



**SO KEN study :
Efficacy of lactium®
on sleep disorders**

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Aim :

The target of this clinical investigation was to study the effects of lactium® intake on sleep disorders.

Protocol

- 165 Japanese healthy males and females aged between 25 and 40, but aware of sleep troubles
- selection of 44 subjects from self evaluation – inclusion criteria :
 - *PSQI* score > 5 and
 - *HAD* score < 10
 - 2 homogenous groups : *lactium®* and placebo
- 1 capsule a day (150 mg lactium®) during 4 weeks
- 4 observation periods in addition to initial screening :
 - during the intake period : weeks 0, 2, 4
 - after the treatment : week 4+1
- evaluation questionnaires : Pittsburgh Sleep Quality Index (PSQI)
Epworth Sleepiness Scale (ESS)



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Pittsburgh Sleep Quality Index (PSQI)

Significant improvement with lactium® only – Trend of improvement with lactium® only

Significant improvement with both groups – Trend of improvement in both groups

Significant improvement with placebo only – Trend of improvement with placebo only

Items	Week	Whole population			Women			Men			Whole population HAD-A<7			Whole population HAD-D<7		
		W 2	W 4	W 4+1	W 2	W 4	W 4+1	W 2	W 4	W 4+1	W 2	W 4	W 4+1	W 2	W 4	W 4+1
Subjective sleep quality		Orange	Orange	Red	Orange	Orange	Red	Red	Red	White	Red	Red	Red	Red	Red	Red
Sleep latency		Green	Orange	Orange	Green	Orange	Orange	White	White	Green	White	White	White	White	White	Orange
Sleep duration		Red	White	Red	Red	Red	White	White	White	White	Red	Red	Red	Red	White	White
Habitual sleep efficiency		Red	Red	Red	Red	Red	White	White	White	White	Red	Red	Red	Red	Red	Red
Sleep disturbances		Orange	Orange	Orange	Orange	Orange	White	White	White	White	Orange	Orange	Orange	Orange	Orange	Orange
Use of sleep medication		Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey
Daytime dysfunction		Red	Orange	Green	White	Red	Green	Green	Green	White	Red	Red	Green	Red	Red	White
Global PSQI score		Orange	Orange	Orange	Orange	Orange	Orange	Red	Red	Green	Red	Red	Red	Red	Orange	Orange

Results obtained with Wilcoxon test and corrected Wilcoxon test (Bonferroni) for men.



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Epworth Sleepiness Scale (ESS)

Significant improvement with lactium® only

Trend of improvement with lactium® only

Significant improvement with placebo only

Items « Dozing (while)... »	Whole population		
	W2	W4	W4+1
Sitting and reading			
Watching TV			
Sitting inactive in a public place			
As a passenger in a car			
Lying down in the afternoon			
Sitting and talking			
Sitting quietly after lunch			
In a car, while stopped			

Results obtained with Wilcoxon test



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Key points

PSQI

PSQI is a suitable index to evaluate the sleep quality of “poor sleepers”

- lactium® shows a positive effect on almost all the tested items in whole population
 - Nevertheless, some positive results are also observed with placebo. The placebo effect is a well-known phenomenon especially :
 - in psychosomatic troubles like sleep disorders,
 - for “expecting people” with severe symptoms.
- It is a short-term effect, as confirmed with the poor placebo results at W4+1.
- In whole population, lactium® intake particularly improves :
 - sleep duration,
 - sleep efficiency.



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Key points

➤ In subjects with a moderate anxiety or depressive profile (HAD-A or HAD-D <7), the benefits of Lactium® are still more noticeable.

Lactium improves significantly the :

- sleep quality
- sleep efficiency
- sleep disturbances
- daytime dysfunction
- Global PSQI score.

➤ it is not the case with placebo.

➤ **Lactium® decreases sleep troubles, probably via physiologic effects.**



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Key points

ESS

ESS is a good tool to evaluate alertness or sleepiness during the day

- 3 key items of ESS are good indicators of alertness and cognitive performances :
 - sitting in active public place (meeting...),
 - sitting and talking to someone
 - driving and stopped at a traffic light.
- the intake of lactium® significantly reduces the diurnal sleepiness for 2 of them, even one week after the treatment.
- lactium® also reduces the sleepiness when being “as a passenger in a car” and “lying down in the afternoon”.
- **lactium® improves diurnal alertness, probably because it restores night’s quality.**

CONCLUSION:

- lactium® decreases the sleep disorders, in particular for people with moderate anxious/depressive profile
- lactium® progressively restores a good sleep without being soporific
- lactium has more a physiological effect, whereas Placebo has a psychological effect only (especially for expecting people)
- For pathological sleep disorders, lactium® could be helpful but it is not a sedative drug.

GOOD NIGHTS FOR GOOD DAYS :

Do you fall asleep during the day (meeting, car travel...) ? That probably means that the quality of your night sleep is not good. If you want to have a good day, have first of all a good night.

Take lactium® and you'll have Good Nights for Good days...