



Immediate Care Training

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# Statement from Mylan on the availability of EpiPen® 0.3mg and 0.15mg Adrenaline Auto-Injectors

We have received the following updated statement from **Mylan** regarding the availability of EpiPen® 0.3mg and EpiPen® Jr 0.15mg Adrenaline Auto-Injector.

## Overview

In 2018 Mylan's manufacturing partner Meridian Medical Technologies, a Pfizer company, experienced interruptions in the production of EpiPen 0.3mg and EpiPen Jr 0.15mg Adrenaline Auto-Injectors (AAls).

During this period, and to help manage product availability on an ongoing basis until a steady supply resumed, Mylan allocated product on a prescription-only basis for both EpiPen 0.3mg and 0.15mg, meaning patients could obtain up to a maximum of two EpiPen AAls per prescription.

Over the last few months, the product has continued to ship, and we are seeing improvement in patient's ability to readily access both EpiPen 0.3mg and EpiPen 0.15mg in the UK.

## Availability of EpiPen 0.3mg Adrenaline Auto-Injectors

There is currently a good availability of EpiPen 0.3mg and the **prescription validation process previously assigned is no longer in place.**

Pharmacies are now able to place orders and hold a supply of EpiPen 0.3mg Adrenaline Auto-Injectors.

Patients can present their prescription to a pharmacy to fulfil their prescription the same day, however, you should check with your pharmacy to ensure that supply has been received and is available.

## **EpiPen 0.3mg Adrenaline Auto-Injectors – Extended Use Beyond Labelled Expiry Date for Select Lots**

To address the previous supply constraints of EpiPen 0.3mg, Mylan UK worked with the MHRA to obtain its approval to the use of nine specific lot (batch) numbers of EpiPen 0.3mg Auto-Injectors beyond the labelled expiry date by four months. Some of the affected lot numbers are listed in the table below.

The extended use beyond expiry date is based on a careful review by Mylan and the MHRA of data about these specific batches provided by Pfizer.

The relevant affected lots, which have labelled expiry dates between September 2018 and November 2018 are listed in the table below.

<b>Lot</b>	<b>Labelled Expiry Date (end of the month)</b>	<b>Extended Use by Date (end of the month)</b>
6FA794J	07.2018	11.2018
6FA795Y	07.2018	11.2018
7FA112F	09.2018	01.2019
7FA106B	09.2018	01.2019
7FA283B	10.2018	02.2019
7FA251D	10.2018	02.2019
7FA250B	10.2018	02.2019
7FA265C	11.2018	03.2019
7FA265B	11.2018	03.2019

**Important: the extended use only applies to the lots of EpiPen 0.3mg auto-injectors listed in the table above.**

**The extension of the use beyond the labelled expiry date does not apply to EpiPen Jr 0.15mg auto-injectors or any EpiPen 0.3mg lot numbers not specified above. Patients must continue to adhere to the manufacturer's expiry date labelled on any EpiPen not covered by the lot numbers above.**

### **Further information**

- To make sure patients can access their medicines during this supply constraint, the period that the nine specific lots of EpiPen 0.3mg (listed above) can be used has been extended by a further four months beyond the labelled expiry date on the pack.
- You can find the lot number on the end-flap of the box and on the EpiPen itself. If you're unsure whether your EpiPen is affected, please talk to your pharmacist.
- This extension of use beyond the labelled expiry date is based on data showing these nine batches of EpiPen 0.3mg auto-injectors will work just as well for this period. This has been reviewed by the UK medicines regulator, MHRA. EpiPen auto-injectors should continue to be stored as labelled on the pack.
- As with all EpiPens, patients should periodically visually inspect the adrenaline solution through the viewing window to make sure the solution is clear and colourless. If it is discoloured or contains solid particles the EpiPen should be replaced as soon as possible.
- At the end of the extended use beyond the labelled expiry date period (the end of the month listed in the right column above), you will still need to obtain a new auto-injector by the usual means.
- Please note that the information provided in this letter supersedes any other communication that you may receive from the Expiry Alert Service.

### **Availability of EpiPen Jr 0.15mg Adrenaline Auto-Injector**

EpiPen Jr 0.15mg Adrenaline Auto-Injectors are currently available.

To help manage product availability on an ongoing basis until a steady supply resumes, pharmacies are allocated product on a prescription-only basis and can

place orders for up to a maximum of two EpiPen Jr 0.15mg Adrenaline Auto-Injectors per prescription.

Patients should present their prescription to a pharmacy who will be able to place an order for up to a maximum of two EpiPen Jr 0.15mg Auto-Injectors per prescription.

Pharmacies are able to place orders for up to a maximum of two EpiPen Jr 0.15mg Adrenaline Auto-Injectors per prescription and should follow the Instructions for Pharmacists when placing orders.

**A reminder that the extension of the use beyond the labelled expiry date for the nine lots of EpiPen 0.3mg listed above does not apply to any EpiPen Jr 0.15mg auto-injectors or any EpiPen 0.3mg lot numbers not specified. Please continue to adhere to the manufacturer's expiry date labelled on any EpiPen 0.3mg not covered by the lot numbers above and all EpiPen Jr 0.15mg auto-injectors.**

### **Information for Prescribers**

Please note, when validating the expiry date of an adrenaline auto-injector, the product expires on the last day of the month indicated. For example, if it expires in February, it remains valid (not expired) until February 28.

### **Instructions for Pharmacists**

Pharmacies that are presented with a prescription for EpiPen Jr 0.15mg Auto-Injectors can place an order for up to a maximum of two EpiPen Jr 0.15mg Auto-Injectors per prescription. Please send anonymized prescriptions to Alliance Healthcare's prescription validation service, either by Fax (0330 332 8126) or email (EOHotline@alliance-healthcare.co.uk). Please include your Alliance Healthcare account number when placing your order.

### **Contact Information**

**Telephone: +44 (0)1707 853 000 | Medical Information e-mail: [info@mylan.co.uk](mailto:info@mylan.co.uk)**

**If you are prescribed AAls, to be well equipped during this time, we advise you to.**

- Check the expiry date on your medication regularly
- If needed, get a repeat prescription from your GP well in advance
- Do not dispose of any 'expired' AAI devices before you have a new AAI prescription

- If necessary, revisit your GP to ask if they can prescribe an alternative medication
- If you are prescribed an alternative AAI device, ensure that you know how to use it and train others that may need to use it in an emergency

Do continue to always carry your AAIs with you and follow your usual risk management techniques to avoid your allergen and reduce the likelihood that you will experience a severe allergic reaction and need to use your adrenaline.

## **Frequently Asked Questions**

### **How do I check the expiry date on AAIs?**

As some of the additional stock available in the UK at present has an expiry date of October 2018, we are advising patients to check the expiry date on their Adrenaline Auto-Injectors when they receive them and not to dispose of any 'expired' AAI devices before they have obtained a new device.

Your AAI devices will have instructions for use printed on the outside and generally will have a shelf life of up to 18 months. The expiry date will be printed on the casing. Each of the three companies who distribute AAIs run an expiry alert service. If you register your device and expiry date with them, they will send you a reminder when it is due to expire.

Whichever devices you have been prescribed, it is important that you keep your AAIs in their original containers to prevent light exposure, do not store them above 25°C and do not freeze them. If the liquid in your AAI appears cloudy or discoloured, it should be replaced with a new device. If the liquid in the device is not cloudy or discoloured, the AAI device can still be used in an emergency.

### **Pharmacist supply issues**

Your pharmacist should contact the supplier of your AAI through their distribution partner e.g. Alliance Healthcare, or their customer service department directly for updates regarding any issues they experience.