

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

Ferring Pharmaceuticals Limited

GONAPEPTYL Depot 3.75mg, Powder and solvent for suspension for injection

PL 03194/0085

SNOMED Code 5615111000001102

Batch Number	Expiry Date	Pack Size	First Distributed
T16656K	Mar 2024	1	19 May 2022
U11271E	Jun 2024	1	15 Jun 2022
U11271F	Jul 2024	1	14 Jun 2022
U11386G	Nov 2024	1	25 Aug 2022
U11570E	Dec 2024	1	09 Nov 2022
U11571E	Dec 2024	1	03 Oct 2022
U15102C	May 2025	1	30 Dec 2022
U15102K	May 2025	1	13 Feb 2023
U15102L	May 2025	1	08 Feb 2023

Active Pharmaceutical Ingredient: Triptorelin

Brief description of the problem

Ferring Pharmaceuticals Limited is recalling the above batches of GONAPEPTYL Depot 3.75mg due to a defect noticed in the seal of the needle wrapping for the CE-marked 30-millimeter (30mm) needle for subcutaneous injection that is supplied with each product pack (see first image in Appendix 1).

Slight damage was detected in some sterile needle blisters, which renders the sealing to be incomplete. A small breach was observed at the peel-away opening of the needle blister, potentially compromising the sterility of the needle. The defect appears as a slight separation between the plastic and paper portions of



the needle packaging (see second image in Appendix 1). There is no quality issue with the drug product.

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for patients

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#). Suspected adverse reactions may also be reported by emailing medical.uk@ferring.com or calling 0800 111 4126.

Further Information

For all medical enquiries, please contact medical information: medical.uk@ferring.com for supply queries, please contact: customer.services@ferring.com

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

23rd March 2023

Pharmaceutical website: <http://www.hscbusiness.hscni.net>

Appendix 1: Images of the content of GONAPEPTYL Depot 3.75mg

Image of the 30mm needle packaged within each pack of GONAPEPTYL Depot 3.75mg:



Close-up image of a small breach observed at the peel-away needle wrapping for the 30mm needle:

