

# QUALITY OF LIFE OF POST MENOPAUSAL WOMEN TREATED FOR 1 YEAR WITH A SOY EXTRACT

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## INTRODUCTION AND OBJECTIVES:

The effects of isoflavones on post menopausal symptoms have been extensively studied in many clinical trials but their results are heterogeneous. These different results may be explained by the fact that the clinical studies were conducted with various extract, different doses and exposure time. Our clinical study was designed to assess the endometrial and breast safety of Phyto Soya<sup>®</sup> as primary objective but we also studied in parallel the quality of life of the post menopausal women treated for 1 year. The hot flushes were monitored very precisely using a patient electronic diary.

## METHODS:

### Study design:

This is an international open study with centres located in Australia, Belgium, France and Spain. 499 post menopausal women have been selected and 395 have been included.

### Treatment:

2 capsules in the morning and 2 capsules in the evening of Phyto Soya<sup>®</sup> corresponding to a daily dose of 70 mg of isoflavone (35 mg daidzin, 21 mg glycitin and 14 mg genistin). Patients were treated for 1 year.

### Main inclusion criteria:

- non hysterectomised women, 45-65 years old, post menopausal since at least 2 years
- women presenting hot flushes or climacteric symptoms
- wash out of 3 months for HRT, DHEA, tibolone, raloxifene, 2 months for isoflavones
- BMI < 30 Kg/m<sup>2</sup>
- no endometrial nor breast abnormality, no thromboembolic disease, no uncontrolled arterial hypertension, no history of hormonodependent malignant tumors

### Monitoring of quality of life :

- 1) Kupperman score : Patients were questioned by the investigator at each visit.
- 2) Patient electronic diary : patients were requested to answer daily to a Symfo Electronic Diary (SED), recording the intensity and the number of hot flushes.

## RESULTS AND CONCLUSIONS:

### Kupperman results:

The total Kupperman score at inclusion was 17.04 ± 7.81 and it decreased by 40.8 % to 10.11 ± 7.84 after one year of treatment. The largest mean decreases from baseline were in hot flushes, nocturnal sweating and nervousness.

### Electronic diary results:

Symfo data are presented for the totality of the population by comparing data obtained for the whole population during selection period versus during treatment period.

	Selection period	Treatment period
Nb of days with Symfo answers	6 932 answers	80 468 answers
<b>Incidence of hot flushes</b>		
0/d	27.5 %	49.4 %
1/d	14.1 %	11.4 %
2/d	14.2 %	13.3 %
3/d	14.3 %	10.7 %
4/d	10.5 %	5.8 %
5/d	8.1 %	4.1 %
More than 5/d	11.3 %	5.4 %
<b>Intensity of hot flushes</b>		
None	27.5 %	49.4 %
Light	34.9 %	29.2 %
Moderate	29.5 %	18.0 %
Severe	8.0 %	3.4 %

This analysis clearly demonstrated an improvement on hot flushes symptoms during treatment period.

A subsequent analysis of SED data has been performed on a sub group of patients who suffered from important hot flushes. This stringent population was defined as patients who reported at least 5 hot flushes/day during 3/4 days of selection period. 71 patients met these criteria.

	Selection period	Treatment period
Nb of days with Symfo answers	1767 answers	19123 answers
<b>Intensity of hot flushes</b>		
None	0.6 %	10.3 %
Light	21.7 %	43.3 %
Moderate	55.9 %	38.37 %
Severe	21.8 %	8.0 %

During the selection phase the days without hot flushes represented 27.5% of answers and they increased to 50% during treatment phase with Phyto Soya<sup>®</sup>

During the selection phase the days with hot flushes of none or light intensity represented 42% and they increased to almost 80% during treatment phase with Phyto Soya<sup>®</sup>.

Number of days of severe intensity represented 22% of answers during selection period whereas it decreased to 8 % with Phyto Soya<sup>®</sup>

## Conclusions:

Reductions from baseline in the frequency and severity of hot flushes as well as decrease in Kupperman score demonstrated that Phyto Soya<sup>®</sup> improved quality of life of post menopausal women.