Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 30 March 2020 EL (20)A/19 Our Ref: MDR 138-03/20

Dear Healthcare Professional,

Rosemont Pharmaceuticals Limited (part of the Perrigo group)

Paracetamol 250mg/5ml Oral Suspension (500ml) PL 00427/0078

Batch Number	Expiry Date	Pack Size	First Distributed
9AL0061	31.12.2020	500ml	Mar 2019
9CL0026	28.02.2021	500ml	Apr 2019
9DL0025	31.05.2021	500ml	Jun 2019
9EL0021	30.06.2021	500ml	Jul 2019
9GL0028	31.07.2021	500ml	Aug 2019
9JL0028	31.08.2021	500ml	Sept 2019
9JL0056	31.10.2021	500ml	Oct 2019
9KL0030	30.11.2021	500ml	Nov 2019
9LL0066	30.11.2021	500ml	Dec 2019
9LL0020	31.12.2021	500ml	Jan 2020
9ML0054	31.12.2021	500ml	Feb 2020
9ML0013	31.01.2022	500ml	Mar 2020

Brief description of the problem
Rosemont Pharmaceuticals Ltd has informed us of an error in the barcode and GTIN number of the label on the bottle of the above batches. When scanned, the barcode identifies the bottle as Paracetamol 120ml/5ml Oral Suspension instead of Paracetamol 250mg/5ml Oral Suspension. The dm&d browser website also identifies this GTIN number and barcode incorrectly as Paracetamol 120ml/5ml Oral Suspension.

The product is not subject to a recall and the strength printed on the bottle label is correctly stated as Paracetamol 250mg/5ml Oral Suspension. The barcode and the GTIN number on the outer box is correct and identifies the strength of the batches as Paracetamol 250mg/5ml Oral Suspension.

Advice for healthcare professional

- When identifying the product strength please go by the labelled contents' not the strength stated when the barcode is scanned or the GTIN number on the dm&d browser website.

Advice for wholesalers

- Please forward this letter on to any pharmacies, hospitals and healthcare professionals that you supply Paracetamol 250mg/5ml Oral Suspension to, within 5 days of receiving this letter.

Further Information

For Customer services queries, please contact Rosemont.customerservices@perrigouk.com or on 0113 244 1999

For medical queries, please contact RosemontPharmacovigilance@perrigouk.com or on 0113 244 1400

For product quality queries, please contact RosemontQAComplaints@perrigouk.com or on 0113 244 1400

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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