

Sérélys



Département de Pharmacologie

Unité de Pharmacologie Clinique

Université Victor Segalen Bordeaux 2



■ Essais cliniques ■

**COSMÉTOLOGIE
COMPLÉMENTS ALIMENTAIRES**

Dr Alain Jacquet ←

Toxicologue EUROTOX

Pr Nicholas Moore

Pharmacologie

**ÉVALUATION DE LA TOLERANCE
ET DE L'EFFICACITÉ D'UN
COMPLÉMENT ALIMENTAIRE "MÉNopause"**

**SÉRÉLYS
(FEMALE tablets)**

Laboratoires HIRAPHARM

RAPPORT STATISTIQUE

Référence : e453-953-rapport du 16 octobre 2008

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Study design

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From October 2007 to July 2008

OPEN STUDY

MULTICENTRIC

102 gynecologists

417 patients

**Statistics analysis: Bordeaux University,
France**

**2 tablets per day
during 12 weeks**



**2 Medical check :
Day 0 and Day 84**

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Inclusion criteria

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✓ **Women in menopause period**

✓ **Acceptance
of the protocol**



✓ **Symptoms linked with menopause**

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Exclusion criteria

- ✓ **Presence of severe pathology**
- ✓ **NO Symptoms linked with menopause**
- ✓ **Known allergie vs products components**
- ✓ **Medication having a potencial interference with the study results**

Day 0

- ✓ Study explanation
- ✓ Clinical exam, medical history, actual treatment(s)
- ✓ Evaluation of menopausal troubles
- ✓ Dossier fill in + visual scale
- ✓ Prescription of Sérélys®

Day 84

- ✓ **Search for adverse events (questions+ clinical examination)**
- ✓ **Evaluation of menopausal troubles**
- ✓ **Dossier fill in + visual scale**
- ✓ **Patient's comments + product rate**
- ✓ **M.D. comments**

TOLERANCE

SCALE 1 to 4 grades

① : Excellent

② : Good

③ : Medium

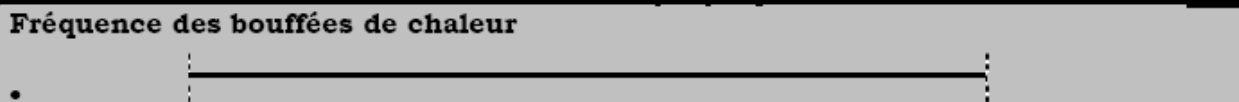
④ : Bad

VISUAL SCALES

- Hot flushes, (frequency, intensity, timing, disturbance)
- Sweating, (frequency, timing, disturbance)
- Irritability
- Sadness
- Tiredness
- Sleep quality
- Skin
- Dryness
- Quality of life
- Vaginal dryness
- Bleeding, others

VISUAL SCALES

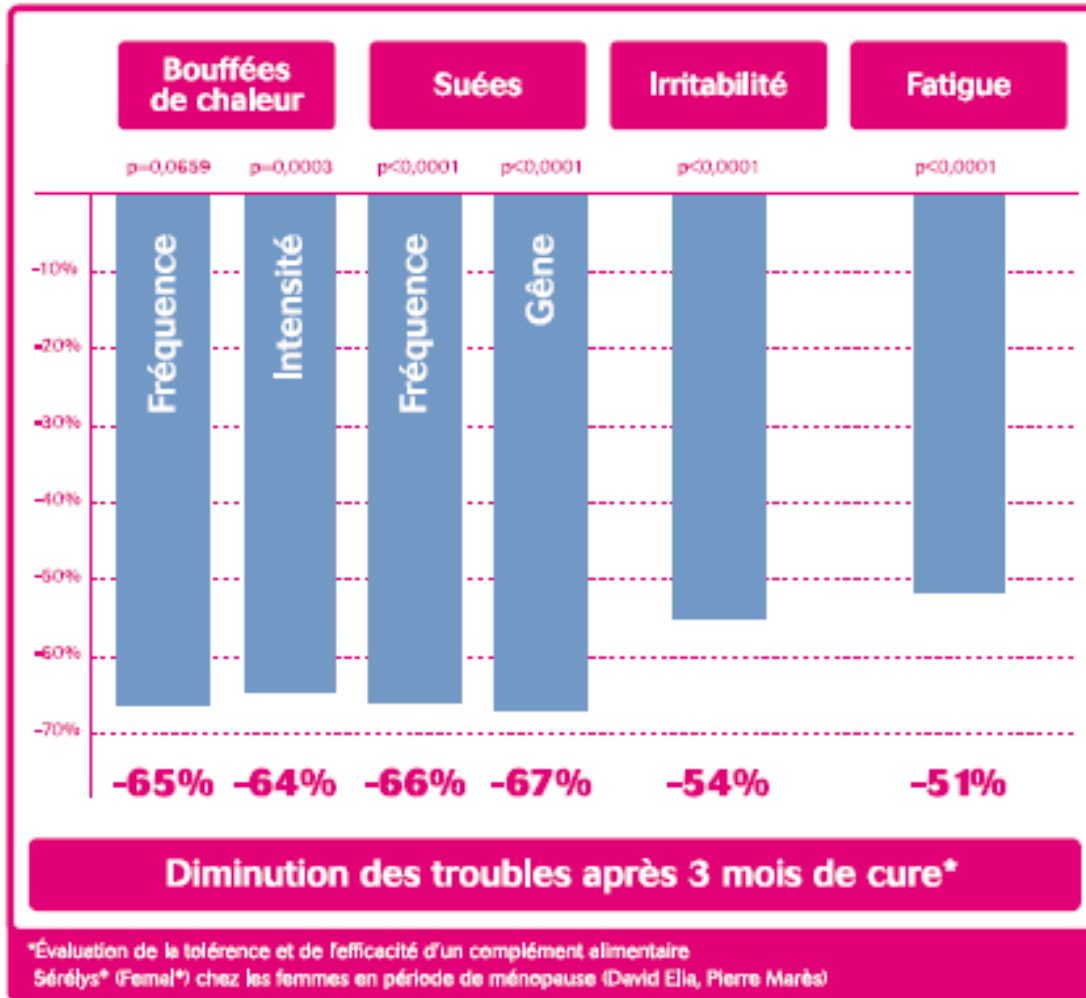
- **Hot flushes, (frequency, intensity, timing, disturbance)**

1.A	BOUFFEES DE CHALEUR - fréquence	0 = Pas de bouffées de chaleur	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Vos bouffées de chaleur sont elles fréquentes ?	1 = 1 ou 2 fois par jour	
		2 = 3 à 6 fois par jour	
		3 = Plus de 6 fois par jour	
Fréquence des bouffées de chaleur		1.A =	
		<input type="text"/>	
Pas de bouffées de chaleur		Bouffées de chaleur très fréquentes	

- *Sweating, (frequency, timing, disturbance)*
- *Irritability*
- *Sadness*
- *Tiredness*
- *Sleep quality*
- *Skin*
- *Dryness*
- *Quality of life*
- *Vaginal dryness*
- *Bleeding, others*

Results – Visual scales

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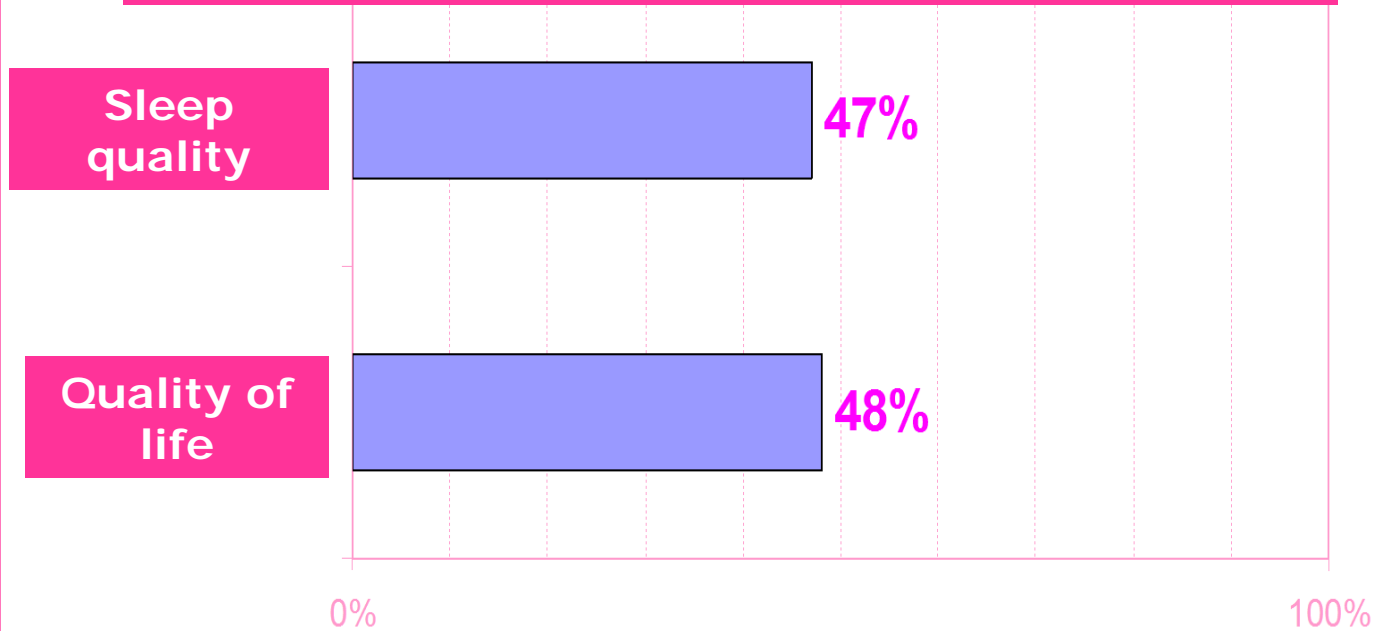


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Results – Visual scales

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POSITIVE EVOLUTION AT DAY 84



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Results – Questions forms

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Hot flushes Frequency	Day 0	Day 84
<i>0 to 2 per day</i>	32%	86 %
<i>3 to 6 and more</i>	68%	14 %

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Results – Questions forms

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Hot flushes When ?	Day 0	Day 84
<i>No hot flushes</i>	3,5 %	24,7 %
<i>DAY</i>	18,9 %	34,1 %
<i>NIGHT</i>	77,6 %	41,2 %

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Results – Questions forms

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Hot flushes Disturbance	Day 0	Day 84
<i>LOW</i>	17,8 %	83,1 %
<i>HIGH</i>	82,2 %	16,9 %

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Patients opinion

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- **FOR 93 % SERELYS® HAS A VERY OR GOOD EFFICACY**
- **FOR 97 % SERELYS® IS WELL TOLERATED**
- **FOR 93 % SERELYS® IS EFFICIENT ON QUALITY OF LIFE IMPROVEMENT**
- **97 % ACCEPT TO CONTINUE THE TREATMENT**



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M.D.'s opinion

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➤ **FOR 93,5 % SERELYS® IS EFFICIENT** ®

➤ **97 % WILL PRESCRIBE OR
CONTINUE TO PRESCRIBE**



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ONLY 3 PATIENTS HAVE A BAD TOLERANCE

- 1. Migraine**
- 2. Digestive trouble**
- 3. Allergic rhinite**

Conclusion

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→ **SERELYS® IS PRESENTING A GOOD EFFICACY ON MENOPAUSAL SYMPTOMS WITH A GOOD TOLERANCE PROFILE THE « MUST » OF NATURAL « NON-HORMONAL » PRODUCT.**

→ **SERELYS® CAN THEREFORE BE CONSIDERED AS A GOOD THERAPY FOR WOMEN WHO DOES NOT WANT OR CANNOT TAKE HORMONES THERAPY FOR THEIR MENOPOSAL SYMPTOMS**



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