the European Medicines Agency's Leuprorelin-containing depot medicines referral page.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Leuprorelin-containing depot medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

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