



T: 0131-244-2528
E: irene.fazakerley@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

28 October 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4- no.51- UPDATE TO DRUG ALERT 49 2024 – CLASS 4
MEDICINES DEFECT INFORMATION – CAUTION IN USE – KENT PHARMA UK –
PARASOLVE (PARACETAMOL) 500MG EFFERVESCENT TABLETS 24 TABLETS (GSL)**

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team





MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Retailer/Pharmacy/Wholesaler Level

Date: 28 October 2024

EL (24)A/51

Our Ref: DMRC-32772688

Dear Healthcare Professional,

Kent Pharma UK

**Parasolve (Paracetamol) 500mg effervescent tablets 24 tablets
(GSL)**

PL 51463/0032

SNOMED Codes: 40848611000001107

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 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. Kent Pharma UK has confirmed that all future batches (not listed in this notification) will contain the updated PIL.

This notification is in addition to [EL 24\(A\)/49](#) and provides further information in relation to the impacted product mentioned in this notification.

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 corrected 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.



Medicines & Healthcare products Regulatory Agency

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

Batch No	Expiry Date	Pack Size	Classification	First Distributed
2PU074A	Oct-25	24	GSL	Jan-2023
3PU021A	Dec-25	24	GSL	Apr-2023
3PU022A	Jan-25	24	GSL	Apr-2023
3PU023A	Jan-25	24	GSL	Apr-2023
3PU024A	Jan-25	24	GSL	Apr-2023
3PU025A	Jan-25	24	GSL	Apr-2023
3PU095A	Jun-26	24	GSL	Sep-2023
3PU134A	Aug-26	24	GSL	Dec-2023
3PU171A	Nov-26	24	GSL	Mar-2024
4PU025A	Mar-27	24	GSL	Jul-2024
4PU026A	Apr-27	24	GSL	Jul-2024
4PU041A	May-27	24	GSL	Sep-2024