

Updates to Instructions for Use of Epinephrine Auto-Injectors

June 15, 2016 · FARE

Given the life-threatening nature of severe allergic reactions, it is critical that patients and caregivers be trained in the proper use of auto-injectors. The U.S. Food and Drug Administration (FDA) has made updates to the [patient instructions](#) for epinephrine auto-injectors. Please note that there are no changes being made to the devices themselves.

The updates are as follows, as provided by Mylan, makers of EpiPen[®] and EpiPen Jr[®] Auto-Injectors:

For epinephrine auto-injectors, including EpiPen[®] and EpiPen Jr[®] Auto-Injectors:

- Hold patient's leg and limit movement during administration

Lacerations, bent needles and embedded needles [have been reported](#) when epinephrine has been injected into the thigh of young children who are uncooperative and kick or move during an injection. In order to minimize the risk of injection-related injury when administering the epinephrine injection to young children, caregivers are advised to hold the child's leg firmly in place and limit movement prior to and during injection.

- Patients should seek medical care if they develop signs or symptoms of infection at the injection site

Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene), have been reported at the injection site. While cleansing with alcohol may reduce the presence of bacteria on the skin, it does not kill Clostridium spores. To decrease the risk of Clostridium infection, do not inject into the buttock. Patients should seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness, at the epinephrine injection site.

For EpiPen[®] and EpiPen Jr[®] Auto-Injectors only:

- Injection hold time reduced from 10 seconds to 3 seconds

After administration, EpiPen[®] Auto-Injector should be held firmly in place for **3 seconds** prior to removal. New patient instructions read, "Hold firmly in place for 3 seconds (count slowly 1,2,3)."

[\(View link to study regarding this change\)](#)