

May 2005

**Evaluation of the Effect of GliSODin® on the Intensity of Actinic Erythema Induced with Radiation.
Besançon Study carried out in Prof. HUMBERT's Department
November - December 2004.**

Protocol:

- Randomised, double blind trial versus placebo
- 50 healthy subjects (25 receiving GliSODin capsules, 25 receiving placebo capsules).

Purpose:

To demonstrate the efficacy of GliSODin on the following parameters:

- Modification of the Minimum Erythematous Dose (MED*)
- Incidence on the induced actinic erythema in healthy subjects:
 - By demonstrating the intensity of the colour by chromometry
 - By observing the micro vascularisation by videocapillaroscopy

* The MED defines the susceptibility of the subject to sunburn, that is, in practice and mainly, ones sensitivity to UVB rays.

Inclusion Criteria:

- 10 phototypes II.
- 20 phototypes III.
- 20 phototypes IV.

Dosage/Length of Treatment:

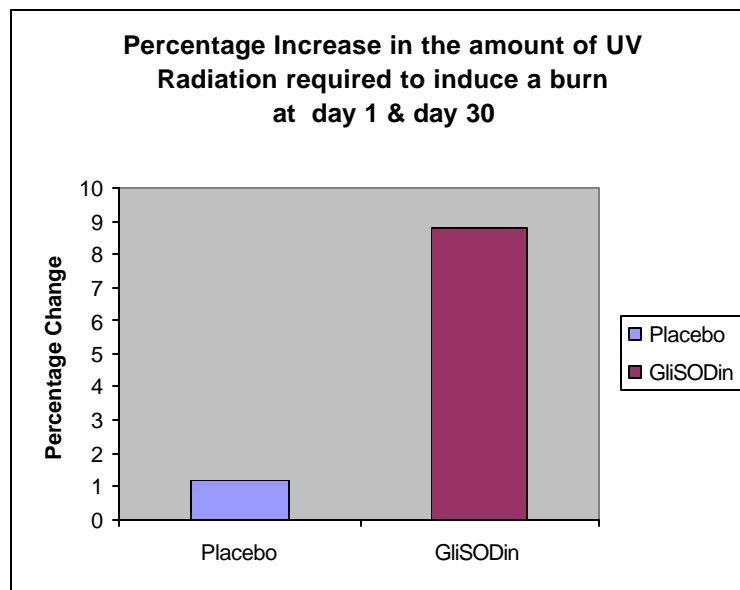
- 2 x 250 mg capsules per day (in the morning at breakfast) as of the **1st day of exposure.**
- Length of treatment: 4 weeks.

NB: the subjects continue to use their regular cleansing products but do not apply any cosmetic on the measurement site except for their usual shower gel or soap.

Results:

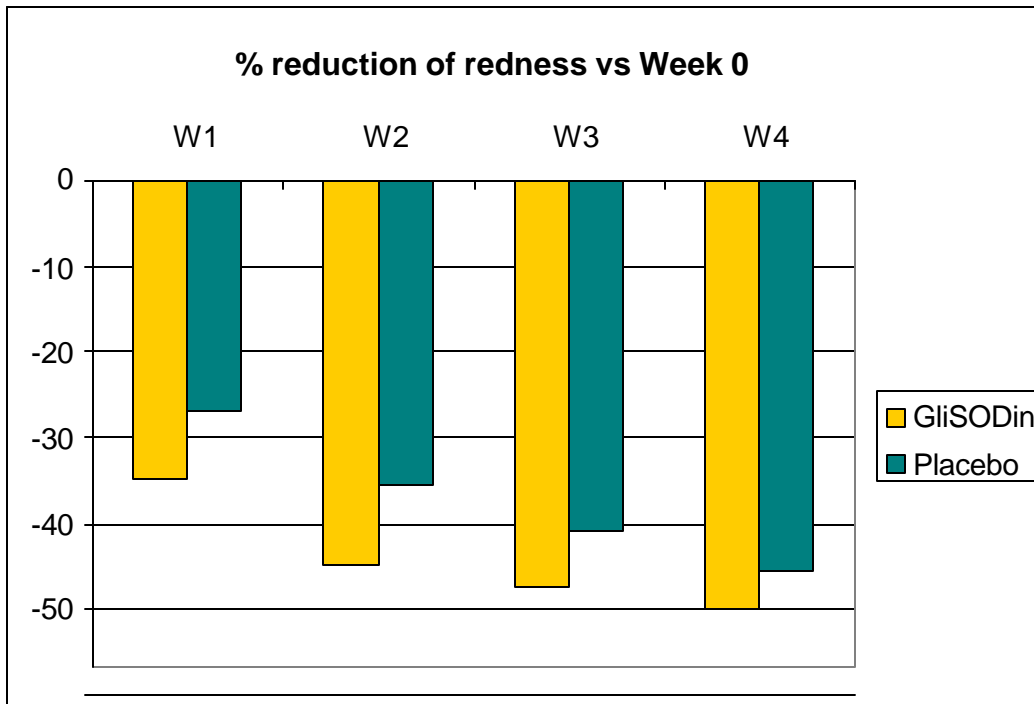
• **MINIMUM ERYTHEMATOUS DOSE:**

- GliSODin induced an increase in the MED in the phototypes II, 8 times greater than that of the placebo.



• **ACTINIC ERYTHEMA:**

- As a result, the redness induced by the actinic erythema decreased more quickly in the GliSODin group. Therefore, the increase in the number of capillaries assessed by videocapillaroscopy was higher in the GliSODin group.

ACTINIC ERYTHEMA**Conclusion:**

The studies already published* have shown that GliSODin protects the cells by activating the internal antioxidant defence system that are necessary for the elimination of the free radicals produced by oxidative stress.

This study confirms the efficacy of GliSODin in the prevention of the consequences of oxidative stress resulting from exposure to the sun. This efficacy is of particular interest for phototypes II that represent a major part of the consultations in dermatology. In the GliSODin group, the MED increased, thereby resulting in a rapid reduction in actinic erythema as from the intake of the product. It would be interesting to develop this study by working on a larger number of phototypes II.

This study was presented on 27 and 28 May at the CARD (Annual Congress of Dermatological Research) meeting in Brest and will be published.

*** References:**

1) MUTH CM, GLENZ Y, KLAUS M, RADERMACHER P, SPEIT G, LEVERVE X. Influence of an Orally Effective SOD on hyperbaric Oxygen-related Cell Damage. Free Rad Res 2004; 38: 927-932.

2) VOULDOUKIS I, LACAN D, KAMATE C, COSTE P, MAZIER D, CONTI M, DUGAS B. Antioxydant and Anti-inflammatory properties of a cucumis melo extract rich in superoxyde dismutase activity. J Ethnopharmacol 2004; 94: 67-75

3) VOULDOUKIS I, CONTI M, KOLB JP, CALEND A, MAZIER D, DUGAS B. Induction of Th-1dependent immunity by an orally-effective melon SOD extract. Res Trends – Curr Trends Immunol 2003; 5: 151-145.

4) VOULDOUKIS I, CONTI M, KRAUSS P, KAMATE C, BLAZQUEZ S, TEFIT M, MAZIER D, CALEND A, DUGAS B. Supplementation with Gliadine-Combined Plant Superoxyde Dismutase Extract Promotes Anti-oxidant Defences and Protects against oxidative stress. Phytoterapy Res 2004; 18: 957-962.

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