

# An innovative nutraceutical compound for post-partum localised overweight or body remodeling

M Moreau<sup>(1)</sup>, N Piccardi<sup>(1)</sup>, B Chadoutaud<sup>(2)</sup>, C de Belilovsky<sup>(3)</sup>, P Msika<sup>(1)</sup>

(1) Laboratoires Expanscience, R&D Center, Epernon, France, (2) ClinrealOnline, Toulouse, France, (3) Dermatologist, Institut Alfred Fournier, Paris, France

## Introduction

New multivitamins soft-capsules have been formulated to induce the elimination of stocked fat during the post partum period. It contains fish oil (rich in Omega 3 fatty acids), evening primrose oil (rich in Omega 6 fatty acids), magnesium oxide (activation of vitamins B), pineapple extract (rich in a proteolytic enzyme: Bromelaïne), zinc

oxide (stimulation of collagen and elastin synthesis), vitamins B 2-3-5-6-8-9-12 (pregnant and breast-feeding women have a potential deficit in B2-5-6-9 vitamins). The capsules are well tolerated and fill all the criteria of the legislation for alimentary products: Quality, Security and Efficacy.

## Laboratory Tests

### Concentrated and purified Evening Primerose Oil +Fish Oil

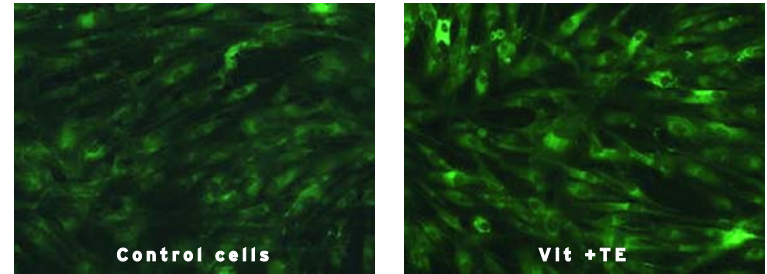
Incubated in adipocytes culture, these components induced a stimulation of lipolysis (+124%) and an inhibition of lipogenesis (-90%). These effects indicate a reduction of adipose tissue.

### Vitamins + Trace-elements (TE)

Vitamins + TE, as contained in the soft capsules, have been introduced in cultures of keratinocytes and fibroblasts during 48H. Results are summarised in table 1 and illustrated in Fig 1.

Vit+TE	Keratinocytes	Fibroblasts
Proliferation	+32%	
Differentiation	+44%	
Proteins	+109%	+43%
Collagen fibres		+381%
Elastin fibres		+42%

Figure 1: Stimulation of the synthesis of collagen I (immunofluorescence on fibroblasts culture)



### Conclusion of laboratory tests

These tests show that the components of these new soft capsules, indicated for post-partum body remodelling, decrease the cutaneous lipid amount and stimulate cutaneous cells, mandatory properties to reduce localised body over-weight and to improve cutaneous strength.

## Clinical Test

### Materials and Methods (tables 2 & 3)

Comparative multicentric study with 25 gynecologists including 52 primipara, non-lactating women, 2 to 3 months post-delivery, for 3 months. Half ingested the new formula (2 capsules per day) and half represented the control group. Clinical examinations were performed at D0, 30, 45, 60 and 90. Quality of Life (QoL) (MOS SF-36) and auto-evaluations were evaluated at D0, D45 and D90. Mann-Whitney (p<15%) and Wilcoxon (p<10%) tests were used.

### Table 2 INCLUSION AND EXCLUSION CRITERIA

- Primipara post-partum women, 2-3 months post-delivery
- Age between 25 and 35
- Weight gain during pregnancy: 12 to 25 kg
- Body Mass Index: 20 to 28
- Non lactating
- No gemellar pregnancy
- No premature delivery
- No similar treatment
- No allergy to components of the capsules

### Table 3 EVALUATION CRITERIA

- Clinical examinations:**
- Striae evaluation (presence, length, width, colour, surface)
  - Body shape (4 measures, scores 0 to 9)
  - Cellulitis (cotations from 0 to 3)
- Body measurements:**
- Weight evolution
  - Body Mass Index: BMI = Weight in kg / height in cm<sup>2</sup>
  - Circumferences of waist, hips and thighs (in cm).
- Auto-evaluations questionnaires (cotations 0 to 9)**
- Quality of Life evaluations: MOS SF-36 questionnaire (divided in physical and mental dimensions)**

### Clinical Results

#### Population

28 women in the treated group vs 24 in the control group. Mean age was respectively 28.9 and 28.5 years old; mean BMI were 23.3 and 23.2.

#### Clinical Examinations

- **Striae:** The 5 clinical characteristics improved at D90/D0 (from 33 to 46%) in the treated group, with no statistical difference vs control group.
- **Cellulitis:** It was statistically improved at D90/D0 (37%) in the treated group vs 20% in the control group (no statistical differences between the 2 groups).

#### Body Measurements (% of improvement)

- **Weight** was significantly and similarly decreased in the 2 groups: -3.8% and -3.9%.

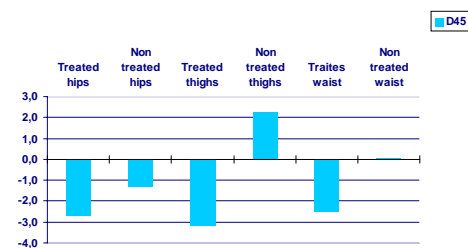
- **Body Measurements** show significant decreases in the treated group/D0 and not in the control group for:

**Hip circumference :** D30: -2.4% vs -0.9%, with confirmation at D45 (-2.7% vs -1.3%)

**Thighs circumference :** D30: -2.4% vs + 3.9%, with continuing improvement at D45 (-3.2% vs +2.3%) and D60 (-3.4% vs -0.8%)

**Waist circumference :** D45: -2.5% vs +0.1%

Figure 2 : BODY MEASUREMENTS



Weight	-13 kg
Hips circumference	-11 cm
Thighs circumference	-7 cm
Waist circumference	-11 cm

Maximal individual performances at D90 were as shown in table 4

### Auto-Evaluations

Comparison of the 2 groups demonstrated statistical superiority of the capsules vs control group for the following items (table 5) :

Global perception of the patients has shown that body shape and skin firmness were rapidly and intensively improved.

Table 5

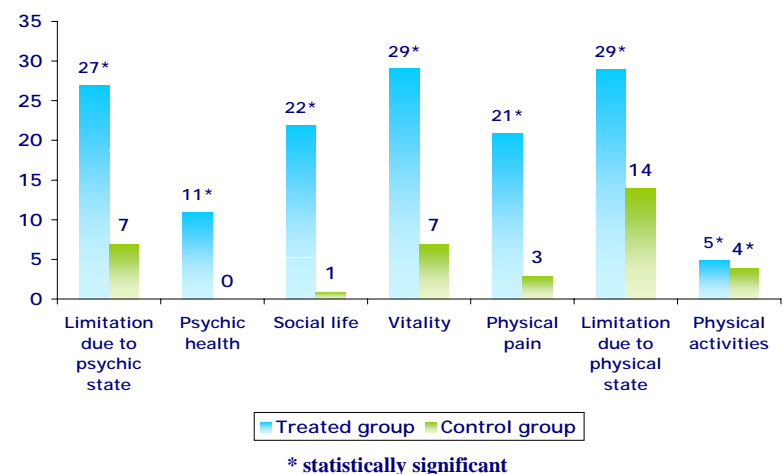
	D45	D60	D90
<b>BIOMECHANICAL PROPERTIES</b>			
Elasticity	X	X	X
Suppleness	X	X	X
Tonicity			X
Less laxicity			X
Strength		X	X
Tension			X
<b>SKIN QUALITIES</b>			
Suppleness		X	X
Satin-smooth		X	X
Quality		X	X
Structure		X	X
Density		X	
Hydration		X	X
Less desquamation			X
<b>GENERAL EFFECT</b>			
Body shape improvement		X	
Less cellulitis			X
Diuretic effect	X	X	X
Less striae			X

X = statistically significance of treated/control group

### Quality of life

MOS SF-36 included 36 questions divided in 9 domains and 2 dimensions (physical and mental).

**Domains:** Statistically significant results of the domains at the end of the study (D90/D0) for the treated group and the control group are summarized in Fig 3. 7 domains were statistically improved with the treatment vs 1 in the control group.



Dimensions at D90/D0 (Table 6)

	Treated group	Control group
Physical score	+6% *	+4%
Mental score	+14.6% *	+0.2%

\* = Statistical differences D90/D0

## Conclusion

A new nutraceutical compound is able to decrease fat accumulated on the waist, hips and thighs in the post-partum period with improvement of skin quality and of Quality of Life of the women treated.