

Epinephrine Auto-Injector Devices Safety Alert

Date of Notice: 06/01/2020

Brief Description of Safety Alert

FDA is alerting patients, caregivers, and health care professionals to immediately inspect certain lots of Amneal and Impax epinephrine auto-injector 0.3 mg to ensure the yellow “stop collar” in the device is present. If the auto-injector is missing the yellow “stop collar” component, the device has the potential safety risk of delivering a double dose of epinephrine to a patient.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G181203X	07/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190302X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190303X	06/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190304X	09/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190305X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190306X	10/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190307X	07/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190401X	10/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190402X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190403X	07/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190501X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190502X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190503X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190504X	

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epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190505X	11/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G19050GX	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190601X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190602X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190603X	07/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190604X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190607X	11/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190701X	10/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190702X	11/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190703X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190704X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190707X	12/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190801X	02/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190802X	10/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190803X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190806X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190901X	12/2020
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190902X	01/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190903X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190904X	02/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190905X	

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epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190906X	02/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G190907X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191003X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191004X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191005X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191006X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191007X	04/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191008X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191009X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191101X	02/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191104X	04/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191105X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191106X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191107X	05/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191108X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191201X	04/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191202X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191203X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191204X	05/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191205X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G191206X	

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epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G200101X	05/2021
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G200102X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G200103X	
epinephrine injection, USP Auto-Injector 0.3 mg	0115-1694-30 (case) 0115-1694-49 (carton)	G200108X	02/2021

Prescriber Information

Patients, pharmacists, and health care professionals who have received Amneal or Impax’s epinephrine auto-injector after December 20, 2018, should immediately visually inspect the auto-injector to confirm the presence of the yellow “stop collar” by:

1. Removing the auto-injector from the carrying case.
2. Placing the auto-injector on a flat surface.
3. Locating the edge of the label that states, “Peel here for further instructions.” Lift the label edge until you see the clear part of the auto-injector.
4. Looking for the yellow “stop collar” inside the clear part of the auto-injector.
5. If the yellow “stop collar” is not visible inside the clear part of the auto-injector, gently rotate the blue sheath remover, without pulling or removing the blue sheath remover, to observe if the yellow “stop collar” comes into view inside the clear part of the auto-injector. If yellow “stop collar” is present, then the product is safe to use, and no further action is necessary. Re-wrap the label to its original position and place the auto-injector into the carrying case.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) 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

Member Information

Epinephrine auto-injectors are not being recalled. FDA urges patients to use the epinephrine auto-injector they have on hand and be aware of the potential issues outlined in the statement above.

RxAdvance Response

RxAdvance has provided education on this safety alert in this notification.

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