

29th June 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Menopur[®] 75 IU Powder and solvent for solution for injection (menotropin) Interim supply of Irish packs to mitigate supply disruptions in UK

Dear Healthcare Professional,

FERRING Pharmaceuticals in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **Menopur is indicated for the treatment of female and male infertility. Women who cannot become pregnant including polycystic ovarian disease, women in assisted reproduction programmes (ART), and men who have low sperm count.**
- **Ferring suspended all shipments of Menopur in all presentations from October 2022 which may lead to potential shortages.**
- **Ferring is working with MHRA to obtain the necessary approvals and ensure continued supply in UK.**
- **3 batches of Menopur 75 IU, packaged with Irish approved labelling have been approved by MHRA to be marketed in UK from early July.**
- **Pharmacist, when dispensing a Menopur pack, should remove the Irish patient information leaflet from the carton and replace it with the UK-approved leaflet (attached to this DHPC letter).**
- **Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.**

Background on the safety concern

Menopur is indicated for the treatment of female and male infertility in the following groups of patients:

- Anovulation, including polycystic ovarian disease (PCOD) in women who have been unresponsive to treatment with clomiphene citrate.
- Women undergoing controlled ovarian hyperstimulation: Menopur can induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g. in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)).
- Hypogonadotrophic hypogonadism in men: Menopur may be given in combination with human chorionic gonadotrophin (e.g. Choragon) for the stimulation of spermatogenesis. Patients with primary testicular failure are usually unresponsive.

Ferring was made aware of unapproved changes made in the manufacturing process of the drug substance for Menopur. As a precautionary measure, Ferring suspended all shipments of Menopur in October 2022, and the manufacturing at the drug substance supplier was paused for a period of time. As a consequence, a market shortage of Menopur is expected.

In order to continue supply of Menopur, MHRA has approved to market Irish labelled packs in UK. Details of the batches affected are provided below;

Product Name	Pack size	Batch Number	Expiry date
Menopur 75 IU, powder and solvent for solution for injection	10 vials of powder and 10 ampoules of solvent	U10421S	29/02/2024
		U10484C	31/03/2024
		U12594M	31/05/2024

The Irish packs have the same formulation as the UK packs and are manufactured according to the same manufacturing process and quality controls as the UK product. The packaging material for both packs are different, the key differences for the carton and vial label are listed in Appendix 1 (attached), followed by an image of the Irish carton pack.

The patient information leaflet is requested to be replaced. The pharmacist when dispensing a Menopur pack should remove the Irish patient information leaflet from the carton and replace it with the UK-approved leaflet (attached to this DHPC letter).

Further information on the UK approved Summary of Product Characteristics and Patient Information Leaflet can be found at: <https://www.medicines.org.uk/emc/search?q=menopur>.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions (ADRs) to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website – <https://yellowcard.mhra.gov.uk/>
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

For further information, please contact Medical Information at Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS.

Tel: 0844 931 0050, Email: contact2@ferring.co.uk.

Yours sincerely,

Nassima Bekkat-Berkani

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Medical Director

Ferring UK and Ireland

Appendix 1: Differences between the Irish and UK Menopur 75 IU packs listed in the table below, followed by an image of carton pack.

Please note: the information which is identical between the packs is NOT listed in the table below.

Packaging material	Irish pack	UK pack
Carton	Active: Menotrophin	Active: HIGHLY PURIFIED MENOTROPHIN
	PC: 05391505670016	PC: 05015919649238
	Excipients: Powder for injection (per vial): Lactose monohydrate (see leaflet for further information), polysorbate 20, sodium hydroxide, hydrochloric acid Solvent (per ampoule): sodium chloride, water for injections, dilute hydrochloric acid	Excipients: Powder for injection (per vial): Lactose monohydrate - 20 milligrams Polysorbate 20 - 0.1 milligrams Sodium hydroxide - 0.8-3 micrograms Hydrochloric acid - 0-0.5 micrograms Solvent (per ampoule): Sodium chloride - 9 milligrams Water for injection - 995.4 milligrams Diluted hydrochloric acid - 7-20 micrograms
	Marketing Authorisation Holder: Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24 Licence No.: PA 1009/15/1	Product Licence Holder: Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, UK Licence No.: Menopur – PL 03194/0074 Sodium Chloride Solution 0.9% w/v – PL 03194/006
	Others: NO Dispensing Label space NO barcode	Others: Dispensing Label space – 70mm x 35mm Barcode – 5015919 649238
Powder label	Menotrophin PA 1009/15/1	Menotrophin equivalent to 75IU FSH + 75IU LH per vial. PL 03194/0074 POM

Please see below a mock-up of the Menopur 75 IU Irish pack, which will be provided:

