

Mylan Initiates Recall of EpiPen® Auto-Injector in New Zealand

EpiPen® 300 microgram (µg) Adrenaline Auto-Injector Batches 5FA665, 5FA6652

Mylan New Zealand Ltd, following consultation with Medsafe, Ministry of Health, New Zealand is recalling the following batches of EpiPen® 300 microgram (µg) Adrenaline Auto-Injectors due to the potential that these devices may contain a defective part that may result in the device failing to activate or requiring increased force to activate.

Batch number	Expiry
5FA665	Apr 17
5FA6652	Apr 17

Two reports overseas have been confirmed of the device failing to activate from a production run of 80,000 devices. From this production run, 1794 devices have been distributed in New Zealand in the above two batches.

EpiPen® Auto-Injector is used for the treatment of allergic emergencies (anaphylaxis). The failure of the auto-injector to activate may result in patients not receiving the required dose of adrenaline resulting in the worsening of symptoms of anaphylaxis or anaphylactic reactions which could be life threatening.

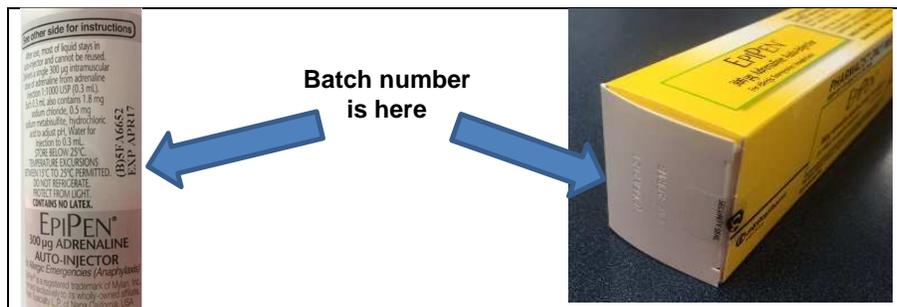
The recalled product was manufactured by Meridian Medical Technologies in St. Louis Missouri, USA.

Mylan New Zealand is undertaking this recall as a precautionary measure and has patient safety as its first priority.

Instructions to consumers who have an EpiPen® Auto-Injector:

IF YOU HAVE AN EPIPEN®:

1. Check whether you have the EpiPen® 300 µg product (yellow carton and label).
2. Check if the batch number is 5FA665 or 5FA6652, expiry Apr17. The batch number and expiry date can be found on the end of the carton or on the label of the pen.



WHAT TO DO NEXT:

3. If you have EpiPen® batch 5FA665 or 5FA6652, you need to replace it with a new one as soon as possible by returning it to your pharmacist.
4. Your pharmacist will replace the EpiPen® 300µg from the affected batch with an EpiPen® 300µg from a different batch FREE OF CHARGE. You will be given a free replacement either immediately or within a few days if your pharmacy needs to order one for you.
5. You must keep your current EpiPen® until you get a replacement and use it if required.

Consumers can call **0800 335 336** if they require further information and support.

EpiPen® Jr 150µg Auto-Injectors and all other batches of EpiPen® 300µg Auto-Injectors are NOT subject to this recall and NO action is required.

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