



27 March 2020

## Important EpiPen® Information

Meridian Medical Technologies, a Pfizer company, the manufacturer of EpiPen® and Mylan, the distributor of EpiPen®, routinely study and evaluate real-world data about how healthcare professionals, patients and carers administer EpiPen, which is a critical life-saving device.

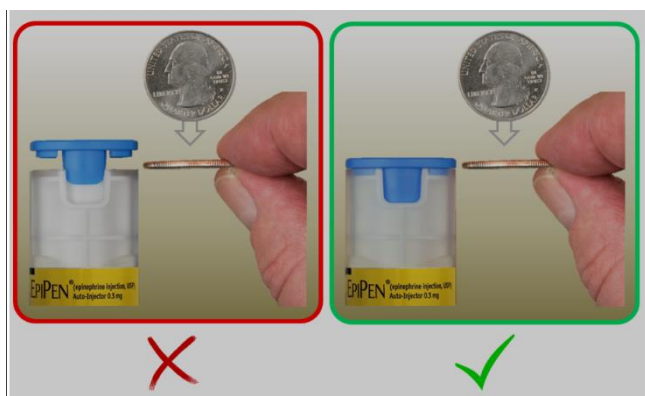
On 24 March 2020 Pfizer and Mylan published a [notification](#) in the US about a very limited number of cases in which the administration of EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injector, and their authorised generic versions of these strengths, may potentially be delayed or prevented.

The information in this notification serves as an important opportunity to provide precautionary handling instructions and remind people with severe allergy and their carers about the correct administration of EpiPen®, and recommendation to carry two EpiPen® or EpiPen® Jr auto-injectors or the authorised generic version at all times. Potential issues and user errors are listed below.

### 1. Device failure from activation caused by sideways force to remove blue safety release

In Australia and New Zealand there have been no reports of such device failure. The advice in Australia and New Zealand is to hold the device in one hand (fist around the device) and remove the blue safety release with the other hand. **Removing the blue safety release using sideways forces may activate the EpiPen prematurely.** To prevent this premature activation, patients and their carers should follow the clear instructions on how to use EpiPen® on the Australasian Society of Clinical Immunology and Allergy (ASCI) website <https://www.allergy.org.au/anaphylaxis> and the Allergy and Anaphylaxis Australia (A&AA) website <https://allergyfacts.org.au>

### 2. Device failure from inadvertent or spontaneous activation due to raised blue safety release



In a very limited number of cases, EpiPen® devices may have a blue safety release that is slightly raised. The function of the blue safety release is to ensure the device does not activate prior to its intended use. It should not be removed until the time of use. If the blue safety release is raised the device may activate prematurely, which could potentially delay or prevent emergency treatment when needed.

If the blue safety release is raised, the auto-injector should NOT be dispensed or used, since premature activation may occur.

Internal testing has shown that the probability of a raised blue safety release at 4.6 mm (height of the raised safe pin in the picture above on the left) resulting in spontaneous activation rate is 4 units in 1 billion.

If the blue safety release is raised as shown in the picture above (on the left), contact Mylan (In Australia: 1800 274 276; In New Zealand: 0800 579 811), to obtain a replacement device at no additional cost. Return the device to the tube and close the lid. Do not attempt to force the blue safety release back down.

### 3. Difficulty removing the device from the carrier tube

EpiPen® marketed in Australia and New Zealand is labelled and packaged in Australia using a different packaging process.

### 4. Certain identified use errors

The issues identified in the US are not relevant in Australia or New Zealand because administration guidelines in Australia and New Zealand do not recommend the swing and jab technique.

If you think you may be experiencing a side effect to a medicine or a problem with a medical device, [seek advice from a health professional](#) as soon as possible. Mylan and the TGA collect adverse event reports to monitor the safety of medicines and medical devices, but cannot provide you with healthcare or health advice. If you would like to report a side effect or a product complaint, please email or telephone Mylan at: [medinfo\\_auz@mylan.com](mailto:medinfo_auz@mylan.com) or 1800 274 276. You may also report a side effect to a medicine directly to the TGA. For more information on how to report side effects to the TGA go to: <https://www.tga.gov.au/reporting-problems>

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