CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-978

SUMMARY REVIEW

NDA 21-978 Verdeso (desonide) Foam, 0.05%
Divisional Summary Memorandum

September 18, 2006

This NDA for desonide foam, 0.05% is recommended to be approved for the indication of the treatment of mild to moderate atopic dermatitis in patients aged 3 months and older.

Safety and Efficacy

As per the biostatistics and medical officer reviews, the efficacy of this product for the indication sought was demonstrated in one robust, adequate, and well-controlled study (DES.C.301). This study was sufficiently powered and included sufficient numbers of pediatric patients to allow for the pediatric indication of atopic dermatitis.

Desonide at 0.05% is already approved in other products. The long term safety update profile for the drug substance at the concentration provided is well known.

The one robust study submitted is sufficient as prior agreement was obtained by the applicant at a pre-IND/End of Phase 2 meeting held on March 30, 2004. Among the pathways for approval, the Agency had advised that "eventual drug approval" was possible with "One very persuasive, robust, double-blind, vehicle-controlled study demonstrating superiority to vehicle. The study should be highly statistically significant with no major flaws and consistent results across centers and subgroups." Indeed, this was the case, with the atopic dermatitis patients using Verdeso with significantly great efficacy in treating mild to moderate atopic dermatitis than placebo ($p<0.0001$). The indication of atopic dermatitis is a subset of the broader indication of corticosteroid responsive dermatosis for which other desonide products are approved.

A small phase 2 study was conducted by the sponsor and is considered to be supportive.

The specific safety concerns that are inherent to topical corticosteroids, i.e. local dermal safety and HPA axis suppression, were explored with regard to this product. While some HPA axis suppression was noted from the cosyntropin stimulation study (see Clinical and Biopharm reviews), the amount and severity of suppression were less than what would be a concern for a prescription product. Labeling will address this safety concern for the product. Sufficient safety was deemed to be present for this lower potency corticosteroid product to allow for safe use in children with atopic dermatitis.

Tradename

The Division of Medication Errors and Technical Support (DMETS) in the Office of Surveillance and Epidemiology has discussed in their review completed September 13, 2006 that the initial submitted name of [redacted] is unacceptable due to potential name confusion with Kirlex, a surgical wound wrap. The second name of Verdeso will be used instead. Discussion with DMETS indicates that this second name does not raise any substantial concerns. Hence, the product will have the name of Verdeso (desonide) Foam, 0.05%.

Chemistry, Manufacturing, and Controls

Adequate information was provided by the applicant to allow for marketing of the product.

Specific concern was raised during review by the reviewers regarding can pressure for this foam product. The applicant committed to looking closely at can pressure data and collecting additional data regarding physical characteristics of the Foam (see CMC review by Gene Holbert).

Pharmacology/Toxicology

Sufficient information was submitted to allow for approval of this product per the Pharm/Tox review. However, the Pharm/Tox team recommends the following Post-marketing commitments be included in the approval letter for the desonide foam product:

1) The applicant commits to conducting a dermal carcinogenicity study with final report submission by December, 2012
2) The applicant commits to conducting a study to determine the photoco-carcinogenic potential of the desonide foam product by December, 2011.

Labeling recommendations from the Pharm/Tox review team have been incorporated.

Clinical Pharmacology

The Clinical Pharmacology reviewer suggests that the desonide foam product under review is of similar potency as Tridesilon (desonide) Cream, 0.05%. This is based on the findings of a comparative vasoconstriction response study.

The Clinical Pharmacology reviewer's assessment of HPA axis study is in agreement with that of the Clinical reviewer.

Conclusion

Based on the above reviews of this application, together with the revisions made to the draft labeling as discussed with the review team, this application for Verdeso (desonide) Foam, 0.05% for the indication of treatment of atopic dermatitis should be approved.

Markham C. Luke, M.D., Ph.D.
Lead Medical Officer, Dermatology

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Markham Luke
9/19/2006 11:11:49 AM
MEDICAL OFFICER

TL Divisional Summary

Stanka Kukich
9/19/2006 01:16:57 PM
MEDICAL OFFICER