

13 FEBRUARY 2020

Availability of EpiPen® 0.3mg and 0.15mg Adrenaline Auto-Injectors

Mylan's manufacturing partner Meridian Medical Technologies, a subsidiary of Pfizer that manufactures EpiPen®, has experienced manufacturing challenges which has resulted in interruptions in the production of EpiPen 0.3mg and EpiPen Jr 0.15mg Adrenaline Auto-Injectors (AAIs).

To help manage product availability on an ongoing basis until a steady supply resumes, Mylan assigned a prescription validation process for EpiPen 0.3mg, meaning patients can obtain up to a maximum of two EpiPen 0.3mg AAIs per prescription.

There is no prescription validation process in place for EpiPen 0.15mg.

Patients should follow the **Instructions for Patients** detailed below to fulfil their prescriptions and pharmacies should follow the **Instructions for Pharmacists** outlined below when placing orders.

Instructions and Information for Patients

Patients requiring **EpiPen 0.3mg** AAI should present their prescription to a pharmacy where an order will be placed for up to a maximum of two EpiPen 0.3mg AAIs per prescription.

Patients requiring **EpiPen Jr 0.15mg** AAI should present their prescription to a pharmacy to fulfil their prescription. Please check with your pharmacy to ensure that supply has been received and is available.

Mylan is unable to make any specific treatment recommendation to individual patients. Patients should speak to their healthcare provider for appropriate action to be taken. However, if you have a question about your EpiPen device please contact our Medical Information team who will be able to help you: +(0) 1707 853 000 or email: info@mylan.co.uk.

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 29 February.

Instructions for Pharmacists

Pharmacies that are presented with a prescription for EpiPen 0.3mg Adrenaline Auto-Injectors can place an order for up to a maximum of two devices per prescription. Please send anonymized prescriptions to Alliance Healthcare's prescription validation service, either by fax (0330 332 8126) or email (scriptvalidation@alliance-healthcare.co.uk). Please include your Alliance Healthcare account number when placing your order.

Orders from schools should be sent to Alliance Healthcare's prescription validation service on the fax number or email address above. Please note that the purchase of EpiPen 0.3mg is currently limited to two devices per order.

Pharmacies can place orders and hold supply of EpiPen® Auto-Injector Jr 0.15mg. Please request supply through Alliance Healthcare, stating your account number when placing your order.

Instructions for Hospitals

Hospitals and healthcare institutions requiring supply of EpiPen 0.3mg Adrenaline Auto-Injectors for emergency use should contact Mylan Customer Service on +44 (0) 1707 853 100.

Instructions for Schools

To support children and young adults who may be at risk of anaphylaxis whilst away from home, the [Human Medicines \(Amendment\) Regulations 2017](#) allows schools, without the need for a prescription, to purchase and hold supply of adrenaline auto-injectors. Regulations allow the purchase of a reasonable number of adrenaline auto-injectors for use on an occasional basis and as required.

Schools requiring a supply of adrenaline auto-injectors to be used in emergency situations are now able to order EpiPen 0.3mg and EpiPen Jr 0.15mg through Mylan's distributor, Alliance Healthcare.

To place your order, please provide your local pharmacy with a letter, written on your school's headed paper and signed by the principal or headteacher. The pharmacy will then send the request to Mylan's distribution partner, Alliance Healthcare.

Please be reminded that the purchase of EpiPen 0.3mg is currently limited to two devices per order.

Extended Expiration Dates for Specific Lots of EpiPen® 0.3mg Adrenaline Auto-Injectors

Extended Use Beyond Labelled Expiry Date for Specific Lots of EpiPen® 0.3mg Adrenaline Auto-Injectors

In August 2019, Mylan was granted approval to a variation to permanently extend the shelf life of EpiPen 0.3mg auto-injectors from 20 months to 24 months.

Mylan UK have obtained acceptance from the MHRA to extend the use of specific lot (batch) numbers of EpiPen® 0.3mg auto-injectors already on the market, 4 months beyond the labelled expiry date. The affected lot numbers are listed in the table below.

EpiPen® 0.3mg (single pack)

LOT	Original Expiry Date	Extended Expiry Date
8FA273E	11/2019	03/2020
8KB332M	02/2020	06/2020
8FA366K	02/2020	06/2020
8FA367B	02/2020	06/2020
8KB478B	04/2020	08/2020
8KB474B	04/2020	08/2020

8KB481B	04/2020	08/2020
8KB510G	05/2020	09/2020
8KB523G	05/2020	09/2020
8KB648B	06/2020	10/2020
8KB587B	06/2020	10/2020
8KB630C	06/2020	10/2020
8KB587F	06/2020	10/2020
8KB671R	07/2020	11/2020
9KB087B	10/2020	02/2021
9KB148B	10/2020	02/2021
9KB177AE	11/2020	03/2021
9KB262B	12/2020	04/2021

EpiPen® 0.3mg (twin pack)

LOT	Original Expiry Date	Extended Expiry Date
8KB558C	05/2020	09/2020
8KB630D	06/2020	10/2020
8KB671F	07/2020	11/2020
9KB148J	10/2020	02/2021
9KB177E	11/2020	03/2021
9KB252P	11/2020	03/2021

9KB301J	12/2020	04/2021
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Important: the extended use only applies to the lots of EpiPen 0.3 mg auto-injectors listed above.

This extended use does not apply to EpiPen® 0.15mg Auto-Injectors or any lot number of EpiPen 0.3 mg auto-injectors not specified. It is important that patients must continue to adhere to the labelled expiry date on any EpiPen® not covered by the lot numbers above.

Further information

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, talk to your pharmacist.

The 4 months extended use beyond the labelled expiry date for the specific lots listed above is based on supportive stability data for EpiPen® 0.3mg auto-injectors and has been reviewed by the MHRA. The EpiPen® 0.3mg auto-injectors of these specific lots will continue to work safely within the extended use by date. The EpiPen® auto-injectors should continue to be stored as labelled on the pack.

At the end of the extended use period (the end of the month listed under "Extended Expiry Date" in the table above), you will still need to obtain a new auto-injector by the usual means.

Please note that the information provided in this communication supersedes any other communication that patients receive from the Expiry Alert Service.

Contact Information

Telephone: +44 (0)1707 853 000

Medical Information e-mail: info@mylan.co.uk