

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

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Dear Healthcare Professional,

**DRUG ALERT NO 24 – CLASS 4**

Please find attached revised drug safety information from the Medicines and Healthcare products Regulatory agency (MHRA) for onward transmission (see list below)

1. Please could all Directors of Pharmacy forward this alert to:-
  - Community Pharmacists
  - Hospital Pharmacists
  - Chief Pharmacists to forward on to Medicines Information Pharmacists
2. Please could Medical Directors forward this alert to:-
  - General Practitioners
  - Relevant clinics
  - Chief Executives of NHS Boards

Thank you for your co-operation.

Yours sincerely

**IRENE FAZAKERLEY**  
Pharmacy Division

Safeguarding public health  
Defective Medicines Report Centre  
151 Buckingham Palace Road  
London  
SW1W 9SZ  
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## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use  
Distribute to Community and Hospital Pharmacist Level

Date: 15 November 2010

EL (10)A/24

Our Ref: MDR 06-11/10

Dear Healthcare Professional,

### Merck Serono UK

**GONAL-f 450 IU/0.75ml solution for injection  
in a pre-filled pen**

**EU/1/95/001/034**

(follitropin alfa, recombinant human follicle  
stimulating hormone)

Batch Number	Expiry Date	Pack Size	First Distributed
Y16B6566	29 Feb 2012	1	25 May 2010
Y16B8134	29 Feb 2012	1	30 Jun 2010
Y17B0532	31 Mar 2012	1	13 Jul 2010
Y17B3604	30 Apr 2012	1	12 Aug 2010
Y17B5827	30 Apr 2012	1	14 Sep 2010
Y18B0602	31 May 2012	1	04 Nov 2010

Merck Serono UK has informed the MHRA that there is an error on the label of the pen injection device for the above batches of GONAL-f 450IU/0.75ml solution for injection in pre-filled pens.

The concentration of the product is stated correctly in the heading (line1) on the pen label against the product name. The delivery dose is repeated on line 4 of the label, but without the product name. Here, it reads 450IU/**0.5ml** instead of 450IU/**0.75ml**. The concentration is stated correctly on the label of the external packaging and in the package leaflet.

The error on the label should not affect the dosage of GONAL-f administered to the patient as the package leaflet clearly specifies that the dose on the pen should be set in IU and not by volume.

#### MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units  
Chief Pharmacists: England, Scotland, Wales, Northern Ireland  
Prison Health Policy Unit (DH)  
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar  
Special Hospitals  
Healthcare Commission for distribution to Independent Health Care Establishments  
Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)  
151 Buckingham Palace Road London SW1W 9SZ UK  
T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health



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We have been asked to advise pharmacists that this information should be relayed to patients when dispensing and should be conveyed to all pharmacists working within their pharmacy.

To avoid stock disruption, distribution of affected stock will continue, therefore further deliveries over the next few months will display this error. The labels are being corrected urgently, but it is unlikely that packs with these labels will be supplied to the market before January 2011

**Further Information**

For further enquiries, please telephone Merck Serono Medical Information on 0208 818 7373

Primary Care Trusts are asked to bring this information to the attention of Community Pharmacists and other concerned Health Professionals by copy of this letter.

Yours faithfully

Alison Bunce  
Pharmaceutical Assessor  
DMRC