

PLEASE READ

**IMPORTANT MEDICINE
SAFETY INFORMATION**

APPROVED
BY THE

HPRA 
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Xnd XXX 2023

Dear Doctor,

New Educational Materials for Eligard® Pre-connected Syringe

To ensure patient safety and efficacy, you are advised that the Educational Materials for **Eligard®** (leuprorelin acetate) have been updated ahead of the upcoming availability of **Eligard®** in a new pre-connected syringe delivery system. This new system simplifies the reconstitution process. The HPRA approved the new pre-connected syringe device in November 2022, and it will be available in the summer of 2023.

The purpose of the educational material is to minimise the possibility of medication errors that could lead to ineffective treatment. Recordati strongly advises you to familiarise yourself with the new educational materials, comprising a poster and video. The educational materials provide detailed instructions for each stage of preparation, reconstitution, and administration. Enclosed with this letter you will find a copy of the updated instructional poster. Additionally, you can watch the video at: www.eligard.eu/en-IE or by scanning the QR code overleaf.

Please be aware that there will be a period when the 'original' **Eligard** device and the new **Eligard** pre-connected syringe system will both be available, to help mitigate against any confusion and minimise the risk of medication error, the educational materials for both presentations are available on the website www.eligard.eu/en-IE.

Original Eligard Device



New Eligard Pre-connected Syringe



RECORDATI IRELAND LTD

Raheens East, Ringaskiddy
Co Cork, P43 KD30, Ireland

TEL. (+353) 21 4379400
FAX (+353) 21 4379280
www.recordati.com

Company. No. 356299
Registered in Ireland VAT No. IE6376299J
Directors: Kevin Buckley/ Tamas Szoga (Hungarian)
Davide Botta (Italian)/Fernando Catrambone (Italian)
Secretary: Kevin Buckley

We recommend that you review the simplified preparation process for **Eligard**[®] now, and again before the first administration using the new device. If you need extra copies of the instructional poster, a copy of the video on a USB device, or have any questions regarding **Eligard**, please contact Recordati Ireland Limited at 021 437 9400, or medinfo@recordati.co.uk.

Electronic versions of the educational materials can also be accessed at the following websites:

- www.hpra.ie (search for ' **Eligard** ' in the 'Find a medicine' box, and click on 'EdM' next to any of the displayed medicines)
- www.medicines.ie (in the product section / Educational Material-HCP)

To access the current version of the **Eligard** SmPC, please refer to www.medicines.ie or to the HPRA website: www.hpra.ie.

Use your phone camera while connected to the internet, and scan the QR code below to access the website containing detailed instructions for each stage of preparation, reconstitution, and administration of either the original **Eligard** Device or the new **Eligard** Pre-connected Syringe.



Please ensure that this information reaches anyone in your team who may come into contact with the new **Eligard** pre-connected syringe device.

Thank you for your attention to this important matter.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'Julian Hammond'.

Julian Hammond
Commercial Operations Director