



ATOPIC ECZEMA/DERMATITIS

CLINICAL DEVELOPMENT STRATEGY OF A MEDICAL DEVICE REPAIRING EMOLLIENT CREAM (MDREC) IN ADULTS AND CHILDREN SUFFERING FROM ATOPIC DERMATITIS (AD).

Nocera Therese⁽¹⁾ - Mengeaud Valerie⁽²⁾

Clinical Skin Research, Development Center Pierre Fabre Dermo- Cosmétique, Dermatology Department, Toulouse University Hospital, Toulouse, France⁽¹⁾ - Medical Department, Laboratoires Dermatologiques Ducray, Les Cauquillous, Na, Lavour, France⁽²⁾

OBJECTIVES: Regular emollient application is recommended for managing atopic dermatitis (AD). Although many emollients are available, only AD-tested, MDRECs, designed to repair and protect the skin barrier, can be recommended for treating and preventing AD skin lesions. We present two clinical studies with the MDREC.

METHODS:* In controlled randomized study (n=54), we examined the added clinical benefit of a MDREC, when used twice daily, in association with a moderately potent topical corticosteroid (TCS) for adults with symmetrical arms adults AD lesions and during maintenance phase period. **Tolerability study, approved by an ethics committee, enrolled paediatric and adult's patients (mild to moderate AD) according to IGA. Investigators and subjects or patient's parent(s) evaluations were compared to AD intensity baseline.

RESULTS: *The comparative study the change in investigator-observed local SCORAD index between day 1 and 3 was - 14.4% with TCS alone and - 24.5% for TCS +MDREC (HS). Between baseline and the end of the treatment phase, all secondary measures of lesion severity decreased more with the combined TCS +MDREC treatment than with the TCS alone. The MDREC also reduced the relapse of AD lesions during the maintenance phase. **Tolerability was very good. Tolerance study: 19 infants, 22 children and 20 adults. The cream was well tolerated and safe in both populations. Few adverse events (AE) related to the product were described for 6 patients (mild pruritus and redness).

CONCLUSION: The results of these controlled randomised and open study support the interest of this new MDREC for atopic skins, alone or in association with TCS during AD flares and, as a maintenance therapy, after treatment with TCS has stopped. The MDREC was well tolerated when applied to AD skin lesions in pediatric subjects and adults and suggests this product can be used daily to control the signs and symptoms of AD.

