

APPENDIX 1

DIVERGENT POSITION DATED 22 June 2017



Although the tablets and the capsule formulations provide acceptable dosing flexibility for the starting dose and for those who can swallow and take 30 mg tablets, the available formulations are not considered adequate for the older children and those at a higher maintenance dose who are not able to swallow. The capsules have proven very difficult to open without damage by trained pharmaceutical assessors and performance in a real life setting may be even worse. Opening the capsule and mixing the granules with food or liquid may be found difficult by the patient or the responsible person such that inaccurate dosing may result. For children and patients with difficulties in swallowing, a large number of capsules (up to 12) may be needed on a daily basis. This would imply substantial discomfort for the patient, parent or care giver. The dose accuracy is also considered questionable, with content uniformity being tested on the entire capsule rather than the contents, essentially the delivered dose. Therefore, for patient's comfort and safety, this kind of administration seems to be questionable and should be reconsidered. A better single-dose container should be developed.

New instructions in the SmPC, the labelling, and the commitments by the applicant are acknowledged. Nonetheless, the current product is still poorly designed and not patient friendly. Replacing the off-label use of crushed tablets with a poorly designed alternative is not considered an improvement. Therefore, the benefit/risk remains negative.

London, 22 June 2017

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