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Review of handling errors with depot formulations of leuprorelin medicines started

EMA has started a review of leuprorelin medicines after reports indicated that handling errors with the products during preparation and administration can cause some patients to receive insufficient amounts of their medicine, thus reducing the benefits of treatment.

This review covers formulations called depot formulations which are given by injection under the skin or into a muscle and release the active substance slowly over 1 to 6 months. These include implants as well as powders and solvents for the preparation of injections.

Several of these formulations require complex steps to prepare the injection. Handling errors with these formulations have reportedly led to problems such as leakages from the syringe or failure to deliver implants from the applicator.

EMA's safety committee, PRAC, will now evaluate all available data and determine whether measures are needed to ensure that the medicines are prepared and administered appropriately.

While the review is ongoing, healthcare professionals should carefully follow the handling instructions for leuprorelin medicines. Patients prescribed leuprorelin medicines who have any concerns should discuss them with their doctor.

More about the medicines

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

Leuprorelin medicines are also available as daily injections but this formulation is not included in the review as there have been no reports of handling errors with this formulation.

Leuprorelin medicines have been authorised via national procedures. They are marketed in many EU countries and are available under several brand names, including Eligard, Eliprogel, Enantone, Ginecrin, Lupron, Lutrate, Politrate, and Procren.

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More about the procedure

The review of leuprorelin depot medicines has been initiated at the request of Germany, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As leuprorelin medicines are all authorised nationally, the PRAC recommendations will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.