

20 December 2019

## **IMPORTANT SUPPLY UPDATE**

### **EpiPen® Jr 150 mcg Adrenaline (epinephrine) Auto-Injector**

Mylan New Zealand is pleased to advise patients, pharmacists and prescribers that EpiPen® Jr 150 mcg Adrenaline (epinephrine) Auto-Injector is now available.

This follows the recent stock shortage situation caused by manufacturing challenges experienced by Meridian Medical Technologies, a subsidiary of Pfizer, the manufacturer of EpiPen® Jr 150 mcg Adrenaline (epinephrine) Auto-Injector.

Due to the need for and recent tight supply of this important product, Mylan has worked closely with Medsafe to enable the release of a batch of EpiPen® Jr that contains trace levels of pralidoxime in the product's adrenaline (epinephrine) solution. Pralidoxime is an active pharmaceutical ingredient (API) associated with the production of another medicine that is used to treat people who have been poisoned by pest-control chemicals and is an API with a well-known safety profile. The presence of trace levels of pralidoxime originated from a manufacturing issue between production batches of different products that has since been fully corrected and production has resumed to expedite further product supply.

Following an exhaustive investigation coupled with a detailed medical and safety risk assessment by Pfizer, it was determined that the adrenaline (epinephrine) auto-injectors from this batch remain safe and effective for the emergency treatment of life-threatening allergic reactions, or anaphylaxis. The trace levels of the pralidoxime in this batch are well below the acceptable daily exposure limits and, as such, represent a very low risk to patients. Medsafe has agreed that the risk associated with withholding treatment for anaphylaxis, or reducing access to an adrenaline auto-injector, exceeds the low risk of exposure to the very small quantity of pralidoxime that may be present in the product.

To ensure patients around New Zealand have equitable access to this batch, distribution continues to be carefully managed by Mylan.

Patients requiring an EpiPen® Jr 150 mcg Adrenaline (epinephrine) Auto-Injector should contact their pharmacy for assistance.

### **Instructions for Pharmacies Ordering EpiPen® Jr 150 mcg Adrenaline (epinephrine) Auto-Injector**

- Mylan is currently not supplying EpiPen® Jr to wholesalers.
- Please phone the Mylan Customer Support Team on 0800 579 811 to place an order.

If you encounter any problems with obtaining EpiPen® 150 mcg Adrenaline (epinephrine) Auto-Injector, phone the Mylan Customer Support team on [0800 579 811](tel:0800579811) to obtain instructions on how to access direct supply.

Additional information is also available from the Allergy New Zealand website <https://allergy.org.nz> and Medsafe website [www.medsafe.govt.nz](http://www.medsafe.govt.nz).