Generic Name:
Epinephrine auto-injectors
Trade Name:
EpiPen, Epi-Pen Jr.
Company:
Mylan
Notes:

FDA is alerting patients, caregivers, and health professionals that the labels attached to some EpiPen 0.3 mg and EpiPen Jr 0.15 mg auto-injectors, and the authorized generic versions, may block access to the auto-injector and prevent the ability to easily access the product.

In a letter to health professionals from Pfizer, the manufacturer of the Mylan EpiPen, the label sticker on the auto-injector unit may have been improperly applied, causing resistance when removing it from the carrier tube. The carrier tube is the immediate package in which the auto-injector is contained. In some cases, the patient or caregiver may not be able to quickly remove the epinephrine auto-injector from the carrier tube.

The auto-injector device and the epinephrine it delivers are not affected by this issue and can be used as prescribed. It is vital for lifesaving products to work as designed in an emergency situation, and patients and caregivers should inspect their epinephrine auto-injector prior to needing it to ensure they can quickly access the product.

The letter also describes how to inspect potentially affected products and explains that patients should contact Mylan Customer Relations at 800-796-9526 if an auto-injector does not slide out easily from the carrier tube OR the label is not fully adhered to the auto-injector. Pharmacists should inspect the products before dispensing them to patients to ensure quick access to the auto-injector and should not dispense any product that does not slide easily out of its carrier tube.

FDA is not aware of any adverse event reports associated with improperly applied EpiPen or EpiPen Jr auto-injectors, or their authorized generics label. As stated on the product label, consumers should always seek emergency medical help right away after using their epinephrine auto-injector.

Medication Monitor Categories:
Alerts and Recalls