

Clinical Trial of the Proprietary Product “C.P.”* (Amplamil)

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Geriatrics

C.P.* = Cernitin™ Powder

I the undersigned, Doctor Jacques DUBRISAY, of 4 avenue Saint Honore d' Eylau, 75-Paris 16e, Consultant to the Ministry of Social Affairs, hereby certify that I have clinically tested the compound AMPLAMIL, at the request of Laboratoires de l' OZOTHINE, 18/22 rue d' Arras, 92 NANTERRE.

Each capsule of AMPLAMIL contains the following ingredients:

- Fat-soluble pollen extract 6 mg
- Water-soluble pollen extract 120 mg
- Excipients q.s. for one gelatine capsule No.1

I declare that I have studied the relevant evaluations, i.e. the laboratory report by G. NETIEN, dated 30 October 1969, as well as the toxicological and teratological report and the pharmacological report, both dated 16 February 1970, by A. SOULAIRAC.

The material supplied for the purposes of clinical evaluation included capsules labeled “C.P. Capsules, Batch No. 2” and a placebo.

Throughout this report, AMPLAMIL is referred to as “C.P. Capsules” or “C.P.”

Conclusion

The compound C.P. was used in a clinical trial conducted by the double-blind technique and involving 48 elderly patients. Twenty-four of the patients were given capsules “A” and the remaining 24 were given capsules “B”.

All the patients were suffering from physical and mental asthenia with severe anorexia and loss of weight.

Analysis of trial results clearly demonstrated that the active compound was that contained in capsules “A”, i.e. C.P. (batch No.2) as opposed to the placebo, contained in capsules “B”.

In Group A patients, appetite was restored, and weight increased, on average, by 3 kg. The period of treatment was 4 weeks, and C.P. was given at a rate of capsules per day.

In patients of Group A, both physical and mental asthenia disappeared and these patients improved to such an extent that by the end of the period of treatment, they were able fully to participate in hospital community life. The improvement in their condition was further demonstrated by ergometric test results and by a sorting test.

Biological test revealed a slight rise in blood cholesterol and blood protein levels and a remarkable rise in urinary 17-ketosteroid and 17-hydroxysteroid levels which suggests stimulation of adrenocortical secretion.

A statistical comparison was made of results obtained in group A (active compound) and in group B (placebo). Parameters and level of probability or significance are listed below:

- Fatigability 1 p. 1,000
- Appetite 1 p. 1,000
- Weight gain 1 p. 1,000
- 17-hydroxysteroids 1 p. 1,000
- 17-ketosteroids 1.6 p. 10,000
- Blood protein 1.p 1,000
- Blood cholesterol 1 p. 10 (limit of significance)
- Ergometric test 1 p. 1,000
- Sorting test:
 - Speed of performance 1 p. 100
 - Concentration 2 p. 100

C.P. was found to be very well tolerated, in terms of both gastrointestinal and general tolerance. No untoward effects were observed especially no sign of allergy, and the only side-effect was slight excitation, where occurred in a few cases, but did not necessitate discontinuation of treatment.

The trials revealed no contraindication.

It is concluded that the compound C.P. is therapeutically useful and has no harmful effects, and that it qualifies for a visa under Article L. 601 of the Public Health Code.

PARIS, 30 November 1970

Doctor DUBRISAY

Expert renouveau

Order dated 24 April 1970

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Clinical Trials

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