MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/10
Caution In Use

Issued 24 February 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Rayner Pharmaceuticals Limited

MEDICINE DETAILS

Dropodex 0.1% w/v Eye Drops, solution

PL: 47069/0003

Active Ingredient: Dexamethasone sodium phosphate

SNOMED code: 23484611000001104

GTIN: 5060132680100

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
C361X	31 Mar 2026	1 carton containing 20 single-dose units	29 Jun 2025
C361Y	31 Mar 2026	1 carton containing 20 single-dose units	31 Jul 2025
D361A	31 Jul 2026	1 carton containing 20 single-dose units	04 Sep 2025
D361B	31 Jul 2026	1 carton containing 20 single-dose units	07 Oct 2025
D361C	31 Jul 2026	1 carton containing 20 single-dose units	31 Oct 2025
E361A	31 Jan 2028	1 carton containing 20 single-dose units	28 Nov 2025

E361F	29 Feb 2028	1 carton containing 20 single-dose units	Not yet distributed
E361D	31 Jan 2028	1 carton containing 20 single-dose units	25 Jan 2026
E361E	31 Jan 2028	1 carton containing 20 single-dose units	Not yet distributed
E361C	31 Jan 2028	1 carton containing 20 single-dose units	28 Dec 2025
E361G	31 May 2028	1 carton containing 20 single-dose units	Not yet distributed
E361H	30 Jun 2028	1 carton containing 20 single-dose units	Not yet distributed
E361L	30 Jun 2028	1 carton containing 20 single-dose units	Not yet distributed
E361M	30 Jun 2028	1 carton containing 20 single-dose units	Not yet distributed
F361A	31 Jul 2028	1 carton containing 20 single-dose units	Not yet distributed

Background

Rayner Pharmaceuticals limited have informed MHRA that the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for the batches listed in this notification were not updated in accordance with the 'Annex to European Commission guideline on excipients in the labelling and package leaflet of medicinal products for human use', which require the concentration of phosphates to be included.

The batches listed as 'not yet distributed' have also been manufactured and packed without the phosphate concentration included in the PIL. 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 this notification.

Information available in the SmPC covers the risk occurrence due to phosphates. However, information on phosphate concentration was missing from the SmPC and PIL, as detailed below.

- **PIL**

Section 2 of the Dropodex PIL will be updated to include the following statement:

> *This medicinal product contains 1.01 mg phosphates in each 0.4 mL dose which is equivalent to 2.52 mg/mL phosphates (from 9.5 mg/mL disodium phosphate dodecahydrate).*

Section 4 of the Dropodex PIL, 'very rare side effects' will be amended to include:

> *If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.*

- **SmPC**

To align with changes in the PIL, the SmPC will include the following statement in Section 4.4:

> *This medicinal product contains 1.01 mg phosphates in each 0.4 mL dose which is equivalent to 2.52 mg/mL phosphates (from 9.5 mg/mL disodium phosphate dodecahydrate).*

Advice for Healthcare Professionals:

This medicinal product contains 1.01 mg phosphates in each 0.4 mL dose which is equivalent to 2.52 mg/mL phosphates (from 9.5 mg/mL disodium phosphate dodecahydrate). This information was not previously included in the product information and will be updated accordingly for new manufactured batches in the product information (SmPC and package leaflet) for HCPs as well as patients.

This medicinal product contains phosphates, which may lead to corneal deposits or corneal opacity when topically administered.

This medicinal product should be used with caution in patients presenting with compromised cornea and in instances where the patient is receiving polypharmacy with other phosphate-containing eye medications.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to use the product as instructed by their healthcare professional. The information missing from the PIL and SmPC relates only to the concentration of phosphates in the eye drops. The quality of the eye drops is not impacted by the missing information. No adverse events have been received for these batches of products. If patients have any questions about this medication, you should speak to your dispensing pharmacy in the first instance.

Patients who experience adverse reactions or have any questions about their 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: medinfo.rayner@apcerls.com, or telephone +44-800-041-8153

For stock control enquiries please email markclayton@rayner.com, or telephone 01903 258777.

Recipients of this Medicines notification 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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