



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

### Caution in Use Pharmacy/Wholesaler Level

Date: 18 November 2024

EL (24)A/55

Our Ref: DMRC-33832314

Dear Healthcare Professional,

### Takeda Pharma A/S trading as Takeda UK Limited

**Entyvio 108mg solution for injection in pre-filled syringe**

**PLGB 15475/0073**

**SNOMED Code:** 38289511000001101

Batch No	Expiry Date	Pack Size	First Distributed
12741441	12.2025	Pack containing 2 pre-filled syringes	06JUN2024
12788930	02.2026	Pack containing 2 pre-filled syringes	29AUG2024
12816782	06.2026	Pack containing 2 pre-filled syringes	15NOV2024

Active Pharmaceutical Ingredient: vedolizumab

#### Brief description of the problem

Takeda UK Limited has informed the MHRA that there is an error in the Patient Information Leaflet for the above specified batches of Entyvio 108mg pre-filled syringes. The errors are as follows:

- Text relating to a patient alert card being given to the patient by the healthcare professional at the time of prescribing should have been deleted.
- Missing information: In section 4, under the heading 'common side effects' the adverse reaction 'infection of the large intestine due to Clostridium difficile bacteria' is missing.
- Miscategorised information: In section 4, under common side effects: In addition to the listed side effects, the following should be included:
  - o pneumonia (should be listed as common, but appears under very rare)
  - o shingles (herpes zoster) (should be listed as common, but appears under uncommon)
  - o blurred vision (loss of sharpness of eyesight) (should be listed as uncommon but appears under very rare)

This error affects the printed leaflet, supplied within the carton for the pre-filled syringe. The text version of the leaflet available online is correct [Entyvio 108mg solution for injection in pre-filled syringe - Patient Information Leaflet \(PIL\) - \(emc\)](#).

#### Advice for healthcare professionals



## Medicines & Healthcare products Regulatory Agency

Healthcare professionals should advise the patient of the possibility of these adverse reactions and refer patients to the electronic version of the patient information leaflet available online [Entyvio 108mg solution for injection in pre-filled syringe - Patient Information Leaflet \(PIL\) - \(emc\)](#).

Patients should also be told that there is no patient alert card with this medicine.

### **Advice for patients**

Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

The text version of the leaflet available online is correct [Entyvio 108mg solution for injection in pre-filled syringe - Patient Information Leaflet \(PIL\) - \(emc\)](#)

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

### **Further Information**

For medical information enquiries please Email [medinfoemea@takeda.com](mailto:medinfoemea@takeda.com) or telephone 03333 000 181

For stock control enquiries please Email [ukie.supplychain@takeda.com](mailto:ukie.supplychain@takeda.com)

Recipients of this Medicines Notifications should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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