Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 20 April 2023 EL (23)A/14 Our Ref: MDR 230-03/23

Dear Healthcare Professional,

Sandoz Limited

Co-amoxiclav 125/31.25mg/5ml powder for oral suspension **PL 04416/0514**

SNOMED Code **6032711000001109**

Batch Number	Expiry Date	Pack Size	First Distributed
KN7289	30/04/2023	1	11/06/2020
KN1408	30/04/2023	1	02/07/2020
KN1409	30/04/2023	1	02/07/2020
KN1406	30/04/2023	1	09/07/2020
KN1410	30/04/2023	1	16/07/2020
KS7930	30/06/2023	1	03/09/2020
KS7928	30/06/2023	1	03/09/2020
KS7929	30/06/2023	1	03/09/2020
KS7925	30/06/2023	1	11/09/2020
KX1634	30/09/2023	1	03/12/2020
KZ5913	31/10/2023	1	26/03/2021
KZ5911	31/10/2023	1	26/03/2021
LA6145	30/11/2023	1	08/04/2021
LA6142	31/10/2023	1	18/05/2021
KZ7804	31/10/2023	1	20/05/2021
LG8908	30/04/2024	1	08/07/2021
LJ0774	31/05/2024	1	15/07/2021
LJ0772	30/04/2024	1	15/07/2021
LJ0777	31/05/2024	1	15/07/2021
LJ8598	31/05/2024	1	29/07/2021
LJ8597	31/05/2024	1	30/07/2021
LR5163	30/09/2024	1	21/12/2021
LV2132	30/09/2024	1	18/03/2022
MB7217	28/02/2025	1	23/05/2022
MB3089	28/02/2025	1	23/05/2022
MB7213	28/02/2025	1	23/05/2022
MB9154	28/02/2025	1	27/06/2022
MH3989	30/06/2025	1	20/09/2022
MJ3047	31/08/2025	1	21/10/2022

MN4528	31/10/2025	1	12/01/2023
MN4525	31/10/2025	1	12/01/2023
MP2985	31/10/2025	1	23/01/2023
MP2984	31/10/2025	1	23/01/2023
MS7591	31/12/2025	1	03/03/2023
MS5699	31/12/2025	1	08/03/2023
MS5698	31/12/2025	1	08/03/2023
MP5588	31/10/2025	1	14/03/2023
MT2296	31/12/2025	1	17/03/2023

Co-amoxiclav 125/31.25mg/5ml powder for oral suspension (ALMUS LIVERY) **PL 04416/0514**

SNOMED Code 6032711000001109

Batch Number	Expiry Date	Pack Size	First Distributed
LL9525	31/05/2024	1	27/08/2021
LM7892	31/05/2024	1	12/11/2021
MB7218	28/02/2025	1	06/05/2022

Co-amoxiclav 250/62.5mg/5ml powder for oral suspension **PL 04416/0515**

SNOMED Code 6034811000001107

Batch Number	Expiry Date	Pack Size	First Distributed
KN7345	30/04/2023	1	24/06/2020
KN7348	30/04/2023	1	24/06/2020
KN7343	30/04/2023	1	24/06/2020
KN7344	30/04/2023	1	26/06/2020
KN7346	30/04/2023	1	29/06/2020
KN7349	30/04/2023	1	29/06/2020
KN7351	30/04/2023	1	09/07/2020
KN7355	30/04/2023	1	09/07/2020
KN7356	30/04/2023	1	10/07/2020
KN7358	30/04/2023	1	10/07/2020
KN7359	30/04/2023	1	04/08/2020
KU1888	31/07/2023	1	21/10/2020
KV9017	31/08/2023	1	12/11/2020
KV9018	31/08/2023	1	12/11/2020
KV9030	31/08/2023	1	19/11/2020
KV9015	31/08/2023	1	24/11/2020
KZ8872	31/10/2023	1	18/02/2021
KZ8870	31/10/2023	1	18/02/2021
KZ8869	31/10/2023	1	18/02/2021
LB0656	30/11/2023	1	22/02/2021
LA1951	31/10/2023	1	22/02/2021

KZ8863	31/10/2023	1	26/03/2021
LA1953	30/11/2023	1	08/04/2021
LA1954	30/11/2023	1	08/04/2021
KZ8864	31/10/2023	1	15/04/2021
KZ8866	31/10/2023	1	07/05/2021
LH0734	30/04/2024	1	24/06/2021
LH0736	30/04/2024	1	01/07/2021
LJ8596	31/12/2023	1	30/07/2021
LL7416	30/06/2024	1	09/09/2021
LM6701	31/08/2024	1	01/11/2021
LM6702	31/08/2024	1	02/11/2021
LM6705	31/08/2024	1	10/11/2021
LM6706	31/08/2024	1	10/11/2021
LR6835	31/10/2024	1	22/02/2022
LL9622	30/06/2024	1	22/02/2022
LP2509	31/08/2024	1	22/02/2022
MB7827	28/02/2025	1	08/07/2022
MG6831	30/06/2025	1	02/09/2022
MF7424	31/05/2025	1	06/09/2022
MG1126	30/06/2025	1	06/09/2022
MG1127	30/06/2025	1	06/09/2022
MG7519	30/06/2025	1	13/09/2022
MG6832	30/06/2025	1	20/09/2022
MG7521	30/06/2025	1	20/09/2022
MG6833	30/06/2025	1	20/09/2022
MH3996	30/06/2025	1	27/09/2022
MJ7424	31/07/2025	1	28/10/2022
MJ7426	31/07/2025	1	25/11/2022
MJ7425	31/07/2025	1	25/11/2022
MJ8744	31/08/2025	1	25/11/2022
MK2855	31/08/2025	1	25/11/2022
ML7555	30/09/2025	1	25/11/2022
ML7558	30/09/2025	1	30/11/2022
MN0722	31/10/2025	1	22/12/2022
MP2508	31/10/2025	1	19/01/2023
MP4622	31/10/2025	1	19/01/2023
MP7479	31/10/2025	1	19/01/2023
MP1482	31/10/2025	1	19/01/2023
MP2509	31/10/2025	1	09/02/2023
MS1090	31/12/2025	1	03/03/2023
MR6781	31/10/2025	1	03/03/2023

Medicines & Healthcare products Regulatory Agency

Co-amoxiclav 250/62.5mg/5ml powder for oral suspension (ALMUS LIVERY) **PL 04416/0515**

SNOMED Code 6034811000001107

Batch Number	Expiry Date	Pack Size	First Distributed
LM6707	31/08/2024	1	27/10/2021
LM7608	31/08/2024	1	08/12/2021
MB7828	28/02/2025	1	08/07/2022
MG9435	30/06/2025	1	20/09/2022

Active Pharmaceutical Ingredient: amoxicillin trihydrate, potassium clavulanate

Brief description of the problem
Sandoz limited has informed the MHRA that the products mentioned in this notification are not sugar free despite the carton stating 'sugar free'. The 'sugar free' text was added to the carton in December 2008 in error. All batches supplied since December 2008 have contained a very small quantity of sugar originating from the flavouring. The contained sugars are dextrose and maltodextrin, which are both composed of glucose. However, for a small cohort of patients the product may not be suitable. The maximum daily intake of sugar from Co-Amoxiclav powder for oral solution is equivalent to less than 1% of the maximum daily intake recommended by the World Health Organisation (WHO). The total amount of sugar at the maximum daily doses equates to 204.3 mg in children, 127.8 mg in adults, based on dosing recommendations as per the Summary of Product Characteristics (SmPC).

SmPC: Co-amoxiclav 125/31.25mg/5ml powder for oral suspension, PL 04416/0514
https://mhraproducts4853.blob.core.windows.net/docs/e3c93505e2240f10ef3e81a1a2953a59a26d7b2e

SmPC: Co-amoxiclav 250/62.5mg/5ml powder for oral suspension, PL 04416/0515
https://mhraproducts4853.blob.core.windows.net/docs/593e8aa9baa0bbe9082c8e54eced1cbd3ec54587

Advice for healthcare professionals
There is no risk to product quality as a result of this issue, and the affected batches are not being recalled. Healthcare professionals are advised to inform patients about the error when dispensing subsequent batches or in discussion with patients who may have concerns related to sugar intake or glucose control, where appropriate.

Healthcare professionals should be aware that due to the continuity of supply, a small number of extra batches of each product, which contain small amounts of sugars, will be released to the market, even though the carton will indicate that these products are 'sugar free'. Sandoz have confirmed that after July 2023 all batches manufactured will contain the correct carton artwork.

Advice for patients
This notification relates to the fact that the products noted above contain a small quantity of sugar while the carton states 'sugar free'. Patients do not need to take any action as the medicine itself is not affected. Any suspected adverse reactions should be reported via the MHRA Yellow Card Scheme.

Medicines & Healthcare products Regulatory Agency

Further Information
For more information, medical information queries, please contact: sandozgb@EU.propharmagroup.com, Telephone: +44 1276 698 101

For stock control queries, please contact: sales.sandoz-gb@sandoz.com, Telephone: +44 1276 698607

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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