



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Retailer/Pharmacy/Wholesaler Level

Date: 21 October 2024

EL (24)A/49

Our Ref: DMRC-32772688

Dear Healthcare Professional,

Kent Pharma UK

Paracetamol 500mg Effervescent x100 Tablets (P)

PL 51463/0031

SNOMED Codes: 1856211000001101 (5x20) & 1856011000001106 (10x10)

Paracetamol 500mg Effervescent x60 Tablets (P)

PL 51463/0031

SNOMED Codes: 1855911000001103

Paracetamol 500mg Effervescent x24 Tablets (GSL)

PL 51463/0032

SNOMED Codes: 2274411000001102

Paracetamol 500mg Effervescent x16 Tablets (GSL)

PL 51463/0032

SNOMED Codes: 2274211000001101

Active Pharmaceutical Ingredient: Paracetamol

Brief description of the problem

Kent Pharma UK has identified an error in the Patient Information Leaflet (PIL) for Paracetamol 500mg Effervescent Tablets. The PIL incorrectly states that the maximum daily dose contains 438mg of sodium, whereas this is the sodium content for a single dose. The maximum daily dose is in fact 3504mg of sodium. The leaflet also inaccurately indicates that the maximum daily dose represents 22% of the WHO recommended daily sodium intake, whereas it should state 175% of the WHO recommended daily sodium intake. These errors may pose a risk to patients who need to control their sodium intake.

This Class 4 Caution In Use notification applies to all batches and all pack sizes for both PL 51463/0031 and PL 51463/0032, and the expiry dates for these batches range from August 2025 to December 2027. Kent Pharma UK has shared further details of all batches impacted in Appendix 1. Due to supply considerations and no current availability of the correct PIL, batches listed as not yet distributed will not



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be repackaged with the updated PIL prior to distribution. The specified 'Not yet distributed' batches are scheduled to be distributed shortly to avoid any supply considerations. Kent Pharma UK has confirmed that all future batches (not listed in this notification) of the product released to market after 01 February 2025 will contain the updated PIL.

Advice for healthcare professionals and retailers

Whilst the correct sodium content per single dosage is provided on the product carton and in the Summary of Product Characteristics (SmPC), healthcare professionals should be aware that the PIL contains incorrect information regarding the sodium content of the maximum daily dosage of product.

When selling or dispensing all batches of this medicine, where possible, advise patients of the correct sodium levels as per the carton. As noted in the PIL, patients should be advised to speak to their pharmacist or doctor if they need effervescent paracetamol on a daily basis for a prolonged period of time, especially if they have been advised to follow a low salt diet.

Advice for patients

The leaflet included with Paracetamol 500mg Effervescent Tablets contains incorrect information about the sodium content in the maximum daily dose for this medicine. The correct sodium content per single dose is provided on the product carton. Each tablet contains 438mg of sodium and maximum amount of sodium that would be consumed will be 3504mg sodium, based on taking the maximum of eight (8) paracetamol tablets in 24 hours.

Patients, especially those on low-sodium diets, are advised to consult their healthcare professional if they need effervescent paracetamol over a prolonged period of time.

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](#).

Further Information

For medical information enquiries please contact medical@kent-athlone.com

For stock control enquiries please contact customer.service@kent-athlone.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



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Appendix 1 – List of batches impacted, including batches which have not yet been distributed

Batch No	Expiry Date	Pack Size	Classification	First Distributed
2PU064A	Aug-25	24	GSL	Dec-2022
2PU065A	Sep 25	24	GSL	Dec-2022
2PU066A	Sep 25	24	GSL	Dec-2022
2PU067A	Sep 25	24	GSL	Dec-2022
2PU068A	Sep 25	24	GSL	Dec-2022
2PU069A	Sep 25	24	GSL	Dec-2022
2PU070A	Sep 25	24	GSL	Dec-2022
2PU071A	Oct-25	16	GSL	Jan-2023
2PU072A	Oct-25	16	GSL	Jan-2023
2PU073A	Oct-25	16	GSL	Jan-2023
2PU075A	Oct-25	24	GSL	Jan-2023
2PU076A	Oct-25	24	GSL	Jan-2023
2PU077A	Oct-25	24	GSL	Jan-2023
2PU080A	Oct-25	24	GSL	Jan-2023
2PU081A	Oct-25	24	GSL	Jan-2023
2PU082A	Oct-25	24	GSL	Jan-2023
2PU083A	Oct-25	24	GSL	Jan-2023
2PU084A	Oct-25	24	GSL	Jan-2023
2PU085A	Oct-25	24	GSL	Jan-2023
2PU086A	Oct-25	24	GSL	Jan-2023
2PU087A	Oct-25	24	GSL	Jan-2023
2PU088A	Oct-25	24	GSL	Jan-2023
2PU089A	Oct-25	24	GSL	Jan-2023
3PU001A	Dec-25	24	GSL	Mar-2023
3PU002A	Dec-25	24	GSL	Mar-2023
3PU003A	Dec-25	24	GSL	Mar-2023
3PU004A	Dec-25	24	GSL	Mar-2023
3PU005A	Dec-25	24	GSL	Mar-2023
3PU006A	Dec-25	24	GSL	Mar-2023
3PU007A	Dec-25	24	GSL	Mar-2023
3PU008A	Dec-25	60	P	Mar-2023
3PU009A	Dec-25	60	P	Mar-2023
3PU010A	Dec-25	60	P	Mar-2023
3PU011A	Dec-25	60	P	Mar-2023
3PU012A	Dec-25	100	P	Mar-2023
3PU013A	Dec-25	100	P	Mar-2023
3PU014A	Dec-25	100	P	Mar-2023
3PU015A	Dec-25	100	P	Mar-2023
3PU016A	Dec-25	100	P	Mar-2023
3PU017A	Dec-25	100	P	Mar-2023
3PU018A	Dec-25	24	GSL	Mar-2023
3PU019A	Dec-25	24	GSL	Mar-2023
3PU020A	Dec-25	24	GSL	Mar-2023
3PU026A	Jan 26	24	GSL	Apr-2023
3PU027A	Jan 26	24	GSL	Apr-2023
3PU028A	Jan 26	24	GSL	Apr-2023



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Batch No	Expiry Date	Pack Size	Classification	First Distributed
3PU029A	Jan 26	24	GSL	Apr-2023
3PU030A	Jan 26	24	GSL	Apr-2023
3PU031A	Jan-26	24	GSL	Apr-2023
3PU032A	Jan-26	24	GSL	Apr-2023
3PU033A	Jan-26	24	GSL	Apr-2023
3PU034A	Jan-26	24	GSL	Apr-2023
3PU035A	Jan-26	24	GSL	Apr-2023
3PU036A	Jan-26	16	GSL	Apr-2023
3PU037A	Jan-26	16	GSL	Apr-2023
3PU038A	Jan-26	16	GSL	Apr-2023
3PU039A	Jan-26	16	GSL	Apr-2023
3PU040A	Jan-26	24	GSL	Apr-2023
3PU041A	Jan-26	24	GSL	Apr-2023
3PU042A	Jan-26	24	GSL	Apr-2023
3PU043A	Jan-26	24	GSL	Apr-2023
3PU044A	Feb-26	24	GSL	May-2023
3PU045A	Feb-26	24	GSL	May-2023
3PU046A	Feb-26	24	GSL	May-2023
3PU047A	Feb-26	24	GSL	May-2023
3PU048A	Feb-26	24	GSL	May-2023
3PU049A	Feb-26	100	P	May-2023
3PU050A	Feb-26	100	P	Jun-2023
3PU051A	Feb-26	100	P	Jun-2023
3PU052A	Feb-26	24	GSL	May-2023
3PU053A	Feb-26	24	GSL	May-2023
3PU054A	Feb-26	16	GSL	Jun-2023
3PU055A	Feb-26	100	P	Jun-2023
3PU056A	Feb-26	100	P	Jun-2023
3PU057A	Mar-26	16	GSL	Jun-2023
3PU058A	Mar-26	16	GSL	Jun-2023
3PU059A	Mar-26	16	GSL	Jun-2023
3PU060A	Mar-26	100	P	Jul-2023
3PU061A	Mar-26	60	P	Jul-2023
3PU062A	Mar-26	60	P	Jul-2023
3PU063A	Apr-26	16	GSL	Jul-2023
3PU064A	Apr-26	16	GSL	Jul-2023
3PU065A	Apr-26	24	GSL	Jul-2023
3PU066A	Apr-26	24	GSL	Jul-2023
3PU067A	Apr-26	24	GSL	Jul-2023
3PU068A	Apr-26	24	GSL	Jul-2023
3PU069A	Apr-26	24	GSL	Jul-2023
3PU070A	Apr-26	24	GSL	Jul-2023
3PU071A	Apr-26	24	GSL	Jul-2023
3PU072A	Apr-26	24	GSL	Jul-2023
3PU073A	Apr-26	24	GSL	Jul-2023
3PU074A	Apr-26	24	GSL	Jul-2023
3PU075A	Apr-26	24	GSL	Jul-2023
3PU076A	Apr-26	24	GSL	Jul-2023



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Batch No	Expiry Date	Pack Size	Classification	First Distributed
3PU077A	Apr-26	24	GSL	Jul-2023
3PU078A	Apr-26	24	GSL	Jul-2023
3PU079A	Apr-26	100	P	Jul-2023
3PU080A	Apr-26	100	P	Jul-2023
3PU081A	Apr-26	100	P	Jul-2023
3PU082A	Apr-26	100	P	Jul-2023
3PU083A	Apr-26	100	P	Aug-2023
3PU084A	Apr-26	100	P	Aug-2023
3PU085A	Apr-26	60	P	Aug-2023
3PU086A	Apr-26	60	P	Aug-2023
3PU087A	Apr-26	60	P	Aug-2023
3PU088A	Apr-26	60	P	Aug-2023
3PU089A	Jun-26	24	GSL	Sep-2023
3PU090A	Jun-26	24	GSL	Sep-2023
3PU091A	Jun-26	24	GSL	Sep-2023
3PU092A	Jun-26	24	GSL	Sep-2023
3PU093A	Jun-26	24	GSL	Sep-2023
3PU094A	Jun-26	24	GSL	Sep-2023
3PU096A	Jun-26	24	GSL	Sep-2023
3PU097A	Jun-26	16	GSL	Sep-2023
3PU098A	Jun-26	16	GSL	Sep-2023
3PU099A	Jun-26	16	GSL	Sep-2023
3PU100A	Jun-26	16	GSL	Sep-2023
3PU101A	Jun-26	16	GSL	Sep-2023
3PU102A	Jun-26	16	GSL	Sep-2023
3PU103A	Jun-26	16	GSL	Sep-2023
3PU104A	Jun-26	16	GSL	Oct-2023
3PU105A	Jun-26	16	GSL	Sep-2023
3PU106A	Jun-26	16	GSL	Sep-2023
3PU107A	Jun-26	16	GSL	Sep-2023
3PU108A	Jun-26	24	GSL	Sep-2023
3PU109A	Jun-26	24	GSL	Sep-2023
3PU110A	Jun-26	24	GSL	Sep-2023
3PU111A	Jul-26	24	GSL	Oct-2023
3PU112A	Jul-26	24	GSL	Oct-2023
3PU113A	Jul-26	24	GSL	Oct-2023
3PU114A	Jul-26	24	GSL	Oct-2023
3PU115A	Jul-26	24	GSL	Oct-2023
3PU116A	Jul-26	24	GSL	Oct-2023
3PU117A	Jul-26	24	GSL	Oct-2023
3PU118A	Jul-26	24	GSL	Oct-2023
3PU119A	Jul-26	24	GSL	Oct-2023
3PU120A	Jul-26	24	GSL	Oct-2023
3PU121A	Jul-26	24	GSL	Oct-2023
3PU122A	Jul-26	24	GSL	Oct-2023
3PU123A	Jul-26	24	GSL	Oct-2023
3PU124A	Jul-26	24	GSL	Oct-2023
3PU125A	Jul-26	60	P	Oct-2023



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Batch No	Expiry Date	Pack Size	Classification	First Distributed
3PU126A	Aug-26	24	GSL	Nov-2023
3PU127A	Aug-26	24	GSL	Nov-2023
3PU128A	Aug-26	24	GSL	Nov-2023
3PU129A	Aug-26	24	GSL	Nov-2023
3PU130A	Aug-26	24	GSL	Nov-2023
3PU131A	Aug-26	24	GSL	Nov-2023
3PU132A	Aug-26	24	GSL	Nov-2023
3PU133A	Aug-26	24	GSL	Nov-2023
3PU135A	Sep-26	24	GSL	Dec-2023
3PU136A	Sep-26	24	GSL	Dec-2023
3PU137A	Sep-26	24	GSL	Dec-2023
3PU138A	Sep-26	24	GSL	Dec-2023
3PU139A	Sep-26	24	GSL	Dec-2023
3PU140A	Sep-26	24	GSL	Dec-2023
3PU141A	Sep-26	24	GSL	Dec-2023
3PU142A	Sep-26	24	GSL	Jan-2024
3PU143A	Sep-26	24	GSL	Jan-2024
3PU144A	Sep-26	24	GSL	Jan-2024
3PU145A	Oct-26	24	GSL	Jan-2024
3PU146A	Oct-26	24	GSL	Feb-2024
3PU147A	Oct-26	24	GSL	Jan-2024
3PU148A	Oct-26	24	GSL	Jan-2024
3PU149A	Oct-26	24	GSL	Jan-2024
3PU150A	Oct-26	24	GSL	Feb-2024
3PU151A	Oct-26	24	GSL	Jan-2024
3PU152A	Oct-26	24	GSL	Jan-2024
3PU153A	Oct-26	24	GSL	Jan-2024
3PU154A	Oct-26	24	GSL	Jan-2024
3PU155A	Oct-26	24	GSL	Jan-2024
3PU156A	Oct-26	24	GSL	Feb-2024
3PU157A	Oct-26	24	GSL	Jan-2024
3PU158A	Oct-26	24	GSL	Jan-2024
3PU159A	Oct-26	24	GSL	Feb-2024
3PU160A	Nov-26	24	GSL	Feb-2024
3PU161A	Nov-26	24	GSL	Feb-2024
3PU162A	Nov-26	24	GSL	Feb-2024
3PU163A	Nov-26	24	GSL	Feb-2024
3PU164A	Nov-26	24	GSL	Feb-2024
3PU165A	Nov-26	24	GSL	Feb-2024
3PU166A	Nov-26	24	GSL	Feb-2024
3PU167A	Nov-26	24	GSL	Feb-2024
3PU168A	Nov-26	24	GSL	Feb-2024
3PU169A	Nov-26	16	GSL	Mar-2024
3PU170A	Nov-26	16	GSL	Mar-2024
3PU172A	Nov-26	24	GSL	Mar-2024
3PU173A	Nov-26	24	GSL	Mar-2024
3PU174A	Nov-26	24	GSL	Mar-2024
3PU175A	Nov-26	24	GSL	Mar-2024



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Batch No	Expiry Date	Pack Size	Classification	First Distributed
3PU176A	Nov-26	24	GSL	Apr-2024
3PU177A	Nov-26	24	GSL	Apr-2024
4PU001A	Dec-26	24	GSL	Apr-2024
4PU002A	Dec-26	24	GSL	Apr-2024
4PU003A	Dec-26	24	GSL	Apr-2024
4PU004A	Dec-26	24	GSL	Apr-2024
4PU005A	Dec-26	24	GSL	Apr-2024
4PU006A	Dec-26	24	GSL	Apr-2024
4PU007A	Dec-26	24	GSL	Apr-2024
4PU008A	Dec-26	24	GSL	Apr-2024
4PU009A	Dec-26	24	GSL	Apr-2024
4PU010A	Dec-26	24	GSL	Apr-2024
4PU011A	Dec-26	24	GSL	Apr-2024
4PU012A	Dec-26	24	GSL	Apr-2024
4PU013A	Dec-26	24	GSL	Apr-2024
4PU014A	Mar-27	24	GSL	Jul-2024
4PU015A	Mar-27	24	GSL	Sep-2024
4PU016A	Mar-27	24	GSL	Jul-2024
4PU017A	Mar-27	24	GSL	Jul-2024
4PU018A	Mar-27	24	GSL	Jul-2024
4PU019A	Mar-27	24	GSL	Jul-2024
4PU020A	Mar-27	24	GSL	Jul-2024
4PU021A	Mar-27	24	GSL	Jul-2024
4PU022A	Mar-27	24	GSL	Jul-2024
4PU023A	Mar-27	24	GSL	Jul-2024
4PU024A	Mar-27	24	GSL	Jul-2024
4PU027A	Apr-27	24	GSL	Jul-2024
4PU028A	Apr-27	24	GSL	Aug-2024
4PU029A	Apr-27	24	GSL	Aug-2024
4PU030A	Apr-27	24	GSL	Aug-2024
4PU031A	Apr-27	24	GSL	Aug-2024
4PU032A	Apr-27	24	GSL	Aug-2024
4PU033A	Apr-27	24	GSL	Sep-2024
4PU034A	Apr-27	16	GSL	Sep-2024
4PU035A	Apr-27	16	GSL	Sep-2024
4PU036A	Apr-27	100	P	Sep-2024
4PU037A	May-27	100	P	Sep-2024
4PU038A	May-27	100	P	Sep-2024
4PU039A	May-27	100	P	Sep-2024
4PU040A	May-27	100	P	Sep-2024
4PU042A	May-27	24	GSL	Not yet distributed
4PU043A	May-27	24	GSL	Not yet distributed
4PU044A	May-27	24	GSL	Not yet distributed
4PU045A	Jun-27	24	GSL	Not yet distributed
4PU045B	Jun-27	24	GSL	Not yet distributed
4PU046A	Jul-27	24	GSL	Not yet distributed
4PU047A	Jul-27	24	GSL	Not yet distributed
4PU048A	Jul-27	24	GSL	Not yet distributed



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Batch No	Expiry Date	Pack Size	Classification	First Distributed
4PU049A	Jul-27	24	GSL	Not yet distributed
4PU050A	Jul-27	24	GSL	Not yet distributed
4PU051A	Jul-27	24	GSL	Not yet distributed
4PU052A	Jul-27	24	GSL	Not yet distributed
4PU053A	Jul-27	24	GSL	Not yet distributed
4PU054A	Aug-27	24	GSL	Not yet distributed
4PU055A	Aug-27	100	P	Not yet distributed
4PU056A	Aug-27	100	P	Not yet distributed
4PU057A	Aug-27	24	GSL	Not yet distributed
4PU058A	Aug-27	60	P	Not yet distributed
4PU059A	Aug-27	24	GSL	Not yet distributed
4PU060A	Aug-27	24	GSL	Not yet distributed
4PU061A	Aug-27	24	GSL	Not yet distributed
4PU062A	Aug-27	24	GSL	Not yet distributed
4PU063A	Aug-27	24	GSL	Not yet distributed
4PU064A	Aug-27	24	GSL	Not yet distributed
4PU065A	Aug-27	24	GSL	Not yet distributed
4PU066A	Aug-27	24	GSL	Not yet distributed
4PU067A	Aug-27	24	GSL	Not yet distributed
4PU068A	Aug-27	24	GSL	Not yet distributed
4PU069A	Aug-27	16	GSL	Not yet distributed
4PU070A	Aug-27	16	GSL	Not yet distributed
4PU071A	Aug-27	16	GSL	Not yet distributed
4PU072A	Aug-27	16	GSL	Not yet distributed
4PU073A	Sep-27	24	GSL	Not yet distributed
4PU074A	Sep-27	24	GSL	Not yet distributed
4PU075A	Sep-27	24	GSL	Not yet distributed
4PU076A	Sep-27	24	GSL	Not yet distributed
4PU077A	Sep-27	24	GSL	Not yet distributed
4PU078A	Sep-27	24	GSL	Not yet distributed
4PU079A	Sep-27	24	GSL	Not yet distributed
4PU080A	Sep-27	16	GSL	Not yet distributed
4PU081A	Sep-27	24	GSL	Not yet distributed