Healthcare Quality and Strategy Directorate
Pharmacy and Medicines Division

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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

9 December 2015

Dear Healthcare Professional,

DRUG ALERT CLASS 4 no 12 2015 – Caution in use

Please see the attached drug alert for onward transmission as below.
Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Healthcare Quality and Strategy Directorate

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

D R U G A L E R T

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Community and Hospital Pharmacy Level Recall

Date: 09 December 2015 EL (15)A/12 Our Ref: MDR 78-11/15

Dear Healthcare Professional,

Pfizer Limited

Genotropin 5.3mg powder for solution for injection (GoQuick pre-filled pen) PL 00057/0987

Genotropin 12mg powder for solution for injection (GoQuick pre-filled pen) PL 00057/0988

(Somatropin)

Pfizer Limited has notified us of a manufacturing defect in the dosing mechanism of some Genotropin GoQuick pens which are used to administer somatropin. The defect has been found to create the possibility of the dose being set to one extra click beyond the dose selected and indicated in the memory window **when the patient turns the dose knob with excessive force.** This may result in a small increase in the dosage administered compared to the preset dose:

- An additional 0.05mg of Genotropin for the 5.3mg Go Quick pre-filled pen
- An additional 0.15mg of Genotropin for the 12mg GoQuick pre-filled pen

All unexpired batches of Genotropin GoQuck are within the scope of this issue although not all pens within these batches are affected. No complaints or adverse reactions relating to this issue have been received by the company to date.

In order to avoid product shortages, affected batches are not being recalled. Healthcare Professionals are asked to remind patients to follow the instruction to align the dose settings in order to avoid the potential for an incorrect dose being administered. Should a patient inform you that they have discovered a defective device, please contact Pfizer's endocrine helpline see details below.

Further Information

Please contact Pfizer's endocrine helpline, tel 0800 521249; email endocrinecare@pfizer.com or alternatively contact Pfizer Medical Information, tel 01304 616161

Cont/……..

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

09 December 2015 EL (15)A/12 MDR 78-11/15

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Alison Bunce

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