

August 2023

Important information for healthcare professionals:

EpiPen 300 micrograms solution for injection in pre-filled pen (PA23355/011/002, formerly PA2010/062/002)

EpiPen Junior 150 micrograms solution for injection in pre-filled pen (PA23355/011/001, formerly PA 2010/062/001)

Clarification regarding the basis for recent update to the hold-time from 5 seconds to 3 seconds

Dear Healthcare Professional,

We are writing in connection with a recent update to the hold-time instructions for EpiPen 300 micrograms and EpiPen Junior 150 micrograms, whereby the hold-time was reduced from 5 seconds to 3 seconds. Updated educational materials were circulated by Viatris Healthcare Limited (formerly Mylan IRE Healthcare Limited) on 3rd November 2022.

Viatris Healthcare Limited (formerly Mylan IRE Healthcare Limited) wishes to clarify that the reduction in the hold-time to 3 seconds was based primarily on data from a pharmacokinetic study. There were also quality and *in vitro* data presented in support of the reduction in hold-time. These data demonstrate that a full dose of adrenaline is administered with a shorter hold-time of 3 seconds.

There are no clinical trial data demonstrating that a reduced hold-time of 3 seconds is a safer option for patients.

This communication has been agreed with the HPRA.

The relevant product information and educational materials are available on the HPRA's website: <https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=EpiPen&field=>

Reporting of Adverse Reactions/Events

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit /risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie

Adverse reactions/events should also be reported to Viatris Healthcare Limited as per the following email address: pv.ireland@viatris.com

Yours sincerely,

Viatris Healthcare Limited (formerly Mylan IRE Healthcare Limited)