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**Flexible and precise dosing of enalapril maleate for all paediatric age groups
utilizing orodispersible minitablets**

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Abstract

Enalapril is an off-patent angiotensin-converting enzyme inhibitor for which no paediatric age-appropriate formulation is commercially available in Europe, and enalapril maleate (EM) orodispersible minitablets (ODMTs) have previously been formulated within the LENA (labelling enalapril from neonates to adolescents) project. In this study, a dilution method has been developed by dispersing the lowest dose strength ODMTs to enable flexible and precise EM dosing during the dose titration phase of the therapy. Furthermore, the physicochemical stability of the ODMTs has been investigated in child-friendly beverages and the administration of ODMTs via nasogastric tubes (NGT) of different sizes and materials has been evaluated. The results for the ODMT dilution procedure reveal that dispersion within an oral syringe is preferred over dispersion in a separate container, leading to flexible and precise dosing down to 0.025 mg EM. Although ODMTs were stable in the beverages over the investigated time period, dispersion in tap water only is recommended due to prolonged disintegration times within the other kon silicone, polyurethane or polyvinyl chloride could be observed. The ODMT concept together with the investigated dispersion method enables the safe administration of EM for all paediatric subpopulations from new-borns to adolescents.

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