IMPORTANT STATEMENT BELOW, PLEASE READ.

EpiPen (Adrenaline) Auto-Injector 0.3 mg: supply of a batch (no. 9FM766) with US-labelled auto-injectors packaged in UK cartons with a UK leaflet

- Mylan has released a batch of US-labelled EpiPen auto-injectors (Batch no. **9FM766**) to enable continuous access of auto-injectors in the UK following approval from the MHRA.
- The EpiPen auto-injectors in this batch are affixed with a US label, and are packaged (as single packs) into UK cartons along with UK patient information leaflets.

- The drug name is epinephrine in the US but is known as adrenaline in the UK. Patients and carers familiar with the term adrenaline may be confused.

- You are advised to communicate these differences to patients if you receive queries and reassure them that this device is exactly the same.

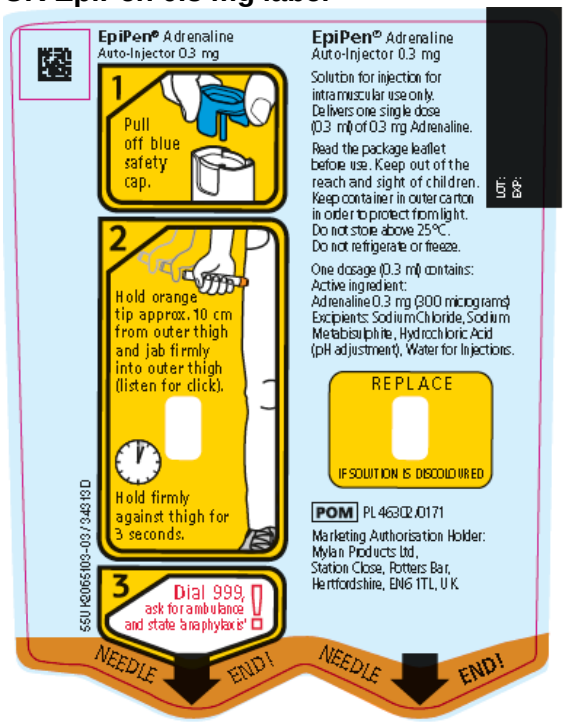
Further information on the safety concern and recommendations to professional bodies and patient support groups

The auto-injector device in this batch is exactly the same as the normal UK EpiPen in every way except for the information on the label on the device.

Other differences between the US-labelled and UK-labelled auto-injectors are:
- The UK label has the instruction to 'Dial 999, ask for ambulance and state 'anaphylaxis!', which is replaced with 'Get emergency medical help!' on the US label.
- The warning 'Keep of the reach and sight of children' is omitted on the US auto-injector label. However, the UK carton and patient information leaflet include this statement.

Please see below a comparison of the US and UK labels on the autoinjectors:

UK EpiPen 0.3 mg label



US EpiPen 0.3 mg label

Remind patients and carers that they should 'Dial 999, ask for an ambulance and state anaphylaxis!' after every use of the EpiPen autoinjector.
Tell patients that the label on the EpiPen (epinephrine) auto-injector is meant for the US and they should read the outer carton and enclosed Patient Information Leaflet which is designed for UK patients.

<u>Call for reporting</u>
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report suspected side effects electronically. You can report side effects via:

- the Yellow Card website https://www.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

If there is no online access to report a suspected side effect to the Yellow Card Scheme, call 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black

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When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point

If you want further information relating to the above, please contact

Mylan Medical Information
Building 4, Trident Place
Mosquito Way, Hatfield
AL10 9UL, UK
Info.uk@mylan.co.uk
Tel: +44 (0)1707 853 000 (option 1)

For further information about EpiPen® please see the Summary of Product Characteristics (SmPC)
available from: http://www.medicines.org.uk/emc/medicine/26974