



Impax Generics Epinephrine Injection Auto-Injector Important Safety Information as of June 18, 2018

Subject: Reminder Advisory - Patient inspection instructions due to potential of particles in Epinephrine Injection auto-injector.

Dear Health Care Provider:

Impax Generics would like to provide important safety information concerning the Epinephrine Injection auto-injector. Some lots of Epinephrine Injection auto-injector have passed all levels of inspection and met product specifications at the manufacturing facility, but have been found to contain particles upon further inspection. A patient reminder advisory has been added to each carton of the impacted lots, instructing patients to visually inspect the epinephrine solution in the auto-injector for particles, per labeled instructions. If the solution contains particles, the patient should not use the product and return it to a pharmacy for replacement.

Impacted Lots:

Product	NDC number	Lot numbers		
0.3 mg Epinephrine Auto-injector	0115-1694-49	G185501X	G185507X	G185513X
		G185502X	G185508X	G185514X
		G185503X	G185509X	G185515X
		G185504X	G185510X	G185516X
		G185505X	G185511X	G185517X
		G185506X	G185512X	

Product	NDC number	Lot numbers	
0.15 mg Epinephrine Auto-injector	0115-1695-49	G183301Z	G183303Z
		G183302Z	G183304Z

Potential Safety Risk of Adverse Events

Epinephrine Injection auto-injector is administered by the subcutaneous or intramuscular route. Our Health Hazard Assessment indicates that risk of injury due to these particles is low and may be limited to minor irritation or perhaps small cutaneous reactions at the injection site. A study has shown that if particles are present and the product is administered, it is unlikely the particles will prevent proper administration of the dose of epinephrine to the patient. Patients should be reminded whenever possible to carry more than one Epinephrine Injection auto-injector in the event they require a second dose.

Due to the critical nature of this product, Impax Generics, is coordinating with FDA, to release the above referenced lots.

For reference the instruction inserted in each carton reads as follows:

*PATIENT INSPECTION INSTRUCTIONS
Epinephrine Injection, USP auto-injector
0.3 mg, 0.15 mg*

This is to remind you to look at the epinephrine solution through the viewing window of the auto-injector before use. If the solution is discolored (pinkish or brown color), cloudy, or contains particles, do not use the auto-injector and return it to your pharmacy for replacement. Please contact Impax Generics at 1-800-934-6729 if you have questions about this information.

Full prescribing information is available at
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e13f05f1-7d21-49bb-b8d5-24bf9301c3d7>

Please contact Impax Generics Customer Service for any questions you may have regarding this notification.

Customer Service:
Phone: (877) 99-Impax (46729), option 3
Email: CustomerServiceGroup@impaxlabs.com

To report adverse reactions or quality issues, contact Impax Generics at:

Phone: (877) 99-Impax (46729), option 2
Phone: (510) 240-6450, option 2
Email: inquiries@impaxlabs.com
Mail: Impax Laboratories, 31047 Genstar Road, Hayward, CA 94544, Attention: Medical Affairs

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or fax: download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

We thank you for your attention to this important matter.

Sincerely,

Deborah M. Penza
Senior Vice President, Chief Compliance Officer