A pilot study of Uretin 45+ in women with urge incontinence and/or a mixture of urge and stress incontinence

Background:

EFLA 940 is a new kind of pumpkin seed extract. It is free from the fats and fatty acids being constituents of pumpkin seeds. In older extracts, these fats were concentrated and believed to be beneficial active ingredients. This new and specially made pumpkin seed extract has already in clinical studies ben reported to be of value for women with age related urinary problems, especially frequent urination, urge incontinence and a mixture of urge and stress incontinence.

The name of the new product is Uretin45+. Before launching the product on the Swedish market, it was decided to perform a consumer test. Volunteers were recruited via ads in a local newspaper.

Inclusion criteria:

Women with age related urinary problems not taking estrogens nor any medication for their urinary problems. They were 45 - 65 years of age.

Medication and dose:

The women were given Uretin45+, two tablets a day for 8 weeks. Each tablet of Uretin45+ contains 250 mg EFLA 940.

Data:

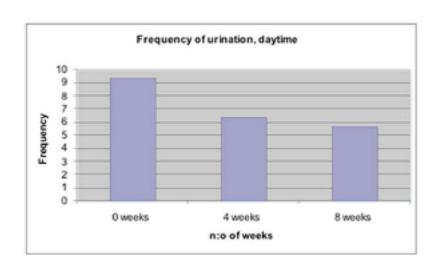
All women filled in reports every day stating the frequency of urination during day time and night time. They also noted the number of incontinence episodes during the day (24 hours). The women were interviewed before the beginning of the study, after four weeks and after eight weeks. At these interviews they were also asked to graduate their appreciation of the product on a scale from 1 to 5.

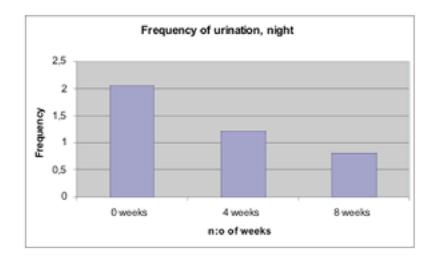
Number of participants:

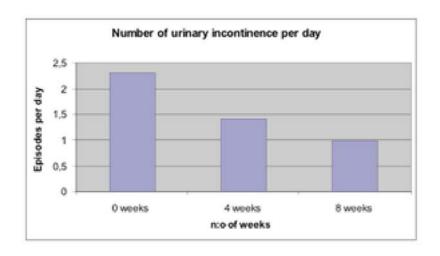
Twelve women were recruited but two of them dropped out for various resons. Thus the data are based on reports from 10 women.

Results:

N = 10	0 week	4 weeks	8 weeks
Frequency of urination, day time	9,33	6,37	5,67
Frequency of urination, night time	2,05	1,21	0,82
Incontinence episodes per day	2,33	1,42	1,00







Consumer satisfaction: (score 1 to 5, where 5 is the best)

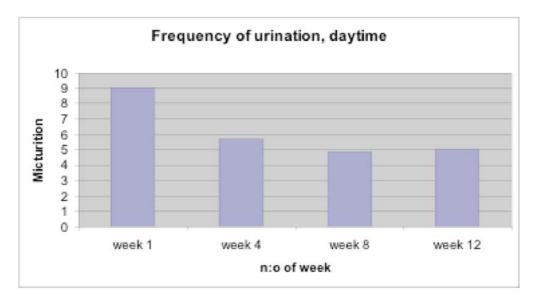
N = 10	4 weeks	8 weeks
Do you sleep better with Uretin45+?	3,2	3,6
Do you feel safer with Uretin45+?	3,2	4,1
Is Uretin45+ a useful medication?	3,4	4,2

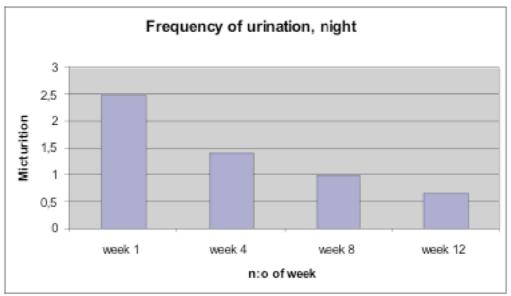
Summary:

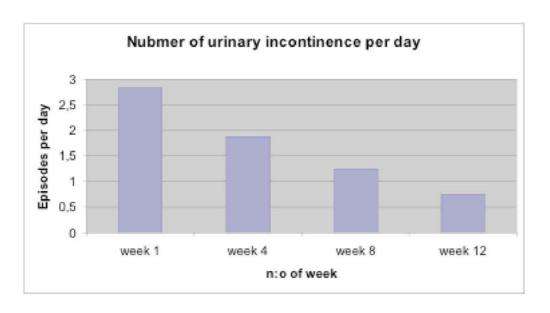
The result of this small study indicates that Uretin45+ is a useful medication for women with age related urinary problems.

Prolongation of the study with four additional weeks

As the result of the above reported study was encouraging, it was decided to prolong the study with an additional 4 week period. The six women, who had responded best during the 8 week study were chosen. Their data are presented in the following three diagrams.







Consumer satisfaction: (score 1 to 5, where 5 is the best)

N = 6	Week 4	Week 8	Week 12
Do you sleep better with Uretin45+?	2,92	3,5	4,08
Do you feel safer with Uretin45+?	3,25	4,17	4,41
Is Uretin45+ a useful medication?	3,5	4,33	4,67

Discussion:

The aim of prolonging the original 8 week study to a 12 week study was to observe if there would be additional benefits for the women with time. The results showed a clear improvement in number of night time micturitions and in incontinence episodes. Regarding day time micturations no changes were recorded, probably due to the fact that normalization had already been achieved.

The results are in a correspondence with previously published data verifying Uretin45+ as an effective and safe medication for age related urinary problems.

Bioaktiva Pharma AB/ Åsa Karlsson and Eva Lundberg, 050118