MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/46

Caution In Use

Issued 05 November 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Sandoz Limited

MEDICINE DETAILS

Co-Amoxiclav powder for oral suspension 250/62.5 mg/5 mL

PL: 04416/0515

Active Ingredient: amoxicillin trihydrate, potassium clavulanate

SNOMED: 43647311000001107

GTIN: 05015915880116

AFFECTED LOT BATCH NUMBERS

All batches are currently impacted.

Background

Sandoz Limited have informed the MHRA of errors in the dosing table in the Summary of Product Characteristics (SmPC) for Co-amoxiclav 250/62.5 mg/5 ml Powder for Oral Suspension. The quality of the powder for oral suspension is not impacted by this defect.

The dosing table in Section 4.2 of the defective SmPC, that provides the instruction for weight adjusted dosing, is incorrect and should not be used. The defective SmPC has been removed from the MHRA products and electronic medicines compendium (eMC) websites.

The defective SmPC dosing table instructed an amount of oral suspension that provided approximately twice the intended, recommended dose.

Advice for Healthcare Professionals:

The corrected dosing information provided by Sandoz Limited is included in Annex 1.

Do not use the Sandoz SmPC for calculating the dosing for weight adjusted administration of this medicine. The defective SmPC has been removed from the MHRA products and electronic medicines compendium (eMC) websites; these will be available once Sandoz has received a granted variation to their market authorisation for the new SmPC.

Based on the defective SmPC instruction, there is a potential for an overdose, this may increase the likelihood of known dose-related adverse effects, such as:

- Increased risk of gastrointestinal symptoms antibiotic-associated diarrhoea, nausea, vomiting and abdominal pain and dehydration, of fluid and electrolyte balance
- Increased risk of hypersensitivity and other adverse reactions
- Amoxicillin crystalluria, including acute renal injury/renal failure, has been reported but is described as very rare and predominantly associated with parenteral therapy.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take this medication as prescribed. If you believe you have taken or administered the higher dose of co-amoxiclav and are currently experiencing any side effects such as diarrhoea, nausea, vomiting or abdominal pain then please seek immediate medical advice.

If you are unsure or have any questions, please seek advice from your pharmacy or other healthcare professionals involved in your treatment.

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 mi.uk@sandoz.com or telephone 01276 698101.

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

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London
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DMRC@mhra.gov.uk

Annex 1 - Updated SmPC text, awaiting approval

Posology

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Co-amoxiclav that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents (see section 4.4)
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below.

The use of alternative presentations of Co-amoxiclav (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary (see sections 4.4 and 5.1).

For children < 40 kg, this formulation of Co-amoxiclav provides a maximum daily dose of 2400 mg amoxicillin/600 mg clavulanic acid, when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Co-amoxiclav is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid (see sections 4.4 and 5.1).

The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review (see section 4.4 regarding prolonged therapy).

Adults and children ³ 40 kg should be treated with the adult formulations of Co-amoxiclav.

Children < 40 kg

Lower dose: 20 mg/5 mg/kg/day to 40 mg/10 mg/kg/day given in three divided doses.

Higher dose: 40 mg/10 mg/kg/day to 60 mg/15 mg/kg/day given in three divided doses.

Body weight (kg)	20 mg/5 mg/kg/day. Dose in ml to be given every 8 hours	40 mg/10 mg/kg/day. Dose in ml to be given every 8 hours	60 mg/15 mg/kg/day. Dose in ml to be given every 8 hours
2.0	0.4	0.6	NR
3.0	0.4	0.8	NR
4.0	0.6	1.2	NR
5.0	0.8	1.4	NR
6.0	0.8	1.6	NR
7.0	1.0	2.0	NR
8.0	1.2	2.2	NR
9.0	1.2	2.4	NR
10.0	1.4	2.8	NR
11.0	1.6	3.0	NR
12.0	1.6	3.2	4.8

13.0	1.8	3.6	5.2
14.0	2.0	3.8	5.6
15.0	2.0	4.0	6
16.0	2.2	4.4	6.4
17.0	2.4	4.6	6.8
18.0	2.4	4.8	7.2
19.0	2.6	5.2	7.6
20.0	2.8	5.4	8
21.0	2.8	5.6	8.4
22.0	3.0	6.0	8.8
23.0	3.2	6.2	9.2
24.0	3.2	6.4	9.6
25.0	3.4	6.8	10
26.0	3.6	7.0	10.4
27.0	3.6	7.2	10.8
28.0	3.8	7.6	11.2
29.0	4.0	7.8	11.6
30.0	4.0	8.0	12
31.0	4.2	8.4	12.4
32.0	4.4	8.6	12.8
33.0	4.4	8.8	13.2
34.0	4.6	9.2	13.6
35.0	4.8	9.4	14
36.0	4.8	9.6	14.4
37.0	5.0	10.0	14.8
38.0	5.2	10.2	15.2
39.0	5.2	10.4	15.6

NR – Not recommended. No clinical data are available on doses of Co-amoxiclav 4:1 formulations higher than 40 mg/10 mg/kg per day in children under 2 years.

Alternative oral formulations of Co-amoxiclav should be considered to deliver practical dose recommendations.

Children may be treated with Co-amoxiclav tablets, suspensions or paediatric sachets. Children aged 6 years and below should preferably be treated with Co-amoxiclav suspension or paediatric sachets.

The dose (ml) to be given to the patient three times daily can also be calculated using the following formula below:

$$\text{Dose (ml) given three times daily} = \frac{\text{Recommended amoxicillin* dose (mg/kg/day) x weight (kg)}}{\text{Reconstituted amoxicillin* in suspension (mg/ml) x 3 (daily doses)}}$$

*Only consideration of the amoxicillin component is required for this calculation.

For example, a 6 kg child treated at 20 mg/5 mg/kg/day:

$$\text{Dose (ml) given three times daily} = \frac{20 \text{ (mg/kg/day)} \times 6 \text{ (kg)}}{50 \text{ (mg/ml)} \times 3 \text{ (daily doses)}}$$

$$\text{Dose (ml) given three times daily} = \frac{120 \text{ (mg)}}{150 \text{ (mg/ml)}}$$

$$\text{Dose (ml) given three times daily} = 0.8 \text{ ml}$$