MEDA

Batch Recall

Epipen 300 micrograms Solution for Injection in Pre-filled Pen, PA1332/50/2

Batch No: 5FA665G, Expiry Date: 05/2017

21st March 2017

Dear Pharmacist / Healthcare Professional,

We wish to advise you that batch no. 5FA665G of Epipen 300 micrograms solution for injection in pre-filled pen, PA 1332/50/2, is being recalled with immediate effect.

This recall is going to **patient level**.

This action has been agreed with the Health Products Regulatory Authority.

The reason for the recall is that a defect in a component part of the auto-injector was observed in a small percentage of pens in this batch, on other markets. This may lead to failure of the firing mechanism and, therefore, failure of administration of the potentially life-saving medicine.

Please immediately quarantine any units of this batch which you have in your possession. For hospital pharmacies, this includes wards, clinics, units at paramedic level and any other relevant locations within your facility.

Quarantined units will be uplifted by United Drug. Please complete the attached fax-back form, indicating to United Drug the number of units which require uplift.

We are requesting that packs from batch 5FA665G are recalled from patients.

- Please check your dispensing records to identify patients to whom the product has been dispensed, from 14 July 2016 to date. Please note that 14 July 2016 is the date on which the impacted batch was first distributed to pharmacies.

- Please endeavour to contact those patients by telephone, to ascertain if they have any remaining unused units from the affected batch. If units are identified by the patient, please request that they return the units to you at their earliest opportunity, for replacement.

- Replacement unaffected batches are available to order through normal wholesaler ordering. This should be done as a priority so that unaffected units are available to provide to patients, should they return their product to you.

- Please check the pack(s) on return to ensure that the batch number stated on the packs is 5FA665G

Unit 34/35, Block A, Dunboyne Business Park, Dunboyne, Co Meath, Ireland.
T: +353 (0) 1 802 6624 F: +353 (0) 1 802 6629 W: www.meda.ie Reg No. 403901 VAT No: 6423901C

- Please quarantine any packs that are returned to you by a patient, ensuring that replacement unaffected packs are available to dispense to patients upon return of units that are subject to the recall

- Please contact United Drug at 01 463 2300 or Quality.Mailbox@united-drug.ie to arrange uplift of units returned by patients

If you have supplied units from these batches to a GP, clinic, another pharmacy or any other party, please forward a copy of this letter to them so that they can perform the requested actions.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Regina Joyce at telephone number 01 802 6624.

Yours sincerely,

Regina Joyce,
Regulatory Affairs Manager
Tel: 01 802 6624

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