



Medicines & Healthcare products
Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/24

Caution In Use

Issued 02 June 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Zentiva Pharma UK Limited

MEDICINE DETAILS

Zentiva Paracetamol Soluble Tablets

PL 17780/0198

Active Ingredient: paracetamol

SNOMED code: 1857611000001102

GTIN: 24 pack: 5000283601807

FOR AFFECTED LOT/BATCH NUMBERS – SEE ANNEX 1

MEDICINE DETAILS

Zentiva Paracetamol Soluble Tablets

PL 17780/0162

Active Ingredient: paracetamol

SNOMED code: 1858211000001100

GTIN: 100 pack: 5000283598565

FOR AFFECTED LOT/BATCH NUMBERS – SEE ANNEX 1

MEDICINE DETAILS

Zentiva Co-Codamol 8/500 Effervescent Tablets

PL 17780/0072

Active Ingredient: paracetamol and codeine phosphate

SNOMED code: 10517611000001104

GTIN: 32 pack:5000283652038

FOR AFFECTED LOT/BATCH NUMBERS – SEE ANNEX 2

MEDICINE DETAILS

Zentiva Co-Codamol 8/500 Effervescent Tablets

PL 17780/0511

Active Ingredient: paracetamol and codeine phosphate

SNOMED code: 1914311000001104

GTIN: 100 pack: 5000283588481

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 2

MEDICINE DETAILS

Zentiva Co-Codamol 30/500 Effervescent Tablets

PL 17780/0046

Active Ingredient: Paracetamol and codeine phosphate

SNOMED code: 5468711000001106

GTIN: 100 pack: 5000283609094

FOR AFFECTED LOT BATCH NUMBERS – SEE ANNEX 3

Background

Zentiva Pharma UK Limited has informed the MHRA that the batches of soluble or effervescent tablets listed in the annexes are taking longer than expected to fully dissolve, resulting in an increase in residual material being observed. Additionally, some tablets may appear as having a rough surface on one side identified during further analysis. Following an investigation at the manufacturing site it is confirmed that the safety and efficacy of the tablets is not affected by these issues.

The batches listed as 'not yet distributed' may also exhibit the same behaviour and take longer than expected to full dissolve . The MHRA, in discussion with Zentiva Pharma UK Limited, considers that there is no patient safety, quality or efficacy risk due to this issue, therefore these are included in the notification and the expected distribution dates for these batches will take place from 02 June 2025. These products are fast moving and the batches listed in this notification are expected to be consumed within 6 months.

Advice for Healthcare Professionals:

Healthcare professionals are advised to review the information contained within this notification and when medicines from the batches included in the tables are supplied or dispensed, please ensure that patients are aware of the following information:

- Tell the patient that there may be an increased length of time required for the tablets to dissolve (approximately 5 minutes);
- The tablets should be dissolved in a full glass of water (approximately 200 ml) and stirred before drinking;
- If after drinking there are residual particles left in the glass, then they should add more water (approximately 100 ml) and stir before drinking;
- The effectiveness of the tablets is not affected by this longer dissolving time;
- Tell the patient that some tablets may appear to have a slightly rough or uneven surface on one side, but this does not affect the effectiveness of the tablet.

Advice for Patients:

Continue to take tablets from these batches as prescribed by your healthcare professional. The effectiveness of the tablets is not affected by this longer dissolving time. To ensure that you get your complete dose:

- Dissolve the tablets in a glass of water (approximately 200ml), allow the tablets to dissolve (approximately 5 minutes) and stir before drinking;
- If after drinking there are residual particles left in the glass, then add more water (approximately 100 ml) and stir before drinking.

Some tablets may appear to have a slightly rough or uneven surface on one side which does not affect the effectiveness of the tablet. If you notice a significant change in the tablet appearance or have any other concerns, please contact your pharmacist.

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 Zentiva medical information via webform (<https://www.zentiva.co.uk/contact/mi-form>), email UKmedinfo@zentiva.com or telephone 0800 090 2408.

For stock control enquiries please email ukcustomerservices@zentiva.com or telephone 08448 793188.

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

ANNEX 1 - Zentiva Paracetamol Soluble Tablets PL 17780/0198

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
219804	31/08/2026	24	25/03/2025

ANNEX 1 - Zentiva Paracetamol Soluble Tablets PL 17780/0162

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
234134	30/11/2027	100	18/04/2025
234125	30/11/2027	100	13/04/2025
234122	30/11/2027	100	03/04/2025
233822	30/11/2027	100	01/04/2025
233819	30/11/2027	100	27/03/2025

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233703	30/11/2027	100	24/03/2025
233702	30/11/2027	100	20/03/2025
233623	30/11/2027	100	17/03/2025
233622	30/11/2027	100	13/03/2025
233553	31/10/2027	100	11/03/2025
233552	31/10/2027	100	11/03/2025
233551	31/10/2027	100	06/03/2025
233550	31/10/2027	100	28/02/2025
233492	31/10/2027	100	25/02/2025
233491	31/10/2027	100	25/02/2025
233488	31/10/2027	100	24/02/2025
233394	31/10/2027	100	21/02/2025
233392	31/10/2027	100	18/02/2025
233390	31/10/2027	100	14/02/2025
233368	31/10/2027	100	07/02/2025
233283	31/10/2027	100	30/01/2025
233281	31/10/2027	100	23/01/2025
233220	31/10/2027	100	15/01/2025
233155	31/10/2027	100	15/01/2025
233087	31/10/2027	100	14/01/2025
233037	31/10/2027	100	13/01/2025
233033	31/10/2027	100	13/01/2025
233005	31/10/2027	100	10/01/2025
233002	31/10/2027	100	09/01/2025
232741	31/10/2027	100	03/01/2025
219938	31/08/2026	100	14/11/2024
219842	31/08/2026	100	04/11/2024

ANNEX 2 - Zentiva Co-Codamol 8/500 Effervescent Tablets PL 17780/0072

AFFECTED LOT BATCH NUMBERS			
Batch No.	Expiry Date	Pack Size	First Distributed
235536	31/12/2027	32	07/04/2025
220136	31/08/2026	32	05/03/2025
220206	31/08/2026	32	07/03/2025
235574	31/12/2027	32	Not yet distributed
235583	31/12/2027	32	Not yet distributed
235683	31/12/2027	32	Not yet distributed
235779	31/12/2027	32	Not yet distributed
235829	31/12/2027	32	Not yet distributed
235830	31/12/2027	32	Not yet distributed
235849	31/12/2027	32	Not yet distributed
235864	31/12/2027	32	Not yet distributed
235898	31/12/2027	32	Not yet distributed
235899	31/12/2027	32	Not yet distributed
235939	31/12/2027	32	Not yet distributed
235961	31/01/2028	32	Not yet distributed
236071	31/01/2028	32	Not yet distributed
236072	31/01/2028	32	Not yet distributed
236151	31/01/2028	32	Not yet distributed
236153	31/01/2028	32	Not yet distributed
236184	31/01/2028	32	Not yet distributed
236197	31/01/2028	32	Not yet distributed
236300	31/01/2028	32	Not yet distributed

ANNEX 2 - Zentiva Co-Codamol 8/500 Effervescent Tablets PL 17780/0511**AFFECTED LOT BATCH NUMBERS**

Batch No.	Expiry Date	Pack Size	First Distributed
222082	31/10/2026	100	06/03/2025

ANNEX 3 - Zentiva Co-Codamol 30/500 Effervescent Tablets PL 17780/0046**AFFECTED LOT BATCH NUMBERS**

Batch No.	Expiry Date	Pack Size	First Distributed
220011	31/08/2026	100	05/03/2025
220072	31/08/2026	100	06/03/2025
222000	31/10/2026	100	11/03/2025
222085	31/10/2026	100	12/03/2025