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Title: Pharmacokinetic and pharmacodynamic evaluation after administration of beclomethasone dipropionate and formoterol fumarate as fixed or free metered-dose inhaler combination in adolescent asthma

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Body: INTRODUCTION: Foster pMDI is a fixed dose combination of beclomethasone dipropionate (BDP) 100µg and formoterol fumarate (FF) 6µg marketed for use in adult asthma with or without a spacer device (AeroChamber Plus™, AC). OBJECTIVE: To investigate the pharmacokinetic (PK), pharmacodynamic (PD) and safety profile of Foster in asthmatic adolescents with or without AC, in comparison to a free combination of marketed pMDI products: Qvar 100µg for BDP and Atimos 6µg for FF. METHODS: Open label, randomized, three-way crossover study on 30 asthmatic adolescents receiving a single dose of BDP/FF (400µg/24µg) as Foster, Foster+AC or Qvar+Atimos. All assessments were performed over 8h post-dose. RESULTS: Foster with or without AC was equivalent to Qvar+Atimos or Foster alone in terms of systemic exposure (AUC_{0-t}) to B17MP (active metabolite of BDP) and FF; 90% CIs for the geometric means ratio fixed/free were within 0.8-1.25. Dose administration with Foster+AC resulted in slightly higher peak concentrations (C_{max}) of B17MP and FF than with Qvar+Atimos or Foster alone. Foster with or without AC showed a similar PD (FEV_1, plasma potassium and glucose) and safety profile (pulse rate) in comparison to Qvar+Atimos. CONCLUSIONS: Overall, data show comparable PK, PD and safety profiles of Foster, with or without AC, in comparison to the free combination of marketed BDP+FF in asthmatic adolescents, with only a slight increase in peak plasma concentrations of B17MP and FF when AC is used, in agreement with data already obtained in the adult population.