

Sanofi US Recalls All *Auvi-Q* Epinephrine Injection

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| [Disclosures](#) | October 29, 2015

Sanofi US is voluntarily recalling all of its epinephrine injection (*Auvi-Q*) on the market because patients taking it for life-threatening anaphylaxis may receive an inaccurate and inadequate dose, the US Food and Drug Administration (FDA) announced today.

The company has received 26 unconfirmed reports of suspected device malfunction from patients in the United States and Canada as of October 26. No one died as a result, but patients continued to experience symptoms of underlying hypersensitivity reaction, the FDA said in a news release.

The agency said that patients using *Auvi-Q* should ask their physician to prescribe an alternate epinephrine autoinjector. If patients experience anaphylaxis, they should only use *Auvi-Q* if no other epinephrine autoinjector is available, and then seek emergency medical care.

Auvi-Q is distributed in packs that contain two active injectors, along with a training injector. There are roughly 490,000 packs of *Auvi-Q* on the market, all of them subject to the recall, Paul Chew, MD, Sanofi's global chief medical officer, told *Medscape Medical News*. Some packs contain epinephrine injection at 0.15 mg strength, and others at 0.3 mg strength.

The recall includes *Auvi-Q* packs in lots numbered 2299596 through 3037230, which expire March 2016 through December 2016.

Sanofi customers with questions about the voluntary recall, including how to return the product, can go to the *Auvi-Q* [website](#) or call 1-866-726-6340. More information about the recall is available on the FDA [website](#).

To report any problems with *Auvi-Q* epinephrine injection, contact MedWatch, the FDA's safety information and adverse event reporting program, by telephone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>; with postage-paid FDA form 3500, available at <http://www.fda.gov/MedWatch/getforms.htm>; or by mail to MedWatch, 5600 Fishers Lane, Rockville, Maryland 20852-9787.