Chief Medical Officer Directorate
Pharmacy and Medicines Division

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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

19 December 2024

Dear Healthcare Professional,

DRUG ALERT CLASS 4 – No 63 2024 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – ARGENX BV – VYGART 1000MG SOLUTION FOR INJECTION

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

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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