

DRUG ALERT CAUTION IN USE

Dear Healthcare Professional

The Department of Health (NI) has been made aware of an issue that has arisen with regard to the measuring spoon provided with Athlone Laboratories Amoxicillin oral suspension PL06453/0022 / PL06453/0050

I enclose an excerpt from Athlone Laboratories' communication:

Athlone Laboratories received complaints from the UK marketplace in relation to the delivery volume of the measuring device (Spoon) packed with the product (Amoxicillin Oral suspension PL06453/0050 and PL06453/0022). The spoon, when filled to the brim with suspension, under controlled conditions, can give a volume overflow of up to 7.8mL. The spoon in question is a Hugo Meding 5mL graduated polypropylene CE marked spoon. Amoxicillin oral suspension is the only product affected.

Athlone Laboratories Quality Unit initiated an investigation into the reported complaints and also arranged for an independent Medical Risk Assessment to be performed.

The investigation to date indicates that the Hugo Meding spoon as a measuring device is not the most appropriate for dispensing the Amoxicillin Oral suspension product only. The spoon has been verified as an appropriate measuring device for all other Athlone Laboratories products.

Furthermore the interpretation of volume when filling to the 5mL mark can vary slightly from person to person. However it is likely that the spoon can only be overfilled when it is placed on a flat surface and that this would not be the case in practical usage of the spoon for patient dosage. It is more likely that care givers dispensing a 5mL dose to a child will hold the bottle of product in one hand, and the spoon in the other and then fill the spoon to below the rim to allow transfer of the spoon contents to the child's mouth, without risk of spillage of the medicine.

Based on the investigation performed and the associated medical risk assessment, it can be concluded that there is no reason to believe that this complaint represents a significant risk of hazardous health consequences arising in the target population.



Athlone Laboratories has sourced an alternative CE spoon to be introduced as soon as possible into production operations. This spoon is a RoviPharm 5mL CE marked, ivory coloured spoon.

The complaints were communicated to the MHRA (DMRC). MHRA (DMRC) has confirmed that it has no objection to the Athlone assessment that the potential overdosing and consequent shortened treatment course do not present a significant risk of hazardous health consequences arising in the target population.

As stated, the risk assessment that Athlone Laboratories has conducted identifies low risk given the safety of amoxicillin. However, we are aware that a measuring spoon provided for one medicine could also be inadvertently used for another medicine.

Queries in respect of this matter can be referred to:

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I am therefore writing to all staff and particularly those involved in the administration of medicines of this risk.

It is recommended that if a patient is unable to use the measuring device provided then validated oral syringes should be considered for the administration of oral medicines'

Recipients of this Drug Alert should bring it to the attention of relevant professionals by copy of this letter.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

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