



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 19 December 2024

EL (24)A/63

Our Ref: DMRC-34131563

Dear Healthcare Professional,

Argenx BV

Vyvgart 1000 mg solution for injection

PLGB 47104/0005

SNOMED Code: 42703811000001101

Batch No	Expiry Date	Pack Size	First Distributed
P99834CE	Mar 2025	1 vial	7 March 2024
P99834CJ	Feb 2025	1 vial	17 Jun 2024
P99834CK	Feb 2025	1 vial	Not yet distributed
P99842CH	Sep 2025	1 vial	Not yet distributed

Active Pharmaceutical Ingredient: efgartigimod alfa

Brief description of the problem

Argenx BV have informed MHRA that the Patient Information Leaflet (PIL) in the affected packs incorrectly contains reference to two subcutaneous injection sites (abdomen and thigh) at Step 20 of the instructions. The correct PIL, approved as part of the GB marketing authorisation, only contains reference to one subcutaneous injection site (abdomen).

Advice for healthcare professionals

Healthcare professionals should only administer the product via the abdomen. This is described in the approved PIL and can be accessed electronically at [VYVGART 1000 mg solution for injection - Patient Information Leaflet \(PIL\) - \(emc\)](#).

Any healthcare professionals providing the affected batches to patients for self-administration should advise patients to administer via the abdomen.

Advice for patients

Patients should continue to take medicines from these batches as prescribed by your healthcare professional. This does not affect the quality of the product. Any patient who has received self-administration training should administer the product via the abdomen. This is described in the approved (correct) PIL and can be accessed electronically at [VYVGART 1000 mg solution for injection - 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](#).



Medicines & Healthcare products Regulatory Agency

Further Information

For medical information enquiries please contact ukmedinfo@argenx.com or +44 (0)20 4532 4016

For stock control enquiries please contact rpi@argenx.com or +44 (0)7801 748936.

Recipients of this Medicines Recall 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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