



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/21

Caution In Use

Issued 13 May 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Chemidex Pharma Ltd

MEDICINE DETAILS

- **Predfoam 20mg/dose Rectal Foam**
- **Prednisolone 20mg/dose Rectal Foam**
- **Beclometasone dipropionate 0.25 mg/g Cream**
- **Beclometasone dipropionate 0.25 mg/g Ointment**
- **Clobetasol propionate/neomycin sulfate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream**
- **Clobetasol propionate/neomycin sulfate/nystatin 0.5 mg/5 mg/100,000 IU/g Ointment**
- **Hydrocortisone 0.5% Cream**
- **Hydrocortisone 2.5% Cream**
- **Hydrocortisone 2.5% Ointment**

For product details and impacted batches, see Appendix 1

Background

Chemidex Pharma Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in their topical steroid products does not contain all the required safety information. Cartons for the products/batches listed are missing side effect information related to Visual Disturbances.

The batches listed as 'not yet distributed' have also been packed with the PIL that is missing the additional side effect information. The MHRA, in discussion with the Department of Health and Social Care, considers these products critical for patients, therefore these batches will not be repackaged and continue to be distributed. They are

therefore included in the notification and the expected distribution dates for these batches will take place from May 2025.

Advice for Healthcare Professionals:

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing these products

When product from batches included in the tables are supplied or dispensed, please ensure that patients are aware of the missing information.

The missing information is:

PIL Section 2

Contact your doctor if you experience blurred vision or other visual disturbances.

PIL Section 4

Side effects where the frequency is not known:

Blurred vision.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take medicines from the impacted batches as prescribed by your healthcare professional. The quality of the impacted batches is not affected which is why the products are not being recalled.

There is some missing information in the patient leaflet which is presented below:

Section 2

Contact your doctor if you experience blurred vision or other visual disturbances.

Section 4

Side effects where the frequency is not known:

- Blurred vision.

If you have any concerns about the information provided with your medicine, please speak with your pharmacy team in the first instance. If you have concerns about a medicine you may be using, please contact 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 medical information enquiries please email essentialpharmaUK@EU.ProPharmaGroup.com, or telephone +44 (0)1423 850700.

For stock control enquiries please email commercial@essentialpharmagroup.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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk

Appendix 1

MEDICINE DETAILS

Predfoam 20mg/dose Rectal Foam

Prednisolone 20mg/dose Rectal Foam

PL: 17736/0130

Active Ingredient: prednisolone

SNOMED code: 38753811000001101

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
XDAM	June-2025	14 doses	01Aug2024
XDAN	Mar-2026	14 doses	10Jan2025
XDANA	Mar-2027	14 doses	Not yet distributed

MEDICINE DETAILS

Beclometasone dipropionate 0.25 mg/g Cream

PL: 17736/0127

Active Ingredient: beclometasone

SNOMED code: 18436411000001103

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5153054	Jan-2026	30 g	18 May 2023
5155361	Feb-2028	30 g	22 Apr 2025

MEDICINE DETAILS

Beclometasone dipropionate 0.25 mg/g Ointment

PL: 17736/0268

Active Ingredient: beclometasone dipropionate

SNOMED code: 18434811000001108

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5154993	Mar-2026	30 g	07 Nov 2024

MEDICINE DETAILS

Clobetasol propionate/neomycin sulfate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream

PL: 17736/0100

Active Ingredient: clobetasol propionate, neomycin sulfate, nystatin

SNOMED code: 18670711000001106

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5155317	Mar-2028	30 g	Not yet distributed
5155318	Mar-2028	30 g	Not yet distributed

MEDICINE DETAILS

Clobetasol propionate/neomycin sulfate/nystatin 0.5 mg/5 mg/100,000 IU/g Ointment

PL: 17736/0101

Active Ingredient: clobetasol propionate, neomycin sulfate, nystatin

SNOMED code: 18670911000001108

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5154048	Apr-2027	30 g	03 Jul 2024

MEDICINE DETAILS

Hydrocortisone 0.5% Cream

PL: 17736/0090

Active Ingredient: hydrocortisone

SNOMED code: 14943211000001105

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5154895	Aug-2026	30 g	13 Dec 2024
5154896	Aug-2026	30 g	13 Dec 2024

MEDICINE DETAILS

Hydrocortisone 2.5% Cream

PL: 17736/0092

Active Ingredient: hydrocortisone

SNOMED code: 14943911000001101

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5155032	Oct-2026	15 g	31 Jan 2025
5154572	Apr-2026	30 g	06 Aug 2024

MEDICINE DETAILS

Hydrocortisone 2.5% Ointment

PL: **17736/0095**

Active Ingredient: hydrocortisone

SNOMED code: 14944911000001104

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5152598	Sep-2025	15 g	04 Apr 2023
5153432	May-2026	15 g	03 Aug 2023
5154575	Apr-2027	15 g	21 Aug 2024
5153431	May-2026	30 g	19 Jul 2023