

23 April 2020

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

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

Supply has stabilised further in the UK and there is good availability of both EpiPen Jr 0.15mg and EpiPen 0.3mg AIs. The prescription validation process previously applied is no longer in place and the limit of two pens per prescription has now been lifted.

Information for Prescribers

The prescription validation previously in place no longer applies and the limit of two pens per prescription has now been lifted.

Prescribers are reminded that Medicines and Health Regulatory Agency (MHRA) guidelines recommend patients carry two adrenaline auto-injectors at all times.

Instructions for Pharmacists

Pharmacies are able to place orders and hold stock of EpiPen Jr 0.15mg and EpiPen 0.3mg AI devices so that patient prescriptions can be fulfilled the same day.

Please place your order through Alliance Healthcare, stating your account number in the request.

Instructions for Hospitals

Hospitals are able to place orders and hold stock of EpiPen Jr 0.15mg and EpiPen 0.3mg AIs.

Please place your order through Alliance Healthcare, stating your account number in the request.

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.

Orders for EpiPen Jr 0.15mg and EpiPen 0.3mg can be made through your local pharmacy. Please provide your 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.

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

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

For AAI already on the market, prior to the permanent extension of shelf life above, Mylan UK obtained approval from the MHRA to extend the use of specific lot (batch) numbers of EpiPen® 0.3mg autoinjectors, 4 months beyond the labelled expiry date. The affected lot numbers are listed in the table below.

This batch-specific extended use does not apply to EpiPen® 0.15mg AAI 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 below.

EpiPen® 0.3mg (single pack)

LOT	Original Expiry Date	Extended Expiry Date
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

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.

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