



29 January 2020

Dear Purchaser,

**Safety Advisory on EpiPen Contamination with Pralidoxime**

Good Pharmaceutical Pte Ltd would like to alert its purchasers that EpiPen® Jr Auto-Injector 0.15mg/0.3ml (SIN13290P) and EpiPen® Auto-Injector 0.3mg/0.3ml (SIN13288P) are found to contain trace levels of pralidoxime chloride. Pralidoxime chloride is an active pharmaceutical ingredient (API) associated with the production of another medicine used to treat people who have been poisoned by pest control chemicals and its safety profile has been well established in humans. The presence of these trace levels of pralidoxime chloride originated from a manufacturing issue between production batches of different products..

**Background**

EpiPen® Jr and EpiPen® Auto-Injectors contain epinephrine, which is used for the emergency treatment of allergic reactions including anaphylaxis in children and adults. As there is a current stock shortage, both EpiPen® Jr and EpiPen® Auto-Injectors are being allowed for release considering that the risk from withholding treatment or not having epinephrine available to treat anaphylaxis is far greater than the risk of being exposed to a very small amount of pralidoxime chloride. Although there is presence of trace levels of pralidoxime chloride, the risk of adverse reactions from exposure to pralidoxime chloride is very low as the trace levels of the pralidoxime tested are significantly below the recommended therapeutic dose of pralidoxime. Purchasers should report any serious adverse events suspected to be associated with the use of EpiPen to Good Pharmaceutical Pte Ltd, at vicki.ang@goodpharmaceutical.com.sg or Tel: +65 9828 7677. Alternatively, this information may be reported to Vigilance & Compliance Branch, Health Regulations Product Group, Health Sciences Authority at Tel: 6866 1111 or Fax: 6478 9069 or report online at [http://www.hsa.gov.sg/ae\\_online](http://www.hsa.gov.sg/ae_online)

Thank you for your kind understanding and co-operation.

Yours sincerely,

Jason Humphries  
Managing Director  
Good Pharmaceutical Pte Ltd

Acknowledged by:

Clinic Name/Stamp:

Medsupply International Pte Ltd.

Signature:

Date:

24/2/2020



Kindly scan the signed acknowledgement back to us at [xinyin.ong@apexpharma.com.sg](mailto:xinyin.ong@apexpharma.com.sg)