Medicines & Healthcare products Regulatory Agency

# **MEDICINES RECALL**

## CLASS 2 MEDICINES RECALL, EL(25)A/29

### Action within 48 hours

Issued 25 June 2025

### Distribute to Pharmacy/Wholesaler Level

### MARKETING AUTHORISATION HOLDER (MAH)

Quadrant Pharmaceuticals Limited / Maxearn Limited

**MEDICINE DETAILS** 

### Depo-Medrone 80mg in 2 mL suspension for injection

PLPI: 20774/1666 Active Ingredient: methylprednisolone acetate SNOMED code: N/A GTIN: 5060537815503

AFFECTED LOT BATCH NUMBERS			
Batch No.	Expiry Date	Pack Size	First Distributed
LG3883 / Max 0943Y	29/02/2029	2ml	13/05/2025

### Background

Maxearn Limited have informed the MHRA that the label on an imported batch of Depo-Medrone has been released to the market with an error. The vial label contains incorrect information regarding volume and total vial content. The label incorrectly states that the total vial content is 40 mg in 1 mL, when the correct total vial content is 80mg in 2 mL (with a concentration of 40mg/ml of methylprednisolone acetate). The error could result in the administration of the incorrect dose.

Maxearn has contacted their distributor, 32 packs have been distributed to pharmacies. The remaining units provided to the distributor have been quarantined.

The error only impacts the parallel imported product repackaged by Maxearn, packs from other sources are not affected and should continue to be dispensed.

#### Image of incorrect over label and impacted vial:



Image of correct over label:



#### Advice for Healthcare Professionals:

Stop supplying the above batch immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

Maxearn can confirm 32 packs were released by the distributor. All other units have been held before onward distribution. Maxearn will arrange for customers who received these units to be contacted.

Healthcare professionals who have been supplied this batch and have administered the medicine to patients should contact the patient to make them aware of this error and provide any relevant clinical advice.

### Advice for Healthcare Professionals to Provide to Patients:

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. Depo-medrone is administered under the supervision of a healthcare professional. Patients who have received this batch will be contacted by your healthcare professional.

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.

#### Additional information:

For all medical information enquiries and information on this product, please email <u>maxearnga@maxearn.co.uk</u> or telephone 01204 471 269.

For stock control enquiries please email <u>maxearnqa@maxearn.co.uk</u> or telephone 01204 471 269.

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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