Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/16

Action within 48 hours

Issued 08 April 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Reig Jofre UK

MEDICINE DETAILS

Synalar GEL 30g

PL: 44095/0004

Active Ingredient: fluocinolone acetonide 0.025%

SNOMED code: 2156911000001100

GTIN: 8435373700332

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
L303A	31/03/2026	1	19/05/2023
L304A	30/04/2026	1	21/08/2023
L401A	31/03/2027	1	10/06/2024
L403A	31/05/2027	1	17/10/2024
L404A	31/05/2027	1	17/10/2024

MEDICINE DETAILS

Synalar GEL 60g

PL: 44095/0004

Active Ingredient: fluocinolone acetonide 0.025%

SNOMED code: 11507311000001100

GTIN: 8435373700349

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
L301A	28/02/2026	1	11/07/2023
L402A	31/03/2027	1	17/10/2024

Background

It has been identified that the batches listed in this notification of Synalar Gel 30g and 60g contain a residual solvent (benzene) at a level exceeding the ICH limit of 2ppm. This solvent has been identified from one of the excipients in the product, carbomer 940, and the theoretical results from the initial investigation prompted the testing of the retention samples. These results have shown some batches are within the limit, whilst some are over the 2ppm limit.

Reig Jofre UK are recalling all these affected batches as a precautionary measure. This recall is at pharmacy and wholesaler level. It is only the specific Synalar Gel batches listed in this notification that are affected. All other presentations of Synalar (Ointment and Cream) are not affected. Due to this recall, there will be a temporary shortage of Synalar Gel and Reig Jofre UK are unable to provide a specific date for when new stock will be available.

Advice for Healthcare Professionals:

Stop supplying the affected batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for Patients:

No further action is required by patients as this is a pharmacy and wholesaler level recall.

Reig Jofre UK have confirmed that the patient risk due to this out of specification result is low based on the initial investigation and assessment, however the recall is a precautionary measure to mitigate any additional dispensing of the product batches.

Patients are advised not to stop any treatments without consulting your relevant healthcare professional. If you have any concerns in relation to the product or any side effects, please contact your pharmacist or GP for more information and assistance.

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 medical information enquiries please contact Reig Jofre UK Medical Information on 0330 1359 434 or by email MedInfoUK@reigjofre.com.

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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