Urgent Epi Pen Recall on Four Defective Batches

Mar 20, 2017

Alphapharm have issued an Urgent Epi Pen Recall on 4 batches of the popular EpiPen 300 microgram adrenaline injection syringe auto-injectors.

EpiPen is used in emergency situations to treat people who are having a severe allergic reaction (also known as anaphylaxis).

The affected EpiPens may contain a defective part resulting in the auto-injector failing to activate or a need to apply more force than normal to activate. Naturally, given the

nature of the product, failure to activate means the user may not get the required dose of adrenaline (or not at all) and consequences could be fatal.

The batches affected by the recall are:

Batch number	Expiry
5FA665	April 2017
5FA6651	April 2017
5FA6652	April 2017
5FA6653	April 2017

There have been two confirmed reports of auto-injectors from these batches failing to activate correctly world-wide from approximately 80,000 devices distributed.

Action to be Taken:

EpiPens from affected batches can be returned to pharmacies for a refund or exchanged for one from a different, unaffected batch free of charge.

Please note that no other batches of EpiPen, including EpiPen Jr 150 microgram adrenaline injection syringe auto-injectors, are known to be affected by this issue and are not subject to this recall.

Information for Consumers

If you or someone you provide care for has an EpiPen 300 microgram adrenaline injection syringe auto-injector, check the batch number and expiry on either the label of the EpiPen or on the end of the carton.

If your EpiPen is from batch 5FA665, 5FA6651, 5FA6652 or 5FA6653 (all Expiring April 2017), return it to your local chemist. Your pharmacist will replace the EpiPen with an EpiPen from a different, unaffected batch free of charge. Alternatively, if you have another unaffected EpiPen available, you can request a refund if you prefer.

While you are advised to return an affected EpiPen as soon as possible, you should keep your current auto-injector until you get the replacement, and use it if required (being mindful that you may need to apply more force than normal to activate it).

As with all medical emergencies, patients and caregivers should be reminded to remain calm and to not hesitate to call 000 if necessary.

If you have any questions or concerns about this issue, contact Alphapharm on 1800 274 276.

Reporting Problems

Consumers are encouraged to report problems with medicines or vaccines. Your report will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medicine or vaccine.