



# MEDICATION SAFETY COMMUNIQUÉ

<b>Subject:</b>	Amoxicillin/Clavulanate 400/57mg per 5mL (Curam DUO®) powder for suspension shortage	
<b>Purpose:</b>	Information	
<b>Approved by</b>	Sonya Stacey, Director Pharmacy, QCH	<b>Issue Date:</b> 18 <sup>th</sup> of March 2020
<b>Issue and Impact within CHQ:</b>	<p>There has been a Customer level recall from Sandoz for Curam DUO powder for suspension (Amoxicillin/Clavulanate Brand 400/57mg per 5mL) (recall notice attached). The QCH Hospital Pharmacy have removed affected batches of this product.</p> <p>Due to this recall, there will be an anticipated short term shortage of the Curam DUO brand of Amoxicillin/Clavulanate 400/57mg per 5mL powder for suspension.</p> <p>QCH Pharmacy has secured enough stock to cover the Queensland Children's hospital's usage until the predicted end of the shortage.</p> <p>Community Pharmacies may not be able to procure stock of the CURAM DUO suspension during the period of the shortage. There is an alternative brand (Augmentin® DUO powder of suspension) available.</p> <p>Please be aware that patients may not be able to source this medication from community pharmacies and will need to collect supply from a Queensland Health Pharmacy.</p>	
<b>Target Audience:</b>	<b>Action Required:</b>	
All CHQ Staff	<p><b>Antimicrobial stewardship principles should be applied to all paediatric prescriptions for Amoxicillin/Clavulanate (oral).</b></p> <ul style="list-style-type: none"><li>• Consider if this is the most appropriate antibiotic choice for the patient's condition or if there is a suitable alternative available?</li><li>• Review microbiology and sensitivity results in context of patient's clinical condition and age when considering most suitable oral antibiotic option.</li></ul> <p><b>Where Amoxicillin/Clavulanate is required:</b></p> <ul style="list-style-type: none"><li>• Maintain children &gt;2 months and less than 10kg, and all patients requiring enteral tube administration on Suspension.</li><li>• Ensure brand substitution is approved on the prescription where the suspension is essential.</li><li>• PBS prescriptions can be dispensed from a community pharmacy. Please inform families that the suspension may be in short supply.</li><li>• Consider changing all other patients to tablets, which are able to be halved, crushed and mixed with a small amount of fluid for administration.</li></ul> <p>Refer to table 1 below. Doses in this table may have been rounded for ease of administration.</p>	



**Table 1. Paediatric Amoxicillin/Clavulanate oral dosing recommendations**

<b>Weight band</b>	<b>Amoxicillin/Clavulanate Dosing recommendation (and appropriate dosage form)</b>
<b>Less than 10kg</b>	<b>Susceptible infections:</b> Give 22.5mg/kg (Amoxicillin component) orally twice daily <b>Cystic fibrosis:</b> 25mg/kg (Amoxicillin component) orally twice daily (Prescribe 400/57mg per 5mL powder for suspension)
<b>10.1 to 15kg</b>	Give half a 500/125mg tablet (equals 250mg Amoxicillin component) twice daily (Prescribe 500/125mg tablets)
<b>15.1 to 20kg</b>	Give three quarters of a 500/125mg tablet (equals 375mg Amoxicillin component) twice daily (Prescribe 500/125mg tablets)
<b>20.1 to 25kg</b>	Give one 500/125mg tablet (equals 500mg Amoxicillin component) twice daily (Prescribe 500/125mg tablets)
<b>25 to 35 kg</b>	<b>Susceptible infections:</b> Give one 500/125mg tablet (equals 500mg Amoxicillin component) twice daily (Prescribe 500/125mg tablets) <b>Cystic fibrosis:</b> Give one and a half of a 500/125mg tablet (equals 625mg Amoxicillin component) twice daily (Prescribe 500/125mg tablets)
<b>More than 35kg</b>	<b>Serious infections and Cystic fibrosis:</b> Give one 875/125mg tablet (equals 875mg Amoxicillin component) twice daily (Prescribe 875/125mg tablets)

**Contact for further information:**

Please contact the Infectious Diseases Team on 07 3068 4421 or the AMS Pharmacist on 0436 815 492, if you need assistance with selecting an alternative antibiotic choice.

Please call Claire George (Clinical Lead – Materials Management) on 07 3068 1945 if you have any questions regarding supply.



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Recall Action Notification

## Curam Duo 400/57 Powder for Oral Suspension

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## Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.
- More information about Australian recall actions is available at <<http://tga.gov.au/safety/recalls-about.htm>>
- If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <<http://www.healthdirect.org.au/>>

### About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

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## Recall detail

<b>Type of Product<sup>i</sup></b>	Medicine
<b>TGA Recall Reference<sup>ii</sup></b>	RC-2020-RN-00241-1
<b>Product Name/Description<sup>iii</sup></b>	<p>Curam Duo 400/57 Powder for Oral Suspension</p> <p>Batch: HB9356, HB9358, JC5418, JC5419, JR0807, JR0810, JR0812, JR0816, JR0822, JR0807</p> <p>ARTG 147109 (CURAM DUO 400/57 amoxicillin 400 mg/5mL (as trihydrate) / clavulanic acid 57 mg/5mL (as potassium clavulanate) powder for suspension bottle)</p>
<b>Recall Action Level<sup>iv</sup></b>	Retail
<b>Recall Action Classification<sup>v</sup></b>	Class II
<b>Recall Action Commencement Date<sup>vi</sup></b>	12/03/2020
<b>Responsible Entity<sup>vii</sup></b>	Sandoz Pty Ltd
<b>Reason / Issue<sup>viii</sup></b>	<p>Following the consumer level recall conducted in May 2019 of Curam Duo 400/57 Powder for Oral Suspension (RC-2019-RN-00742-1) in relation to complaints for lumps of powder in overseas batches, several improvements and CAPAs have been implemented at the manufacturing site. The incidence of unsealed bottles/ incorrectly sealed bottles has been substantially reduced, however a residual risk of a minimal number of bottles to be incorrectly sealed remains statistically possible.</p> <p>To date, no complaints have been received in Australia prior to or post the Consumer Level Recall in May 2019.</p>
<b>Recall Action<sup>ix</sup></b>	Product Defect Correction
<b>Recall Action Instructions<sup>x</sup></b>	<p>Sandoz is requesting all customers visually inspect all bottles to confirm that there is no evidence of lumps in the contents of the bottle prior to reconstitution.</p> <p>If a poor seal or lumps are identified, the bottle must be returned to Sandoz for evaluation with appropriate notification of the potential defect. Sandoz will replace the affected product free of charge.</p> <p>Sandoz is providing impacted customers a pamphlet that explains the checking process.</p>
<b>Contact Information<sup>xi</sup></b>	1800 726 369 - Sandoz Med Info.

## Footnotes

<sup>i</sup> Type of Product: Medicine, Medical Device, or Biological

<sup>ii</sup> TGA Recall Reference: Unique number given by the TGA

iii Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

iv Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

v Recall Action Classification\*\*: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III** - A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

vi Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

vii Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

viii Reason / Issue: Reason for the recall action.

ix Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

x Recall Action Instructions: What customers with affected goods should do.

xi Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

\*\* These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at <https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf>