#1434 - Oral dissolvable film containing dexamethasone: a promising novel alternative to tablets for rescue applications in allergy

Diamant, Zuzana / Samuelsson Palmgren, Gabriella / Westrin, Bengt / Bjermer, Leif

Introduction
Systemic corticosteroids (SC) are anti-inflammatory agents with dexamethasone as one of the most potent in class. Within (respiratory) allergy, SC are usually applied in medical emergencies. In these situations, patients may experience problems with swallowing oral formulations, e.g. because no water is available or because the patient is in severe (respiratory) distress. For this unmet need, Dexa ODF, an oral dissolvable film containing dexamethasone, was developed.
Objectives
We evaluated and compared the safety, tolerability and pharmacokinetics (PK) of Dexa ODF with Fortecortin (dexamethasone) tablets in healthy subjects. Thirty male subjects (19-37 years) were enrolled in this randomized, open label, 2-way, cross-over study, consisting of two dosing days separated by 5-10 days (washout) and a follow-up visit. On both dosing days, subjects randomly received one single dose of Dexa ODF (D; one strip, 8 mg dexamethasone) or one single dose of Fortecortin (F; two 4 mg tablets). Safety evaluations were performed and blood samples for PK analysis were drawn at predefined time points from pre-dose until 48 h post-dose. Bioequivalence (BE) analysis was performed on three PK parameters: AUC(0-t), AUC(0-∞) and Cmax
Results
All subjects completed the study. Both study medications were well-tolerated and overall, only mild and self-limiting adverse events (AEs) were reported (24 AEs during D; 19 AEs during F). approximately 50% of AEs were deemed 'possibly related' to treatment (14 on D; 12 on F). Most frequent AEs consisted of headache, fatigue and polyuria. Mean tmax for D was shorter compared to F (87 and 107.6 mins, respectively; p=0.0575), indicative of an improved absorption rate. For the three PK parameters the 90% CIs were within the acceptance limits of BE (0.8;1.25).
Conclusions
In this phase I study, we demonstrated good tolerability and bioequivalence of Dexa ODF (8 mg dexamethasone) compared to dexamethasone tablets (2x4 mg). Dexa ODF is currently under development as an innovative treatment for use within respiratory and allergic conditions, including anaphylaxis, allergic syndromes and acute asthmatic or croup-related airway obstruction.