SANDOZ A Novartis Division

Direct Healthcare Professional Communication

21 July 2023

Co-amoxiclav powder for oral suspension (amoxicillin, clavulanic acid), Amoxicillin Suspension (amoxicillin): wrong 'sugar free' label on outer package

Dear Healthcare Professional,

Sandoz in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Alerts, recalls and safety information: drugs and medical devices - GOV.UK (www.gov.uk)

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.

Summary

- The following products are not sugar free despite the carton stating 'sugar free'.
  - Co-amoxiclav 125/31.25mg/5ml powder for oral suspension
  - Co-amoxiclav 125/31.25mg/5ml powder for oral suspension (Almus)
  - Co-amoxiclav 250/62.5mg/5ml powder for oral suspension
  - Co-amoxiclav 250/62.5mg/5ml powder for oral suspension (Almus)
- The 'sugar free' text was added to the carton in December 2008 in error.
- All batches supplied after this date have contained a very small quantity of sugar (dextrose, maltodextrin) originating from the flavoring.
- 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'.
- For a small cohort of patients the product may not be suitable, such as those with concerns about sugar intake or glucose control – ensure patients are aware of this when dispensing
- Sandoz have confirmed that after July 2023 all batches manufactured will contain the correct carton artwork.

Background on the safety concern

Amoxicillin/clavulanic acid is an antibiotic, indicated for the treatment of the following infections in adults and children: acute bacterial sinusitis (adequately diagnosed), acute otitis media, acute exacerbations of chronic bronchitis (adequately diagnosed), community-acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, bone and joint infections, in particular osteomyelitis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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, such as those with concerns about sugar intake or glucose control. 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 Co-amoxiclav 125/31.25 mg/5 ml Powder for Oral Suspension - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

SmPC: Co-amoxiclav 250/62.5mg/5ml powder for oral suspension, PL 04416/0515 Co-amoxiclav 250/62.5 mg/5 ml Powder for Oral Suspension - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

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. Sandoz has confirmed that after July 2023 all batches manufactured will contain the correct carton artwork. In the meantime:

- 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.
- 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'.

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 – see below "Call for reporting".

Call for reporting

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse events should also be reported to Sandoz via adverse.event.uk@sandoz.com or online through the pharmacovigilance intake (PVI) tool at https://pvi1j.solutions.iqvia.com

Company contact point

If you have any questions or require further information, please contact Sandoz Medical Information department on +44 1276 698 101 or email sandozgb@EU.propharmagroup.com.

Yours faithfully,

Sandoz UK

In accordance with our Privacy Notices (novartis.com/uk-en/privacy-policy).