

Dear Customer,

A discrepancy has been identified in the dosage text printed on the bottle label of ALMUS Paracetamol 250 mg/5 ml Oral Suspension for the 12-16-year-olds age group. The label incorrectly states the dose as 'Two 5 ml spoonfuls', whereas the correct and approved dosage is 'Two to three 5 ml spoonfuls', which is accurately reflected on both the carton and the Patient Information Leaflet (PIL).

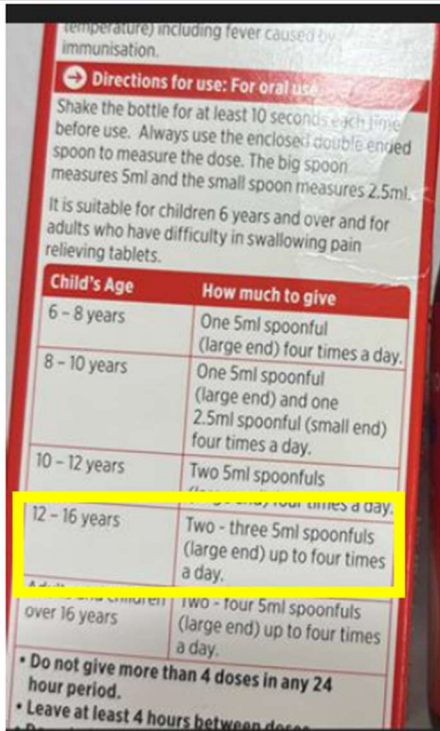
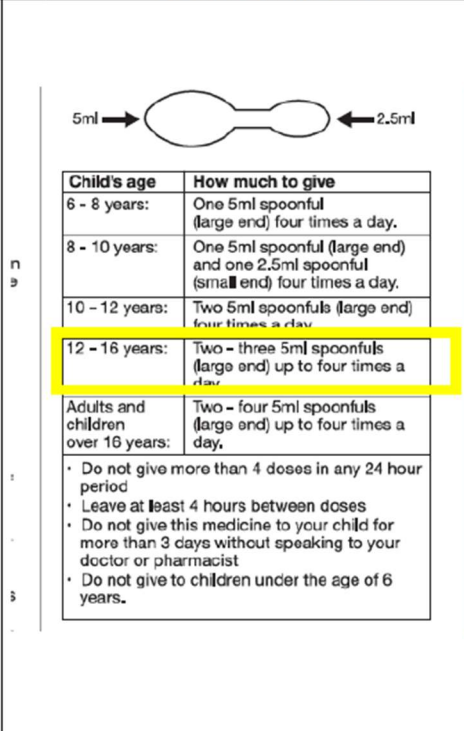
Following a detailed investigation, we confirm the below:

- The **dosage information printed on the carton and PIL is fully correct** and aligned with the approved product information.
- The discrepancy is limited to the bottle label artwork codes L0628 and L0749, where the dosage for the age group 12-16-year-olds is understated.
- As per investigation it has been identified that the issue originated from the approved label artwork used for the inner packaging.
- As an immediate action, updated bottle label artwork with correct dosage information. The remaining stock of bottle labels printed with the affected artwork codes has been destroyed.
- Future batches will be packed using the corrected approved artwork only.

Please be assured that this discrepancy does not pose any patient safety risk and has no impact on product quality, efficacy, or safety. The correct dosage information remains clearly communicated on the carton and the Patient Information Leaflet (PIL). Crescent Pharma quality team is effectively monitoring any future complaints or inquiries related to this issue. You can contact complaints@crescentpharma.com if you need any further advice.

Please note that this issue has already been communicated to DMRC.

Below photographs for reference only

Correct Dosage on Carton	Correct Dosage on PIL	Understated dosage in bottle Label																																				
 temperature) including fever caused by immunisation. Directions for use: For oral use. Shake the bottle for at least 10 seconds each time before use. Always use the enclosed double ended spoon to measure the dose. The big spoon measures 5ml and the small spoon measures 2.5ml. It is suitable for children 6 years and over and for adults who have difficulty in swallowing pain relieving tablets. <table><tr><th>Child's Age</th><th>How much to give</th></tr><tr><td>6 - 8 years</td><td>One 5ml spoonful (large end) four times a day.</td></tr><tr><td>8 - 10 years</td><td>One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.</td></tr><tr><td>10 - 12 years</td><td>Two 5ml spoonfuls four times a day.</td></tr><tr><td>12 - 16 years</td><td>Two - three 5ml spoonfuls (large end) up to four times a day.</td></tr><tr><td>over 16 years</td><td>Two - four 5ml spoonfuls (large end) up to four times a day.</td></tr></table> • Do not give more than 4 doses in any 24 hour period. • Leave at least 4 hours between doses.	Child's Age	How much to give	6 - 8 years	One 5ml spoonful (large end) four times a day.	8 - 10 years	One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.	10 - 12 years	Two 5ml spoonfuls four times a day.	12 - 16 years	Two - three 5ml spoonfuls (large end) up to four times a day.	over 16 years	Two - four 5ml spoonfuls (large end) up to four times a day.	 5ml → ← 2.5ml <table><tr><th>Child's age</th><th>How much to give</th></tr><tr><td>6 - 8 years:</td><td>One 5ml spoonful (large end) four times a day.</td></tr><tr><td>8 - 10 years:</td><td>One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.</td></tr><tr><td>10 - 12 years:</td><td>Two 5ml spoonfuls (large end) four times a day.</td></tr><tr><td>12 - 16 years:</td><td>Two - three 5ml spoonfuls (large end) up to four times a day.</td></tr><tr><td>Adults and children over 16 years:</td><td>Two - four 5ml spoonfuls (large end) up to four times a day.</td></tr></table> • Do not give more than 4 doses in any 24 hour period • Leave at least 4 hours between doses • Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist • Do not give to children under the age of 6 years.	Child's age	How much to give	6 - 8 years:	One 5ml spoonful (large end) four times a day.	8 - 10 years:	One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.	10 - 12 years:	Two 5ml spoonfuls (large end) four times a day.	12 - 16 years:	Two - three 5ml spoonfuls (large end) up to four times a day.	Adults and children over 16 years:	Two - four 5ml spoonfuls (large end) up to four times a day.	 Read the enclosed leaflet carefully before use. Directions for use: For oral use. Shake the bottle for at least 10 seconds before use. Always use the enclosed double ended spoon to measure the dose. The big spoon measures 5ml and the small spoon measures 2.5ml. <table><tr><th>Child's Age</th><th>How much to give</th></tr><tr><td>6 - 8 years</td><td>One 5ml spoonful (large end) four times a day.</td></tr><tr><td>8 - 10 years</td><td>One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.</td></tr><tr><td>10 - 12 years</td><td>Two 5ml spoonfuls (large end) four times a day.</td></tr><tr><td>12 - 16 years</td><td>Two 5ml spoonfuls (large end) four times a day.</td></tr><tr><td>over 16 years</td><td>Two - four 5ml spoonfuls (large end) up to four times a day.</td></tr></table> • Do not give more than 4 doses in any 24 hour period. • Leave at least 4 hours between doses. • Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist. • Do not give children under the age of 6 years. Do not give anything else containing paracetamol while giving this medicine. Talk to a doctor at once if your child takes too much of this medicine, even if it is only once.	Child's Age	How much to give	6 - 8 years	One 5ml spoonful (large end) four times a day.	8 - 10 years	One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.	10 - 12 years	Two 5ml spoonfuls (large end) four times a day.	12 - 16 years	Two 5ml spoonfuls (large end) four times a day.	over 16 years	Two - four 5ml spoonfuls (large end) up to four times a day.
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Crescent pharma quality team.