MEDICAL MUTUAL OF OHIO®

Medical Mutual®
2060 East Ninth Street
Cleveland, Ohio 44115-1355

MedMutual.com

April XX, 2020

First Name/Last Name
Address Line 1
Address Line 2
City, ST ZIP Code

Dear [Member First Name],

At Medical Mutual, your care is very important to us. We want to make you aware of a recent alert that the Food and Drug Administration (FDA) issued concerning potential errors with prescription medical devices. You have received this letter because our records indicate that you have filled a prescription for at least one of the following devices:

Mylan EpiPen 0.3mg, EpiPen Jr 0.15mg auto-injectors and authorized generic versions

Errors with these devices could either delay or prevent emergency treatment when needed.

Below is a summary of the concerns, as well as information on how to contact the manufacturer to report issues and/or obtain a replacement injector at no additional cost. As stated on the product label, patients should always seek emergency medical help right away after using their epinephrine auto-injector.

Potential device malfunctions and user administration errors include:

1. Device failure from spontaneous activation caused by holding a device with only one hand and using a sideways force with the thumb to remove the blue safety release.
    - Prior to use, the blue safety release should be removed by pulling straight up with one hand and holding the device with the other hand.
2. Device failure from inadvertent or spontaneous activation due to a raised blue safety release.
3. Device may not slide out of the carrier tube easily, or potentially at all, due to a slight deformation on the rim of the carrier tube.
4. Certain identified user errors can delay or prevent the administration of the intended dose of epinephrine. To successfully administer an injection, please note:
    - The device will not activate if the blue safety release is in place.
    - Ensure the needle end (orange end of the device) is in contact with the outer thigh (upper leg) prior to and during activation. The device should be administered by swinging and pushing firmly against the outer thigh until it “clicks.” This signals that injection has started.
    - Ensure the device is held in place for a minimum of three seconds following activation.

What should you do next?
Contact Mylan Customer Relations at 1-800-796-9526 (Monday – Friday, 8 a.m. – 5 p.m. ET) if you find or suspect an issue with your auto-injector and would like to obtain a replacement at no additional cost or if you have questions about the issue. You can also get more information by visiting the U.S. Food and Drug Administration (FDA) website at www.fda.gov. Click on "Drugs," and then go to "Drug Information, Safety, and Availability." Select "Drug Alerts and Statements" on the left-hand side of your screen, and the Alert for EpiPen Auto-injector Errors can be found under 3/24/2020.

We also encourage you to review instructions on the administration of EpiPens which can be found on the product website at www.epipen.com/about-epipen-and-generic/how-to-use-epipen, as well as the official EpiPen YouTube channel at www.youtube.com/user/EpiPenOfficial.

These malfunctions and user errors were found because health care professionals and patients reported issues through the FDA MedWatch Adverse Events Reporting Program. If you ever have a concern about an adverse event or quality problem related to the use of the drug, please report it to the FDA by calling 1-800-FDA-1088 or go to www.fda.gov/medwatch/report.htm. The process is simple and can help save lives.

Sincerely,

Kathryn Canaday, PharmD
Vice President, Pharmacy Management