

Recall of one lot of Epipen 300mcg to patient level in Ireland

Notice type: Recall

Date: 21/03/2017

Product name or type:

Epipen 300mcg Solution for Injection in a Pre-filled Pen

Reference:

QDR-H-17-108

Authorisation Number:

PA1332/50/2

Active Substance:

Adrenaline Ph. Eur.

Product Classification:

Prescription-only medicine

Serial Or Batch Number And Expiry Date:

Lot No.	Expiry date
5FA665G	05/2017

The lot was first distributed in Ireland on 14th July 2016.

Prescription Required:

Yes

Recall Classification:

Wholesale, Pharmacy and Patient Level

Target Audience:

Patients / Carers, Pharmacists and other relevant Healthcare Professionals and Wholesalers

Problem Or Issue:

The HPRA wishes to advise that one lot of Epipen 300mcg Pre-filled Pens is being recalled to patient level in Ireland.

Epipen is administered through a pre-filled pen, or autoinjector. The reason for the recall is that a defect in a component part of the autoinjector assembly was observed, in a small percentage of pens from lot 5FA665G, on other markets. This may lead to failure of the firing mechanism and, therefore, failure of administration of the potentially life-saving medicine.

The HPRA considers that the quality defect issue could potentially affect a very small number of pens from this lot. It states it has received no reports from patients or the medical profession in Ireland of injection failure associated with this lot of product.

Actions To Be Taken:

Information for Patients / Carers:

Patients and carers are advised to check the lot number on all Epipens within their possession, or in other locations such as schools or workplace, and to return any units of the affected lot to their pharmacy, where a replacement, unaffected unit will be provided.

- If you have an Epipen 300mcg in your possession, check the lot number to confirm if it is from lot 5FA665G being recalled. The lot number can be found on the parts of the label and carton pictured below.



(Please also find link to image - [EpiPen - Precautionary recall image 21.03.2017](#))

- If you are in possession of a pack from the affected lot listed above, please return it to your pharmacy where you will receive a replacement, unaffected pack.
- If you are in possession of an EpiPen 300mcg pen with a lot number not mentioned above, you do not need to return the unit to your pharmacy

*See www.hpra.ie for specific information for Pharmacists, Healthcare professional & Wholesaler.