

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 3<sup>rd</sup> 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](http://www.hpra.ie)

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

Yours sincerely,

**Viatris Healthcare Limited (formerly Mylan IRE Healthcare Limited)**