Active ingredient: Bexarotene

Form/Route: Capsule/Oral

Recommended studies: 1 study

Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 75 mg
Subjects: Healthy males, general population.
Additional comments:

1. Females should be excluded from study given the potential for embryo-fetal toxicity.
2. The protocol should specify and require both formal pregnancy counseling for male subjects regarding the risk to their female partner and a section regarding the counseling in the Informed Consent document.
3. Adequate contraception must be continued for at least 1 month following the last dose of bexarotene.
4. The protocol should include following specific exclusion criteria in addition to other exclusion criteria:
    - Subjects demonstrating abnormalities in lipid profile or thyroid-function on screening laboratory evaluations.
    - Subjects receiving systemic therapy with Vitamin A in doses of greater than 15000 IU (5000 mcg) per day.
    - Subjects who are taking gemfibrozil or tamoxifen.
    - Use of any other retinoid class drug (e.g. Isotretinoin) within 30 days of entry into the study.
    - Use of topical medications such as corticosteroids or tar baths.
5. In addition to the exclusion of drugs that are also know to cause photosensitivity, subjects should be advised to avoid prolonged exposure to the sun or UV light during the study. Similarly, it would be prudent to exclude subjects with a known history of skin cancer.
6. The protocol should include an appropriate plan for continued follow-up, standard care for subsequent follow up, and treatment of subjects who continue to demonstrate thyroid and/or lipid abnormalities at the end of study laboratory evaluations.

Analytes to measure (in appropriate biological fluid): Bexarotene in plasma

Bioequivalence based on (90% CI): Bexarotene

Waiver request of in vivo testing: Not Applicable

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units of the test and reference products. Specifications will be determined upon review of the application.