

CINERARIA MARITIMA

(EUPHRASIA EYE DROPS)

EXPERT APPRAISAL OF A **DOUBLE- BLIND, RANDOMISED CONTROLLED TRIAL** **CARRIED OUT ON TWO TYPES OF EYE DROPS IN 60 PATIENTS** **IN THE TREATMENT OF CONJUNCTIVITIS**

I, Roland Questel, have appraised the action and tolerance 'CINERARIA MARITIMA EUPHRASIA EYE DROPS' eyedrops on the one hand and a placebo (eyedrops composed of solvent) on the other hand, in the treatment of conjunctivitis, with examination through conjunctival capillarography on Day '0' (just prior to treatment) and on Day 6 (at the end of treatment). The assay was carried out on 60 patients who were allotted to 2 groups of 30 patients each after randomisation.

The selected symptoms were the analysis of microphotographs of conjunctival capillarographs, as well as the following symptoms : Pruritus, pain, watering eyes, photophobia, vascular dilatation, oedema, capillary exudation. In addition the clinical investigators kept track of the pathological symptoms, with three options : unchanged, improved, eliminated (cured). The patients were asked to judge the action of the product, on scale of 0 to 5.

The objective assay, both by the analysis of the macrophotographs and the statistical analysis of the quantifiable variables, shows that the product CINERARIA MARITIMA EUPHRASIA EYE DROPS permits statistically - significant, considerable therapeutic improvement within 6 days. On the other hand, the placebo does not make it possible to objectivize the differences before and after treatment. In addition at the end of the treatment, the difference concerning each of the items, between CINERARIA MARITIMA EUPHRASIA EYE DROPS and the placebo, is statistically significant.

CINERARIA MARITIMA EUPHRASIA EYE DROPS

Cineraria maritima MT	1.50 g
Euphrasia officinalis MT	1.00 g
Calendula officinalis MT	0.25 g
Kalium muriaticum 10 X	0.25 g
Calcarea fluorica 10 X	0.25 g
Silicea 10 X	0.25 g
Excipient q.s. To 100g	

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RANDOMISED TRIAL REF. 1995 / REF. 1996

DR. ROLAND : EXPERT PHYSICIAN

The random trial which was conducted compared the activity and tolerance of two preparations bearing the code number 1995 (CME eye drops) and 1996 (Placebo) in conjunctivitis after 6 days of treatment with the use of 1 drop of the eye drop six times daily.

The patients who were to be on trial were chosen from the clinic of presles.

One day 1, they underwent a conjunctival capillography and on Day 6 after treatment with either of the eye drops mentioned they underwent another capillography.

The clinical estimation of the two groups was determined by the microphotographs and by the following symptoms : Pruritus, pain, lachrymation, photophobia, vascular dilatation, oedema, capillary exudation.

The physicians noted the pathological manifestations with 3 options - unchanged, improved, eliminated (cured).

The patients were asked to judge the action of the product on the scale of 0 to 5.

Table 1 : The Population Treated

	Average Age	F	M
REF. 1995	27.4 ± 11.9	25	5
REF. 1996	43.2 ± 13.7	24	6

Table 2 : Initial Clinical Picture

	Pruritus		Pain		Lachrymation		Photophobia		Dilatation (Vascular)		Oedema		Capillary exudation	
	+	-	+	-	+	-	+	-	+	-	+	-	+	-
REF.1995	28	2	14	16	29	1	30	0	26	4	25	5	26	4
REF.1996	29	1	15	15	27	3	27	3	27	3	25	5	25	5
X ²	0.3 NS		0.6NS		1 NS		3 NS		0.1 NS		0 NS		0 NS	

Table - 3
EVALUATION AFTER TREATMENT

		Unchanged	Improved	Eliminated (Cured)	Total
PRURITUS	REF. 1995	5	22	1	28
	REF.1996	10	19	0	29
	$X^2 = 2.8$ NS				
PAIN	REF.1995	2	11	1	14
	REF.1996	11	3	1	15
	$X^2 = 11.6$ Sp < 0.01				
LACHRYMATION	REF.1995	11	12	6	29
	REF. 1996	15	12	0	27
	$X^2 = 6.9$ Sp < 0.05				
PHOTOPHOBIA	REF.1995	11	13	6	30
	REF.1996	20	6	1	27
	$X^2 = 8.6$ sp < 0.02				
VASCULAR DILATATION	REF.1995	16	10	0	26
	REF.1996	20	7	0	27
	$X^2 = 0.9$ ns				
OEDEMA	REF.1995	11	11	3	25
	REF.1996	18	7	0	25
	$X^2 = 5.5$ ns				
EXUDATION	REF.1995	4	20	2	26
	REF.1996	18	7	0	25
	$X^2 = 17$ Sp < 0.01				

Table - 4

Concordance between the judgement of the physicians and the notings of the Patient.

REF.	1995	r	=	0.902	S p < 0.001
REF.	1995	r	=	0.917	S p < 0.001

There exists a remarkable similarity between the judgement of the patients and the objective tests.

CONCLUSION

It appears clearly that during the course of the trial, the examination of the microphotographs, on analysis of the statistical qualified parameters that the therapeutic effect is unequal in both the groups.

The group that had received product coded 1995 showed a therapeutic benefit much superior to the group that received product 1996. notably in the following pathological manifestations exudation, pain, photophobia, lachrymation.

In this trial limited to 60 cases, we did not find any sign of intolerance.