2. SYNOPSIS

**Title of Study**  
Phototoxicity Study: Assessment of the phototoxic potential of Daivobet®/Dovobet® ointment (betamethasone dipropionate 0.5mg/g and calcipotriol 50μg/g)

**Investigator**  
Prof. Dr. [Name Redacted], M.D.

**Study Center**  
[Center Name Redacted]

**Study phase**  
Phase I

**Investigational products**  
Daivobet®/Dovobet® ointment (combination of betamethasone dipropionate 0.5mg/g and calcipotriol 50μg/g)

**Route of administration and dosage:**  
50 μl was applied under occlusive conditions in duplicate on subject's back on Day 1 for 24 hours

**Reference product(s)**  
No reference product was included

**Control product(s)**  
Ointment vehicle of Daivobet®/Dovobet®

**Study objective**  
The objective of this study was to evaluate the phototoxic potential of Daivobet®/Dovobet® ointment

**Study population**  
Healthy volunteers of either sex between 18 and 65 years old meeting specific inclusion/exclusion criteria

**Study design**  
Single center, randomized, investigator blinded study with intra-individual comparison of treatments

**Duration of application**  
24 hours; the whole study participation was 5 consecutive days.

**Methodology**  
Day 1 and Day 2: Assessment of minimal erythema dose (MED) by irradiation of six small test areas with UVA/B on upper back.

Day 1: Application of test chambers with the two test formulations in duplicate on designated test areas on both sides of mid back.

Day 2: Removal of test chambers after 24 hours, irradiation of the test areas (20 J/cm² UVA + 0.75 x MED UVA+UVB) on the left side of mid back. The set of 3 patch areas of the right side served as non-irradiated control.

All patch sites were evaluated 60 min after irradiation, and then 24h (Day 3), 48h (Day 4) and 72h (Day 5) after the irradiation procedure.
Evaluation Criteria

The phototoxicity reaction on the test area was assessed using a 6 point scale. All test areas were evaluated for phototoxic reaction at 1, 24, 48 and 72 hours after irradiation.

Other Evaluations

Other signs of skin reactions had to be reported.

Statistical Method(s)

At the end of the study, the Investigator assessed the occurrence of a possible phototoxic reaction.

The number of volunteers who experienced a phototoxic reaction during the study determined the phototoxic potential of the test formulation(s).

Data had to be summarized using descriptive statistics. Comparative statistics were not planned.

Manufacturer of the investigational products

LEO Pharma

Study Dates

The first subject was enrolled on 8 October 2001 and the last patient to complete the study attended the final visit on 19 October 2001.

Results:

32 Subjects enrolled and completed the study.

No phototoxic reaction was observed for any of the tested products.

Adverse events

One adverse event was reported and was judged as not related to study products.

Conclusion

The results observed in this study indicate that no phototoxic reaction was observed at any evaluation time neither for Daivobet®/Dovobet® ointment (betamethasone dipropionate 0.5mg/g and calcipotriol 50μg/g) nor for the ointment vehicle of Daivobet®/Dovobet®.