

PHARMASWISS ČESKÁ REPUBLIKA S.R.O., INITIATES MEDICINAL PRODUCT RECALL IN IRELAND FOR EMERADE (ADRENALINE TARTRATE) PENS

PharmaSwiss Česká Republiká s.r.o., an entity of Bausch + Lomb, (the Company) has initiated a patient-level recall of Emerade (adrenaline tartrate) 150/300/500 mcg pens in Ireland following complaints of non-activation of the pens. The Company issued the following statement:

Nothing is more important to us than the safety of our medicines and the patients who use them. At the request of the Health Products Regulatory Authority (HPRA), the Company has initiated a recall of Emerade pens as a precautionary measure and in full collaboration with the HPRA following these complaints. An investigation is in progress, and the cause of the problem is still not known at this time.

Please immediately return any pens you have in your possession to your pharmacy. Included in the recall are all in-date batches, as follows:

- Emerade 150 micrograms solution for injection in pre-filled pen PA1696/009/001
- Emerade 300 micrograms solution for injection in pre-filled pen PA1696/009/002
- Emerade 500 micrograms solution for injection in pre-filled pen PA1696/009/003

Reporting of suspected adverse reactions

Any side effects should be reported. This includes any possible side effects not listed in the package leaflet. You can report side effects directly to the HPRA. The address is: HPRA Pharmacovigilance, Kevin O'Malley House, Earlsfort Terrace, Dublin 2. You may also report via telephone at +353 1 6764971, by Fax: +353 1 6762517, via the Website: www.hpra.ie and by e-mail: medsafety@hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events can also be reported to Bausch Health directly on +44 208 781 2993 or by e-mail at Pharmacovigilance.UK@bausch.com.

For customer service enquiries please contact Bausch & Lomb Customer Services, Telephone number: +44 208781 2991; Email Pharma_CS@bausch.com