

Patients suffering from chronic soft tissue pain

Pain sum scores: absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	20,75	3,08	12	28	64
	Visit 2	15,61	4,41	5	28	64
	Absolute reduction	5,14	3,85	-3	14	64
	% reduction	24,63	18,64	-25	74	64
	Visit 3	12,58	5,77	2	28	64
	Absolute reduction	8,17	5,14	-4	19	64
	% reduction	39,94	25,40	-18	86	64
	Visit 4	10,30	6,58	0	26	64
	Absolute reduction	10,45	6,32	-4	22	64
	% reduction	50,57	30,74	-18	100	64
Placebo	Visit 1	21,15	3,07	13	28	66
	Visit 2	16,42	5,43	3	27	66
	Absolute reduction	4,73	5,43	-3	24	66
	% reduction	21,74	24,86	-14	86	66
	Visit 3	15,00	5,40	3	25	66
	Absolute reduction	6,15	5,86	-2	25	66
	% reduction	28,02	25,99	-10	89	66
	Visit 4	14,02	5,90	0	24	66
	Absolute reduction	7,14	6,42	-1	24	66
	% reduction	32,70	28,62	-6	100	66

Pain sum scores: absolute scores and reduction since visit 1, percentiles (ITT, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	16,0	19,0	21,0	22,0	25,8
	Visit 2	9,0	13,0	16,0	17,0	23,5
	Absolute reduction	-1,5	3,0	5,0	8,0	12,0
	% reduction	-5,8	12,3	24,4	37,2	54,0
	Visit 3	3,0	9,0	13,0	16,0	22,0
	Absolute reduction	,0	4,0	9,0	12,0	16,0
	% reduction	,0	20,9	40,5	58,9	84,2

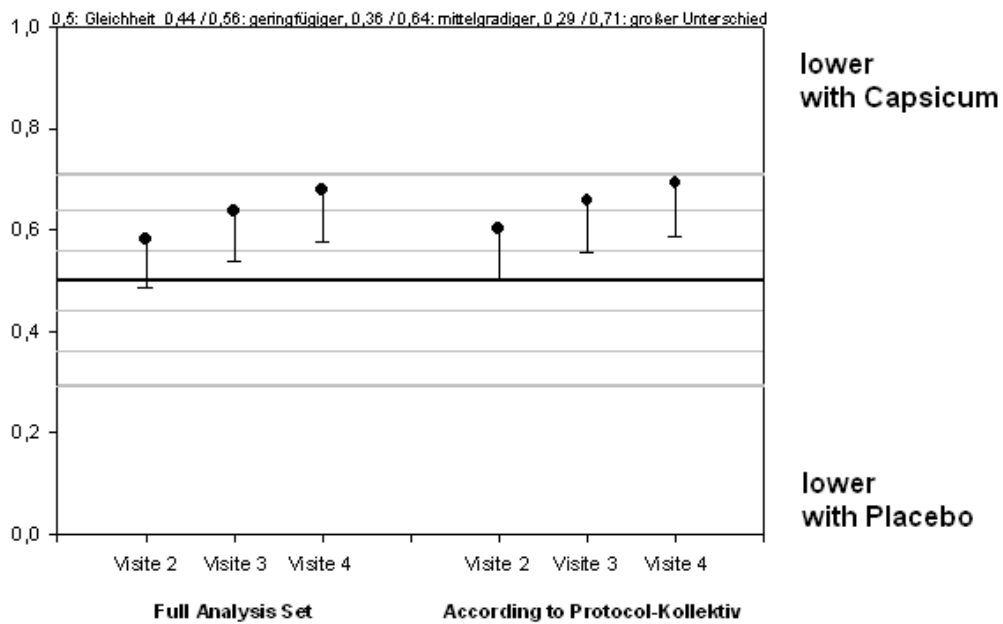
Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
	Visit 4	,3	4,3	10,0	15,0	22,0
	Absolute reduction	,0	6,3	11,0	15,0	20,0
	% reduction	,0	29,8	48,9	79,4	98,9
Placebo	Visit 1	16,0	19,0	21,0	23,0	27,7
	Visit 2	4,0	14,0	18,0	19,0	24,0
	Absolute reduction	-1,7	,0	4,0	8,0	15,7
	% reduction	-7,9	,0	16,6	35,9	82,8
	Visit 3	4,0	10,0	16,0	19,0	22,7
	Absolute reduction	-1,0	1,0	4,5	11,0	16,7
	% reduction	-4,7	7,1	21,1	46,7	81,2
	Visit 4	1,4	10,0	16,0	18,3	21,7
	Absolute reduction	-,6	2,0	5,0	12,0	20,0
	% reduction	-3,2	10,4	22,5	54,3	93,2

Exploratory between-group comparison of pain sum score by means of Mann Whitney statistic (ITT, locf)

Higher Mann-Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,5234	0,441	0,605	0,6438
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,5819	0,484	-	0,0542
Absolute reduction	0,5664	0,468	-	0,0962
% reduction	0,5827	0,484	-	0,0528
Visit 3	0,6373	0,538	-	0,0039 **
Absolute reduction	0,6219	0,523	-	0,0089 *
% reduction	0,6384	0,538	-	0,0037 **
Visit 4	0,6778	0,577	-	0,0003 ***
Absolute reduction	0,6568	0,557	-	0,0012 **
% reduction	0,6694	0,568	-	0,0006 **

Pain sum scores: Mann-Whitney statistic with 97.5% CI



The results of the ITT analysis are largely supported by the PP analysis with the baseline scores being comparable ($p = 0.06953$), exploratory analysis yielded significant differences from visit 3 on.

Pain sum score. absolute scores and reduction since visit 1 - basic statistics (PP analysis, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	20,72	2,89	12	28	58
	Visit 2	15,40	4,25	5	28	58
	Absolute reduction	5,33	3,84	-3	14	58
	% reduction	25,50	18,61	-25	74	58
	Visit 3	12,36	5,62	2	28	58
	Absolute reduction	8,36	4,98	-4	19	58
	% reduction	40,97	24,64	-18	86	58
	Visit 4	9,95	6,52	0	26	58
	Absolute reduction	10,78	6,29	-4	22	58
% reduction	52,20	30,54	-18	100	58	
Placebo	Visit 1	21,15	3,16	13	28	62
	Visit 2	16,60	5,35	3	27	62
	Absolute reduction	4,55	5,31	-3	24	62

	% reduction	20,91	24,35	-14	86	62
	Visit 3	15,15	5,33	3	25	62
	Absolute reduction	6,00	5,82	-2	25	62
	% reduction	27,27	25,71	-10	89	62
	Visit 4	14,03	5,91	0	24	62
	Absolute reduction	7,11	6,44	-1	24	62
	% reduction	32,58	28,67	-6	100	62

Exploratory between-group comparison of pain sum score by means of Mann Whitney statistics (PP analysis, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visite 1	0,5207	0,435	0,606	0,6953
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,6034	0,501	-	0,0262 +
Absolute reduction	0,5884	0,486	-	0,0471 +
% reduction	0,6040	0,500	-	0,0258 +
Visit 3	0,6582	0,554	-	0,0017 **
Absolute reduction	0,6406	0,537	-	0,0045 **
% reduction	0,6606	0,556	-	0,0015 **
Visit 4	0,6926	0,587	-	0,0002 ***
Absolute reduction	0,6710	0,566	-	0,0008 **
% reduction	0,6853	0,579	-	0,0003 ***

Pain sum score: Absolute scores and reduction since visit 1 - Percentiles (PP analysis, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	15,9	19,0	21,0	22,0	25,0
	Visit 2	8,8	13,0	16,0	17,0	22,1
	Absolute reduction	-2,0	3,0	5,0	8,0	12,1
	% reduction	-7,8	13,5	25,5	37,9	55,5
	Visit 3	3,0	9,0	13,0	16,0	22,2
	Absolute reduction	-,1	4,8	9,0	12,0	16,0
	% reduction	-,4	23,7	40,9	60,2	84,3
	Visit 4	,0	4,0	9,5	14,3	22,1

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
	Absolute reduction	,0	6,8	11,0	15,3	20,0
	% reduction	-,4	32,9	54,8	81,8	100,0
Placebo	Visit 1	16,0	19,0	21,0	23,0	27,9
	Visit 2	4,3	14,0	18,0	19,3	24,0
	Absolute reduction	-1,9	,0	3,5	8,0	14,9
	% reduction	-8,0	,0	15,3	35,9	81,3
	Visit 3	4,2	10,0	16,0	19,0	22,9
	Absolute reduction	-1,0	1,0	4,0	11,0	15,9
	% reduction	-4,9	5,3	20,5	46,7	79,1
	Visit 4	1,2	10,0	16,0	19,0	21,9
	Absolute reduction	-,9	2,0	5,0	12,0	20,0
	% reduction	-4,3	10,3	22,5	54,3	93,9

Patients suffering from chronic back pain

Pain sum score: Absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	20,52	2,35	16	25	71
	Visit 2	15,04	4,80	5	25	71
	Absolute reduction	5,48	4,66	-5	16	71
	% reduction	26,58	22,50	-25	73	71
	Visit 3	12,75	5,60	0	24	71
	Absolute reduction	7,77	5,83	-2	22	71
	% reduction	37,45	27,21	-10	100	71
	Visit 4	9,96	6,73	0	26	71
	Absolute reduction	10,56	7,04	-6	23	71
	% reduction	51,00	32,87	-30	100	71
Placebo	Visit 1	20,49	2,62	16	26	71
	Visit 2	16,49	4,79	2	28	71
	Absolute reduction	4,00	4,00	-4	18	71
	% reduction	19,83	20,51	-17	90	71
	Visit 3	14,15	5,20	2	27	71

Statistics		M	S	Min	Max	N
	Absolute reduction	6,34	4,97	-3	18	71
	% reduction	30,84	24,36	-13	90	71
	Visit 4	12,80	6,61	0	27	71
	Absolute reduction	7,69	6,35	-3	21	71
	% reduction	37,63	31,81	-19	100	71

Pain sum score: absolute score and reduction since visit 1 - percentiles (ITT, locf)

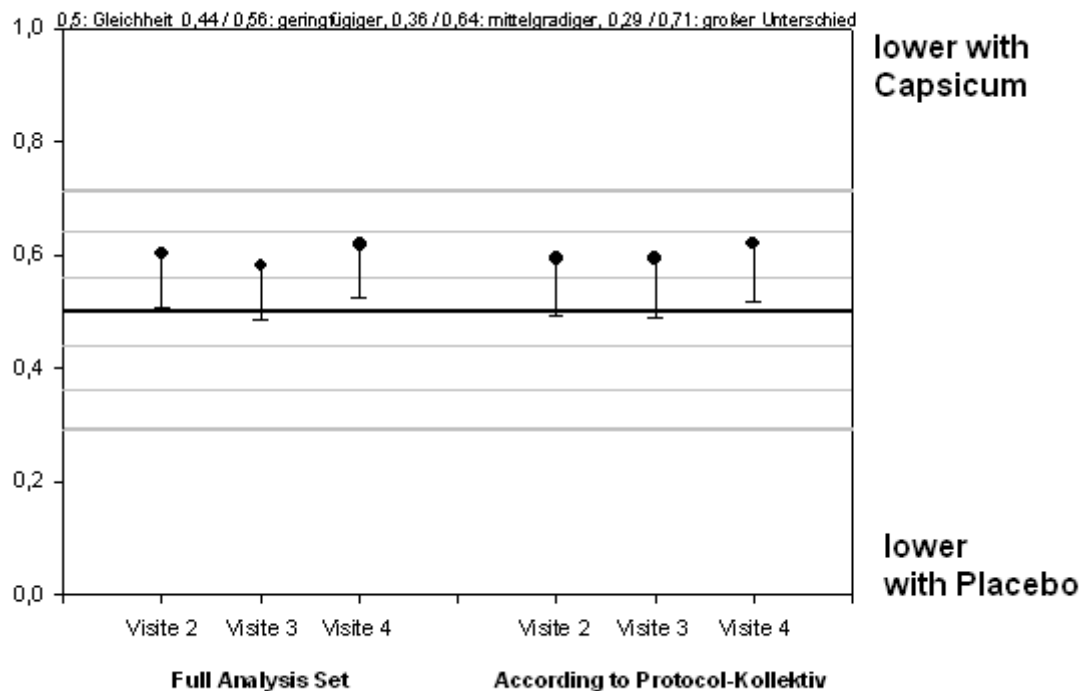
Percentiles		5 %	25 % (I. Q)	50 % Median)	75 % (III. Q)	95%
Capsicum	Visit 1	17,0	18,0	21,0	22,0	25,0
	Visit 2	6,0	12,0	15,0	19,0	24,0
	Absolute reduction	-1,0	2,0	6,0	9,0	13,0
	% reduction	-5,9	9,1	27,8	40,9	69,9
	Visit 3	4,6	9,0	12,0	18,0	22,0
	Absolute reduction	-1,4	3,0	8,0	13,0	16,0
	% reduction	-7,2	13,6	40,0	60,0	78,7
	Visit 4	,0	5,0	8,0	15,0	22,0
	Absolute reduction	-1,4	5,0	11,0	16,0	21,4
	% reduction	-6,6	27,3	57,9	75,0	100,0
Placebo	Visit 1	16,0	19,0	21,0	23,0	24,4
	Visit 2	6,0	14,0	17,0	19,0	23,4
	Absolute reduction	-,4	1,0	3,0	6,0	11,4
	% reduction	-1,9	5,0	15,0	29,2	64,2
	Visit 3	5,2	9,0	16,0	18,0	21,0
	Absolute reduction	,0	2,0	6,0	10,0	15,0
	% reduction	,0	9,5	25,0	52,4	73,4
	Visit 4	2,0	6,0	15,0	18,0	21,4
	Absolute reduction	-,4	2,0	6,0	14,0	18,4
	% reduction	-2,5	11,1	29,2	68,4	90,2

Exploratory between-group comparison of pain sum score by means of Mann Whitney statistic (ITT, locf)

Higher Mann-Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,4939	0,416	0,572	0,8998
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,6014	0,507	-	0,0191 *
Absolute reduction	0,6043	0,510	-	0,0165 *
% reduction	0,6051	0,510	-	0,0161 *
Visit 3	0,5808	0,486	-	0,0488 +
Absolute reduction	0,5710	0,477	-	0,0728
% reduction	0,5722	0,478	-	0,0698
Visit 4	0,6178	0,523	-	0,0082 *
Absolute reduction	0,6205	0,525	-	0,0071 *
% reduction	0,6160	0,521	-	0,0092 *

Pain sum scores:(Mann-Whitney statistic with 97.5% CI



The results of the ITT analysis are largely supported by the PP analysis. With the baseline scores being comparable ($p = 0.7102$), exploratory analysis yielded significant differences for visits 2 and 4.

Pain sum score. absolute scores and reduction since visit 1 - basic statistics (PP analysis, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	20,45	2,32	16	25	58
	Visit 2	14,95	5,06	5	25	58
	Absolute reduction	5,50	4,77	-5	16	58
	% reduction	26,99	23,20	-25	73	58
	Visit 3	12,50	5,77	0	24	58
	Absolute reduction	7,95	5,82	-2	22	58
	% reduction	38,72	27,42	-10	100	58
	Visit 4	9,83	6,83	0	26	58
	Absolute reduction	10,62	6,94	-6	23	58
	% reduction	51,83	32,96	-30	100	58
Placebo	Visit 1	20,30	2,56	16	26	67
	Visit 2	16,36	4,86	2	28	67
	Absolute reduction	3,94	4,08	-4	18	67
	% reduction	19,75	21,03	-17	90	67
	Visit 3	14,16	5,20	2	27	67
	Absolute reduction	6,13	4,93	-3	18	67
	% reduction	30,19	24,44	-13	90	67
	Visit 4	12,75	6,68	0	27	67
	Absolute reduction	7,55	6,38	-3	21	67
	% reduction	37,37	32,28	-19	100	67

Exploratory between-group comparison of pain sum score by means of Mann Whitney statistic (PP analysis, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,4807	0,398	0,563	0,7102
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,5933	0,492	-	0,0371 +
Absolute reduction	0,6101	0,509	-	0,0178 *
% reduction	0,6112	0,508	-	0,0172 *
Visit 3	0,5921	0,490	-	0,0389 +
Absolute reduction	0,5944	0,493	-	0,0356 +
% reduction	0,5938	0,491	-	0,0368 +
Visit 4	0,6189	0,516	-	0,0118 *
Absolute reduction	0,6319	0,529	-	0,0062 *
% reduction	0,6258	0,522	-	0,0085 *

Pain sum score. Absolute scores and reduction since visit 1 - Percentiles (PP analysis, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	17,0	18,0	20,5	22,0	25,0
	Visit 2	6,0	10,8	15,0	19,0	24,0
	Absolute reduction	-1,1	2,0	5,5	9,3	13,1
	% reduction	-6,6	9,4	27,8	45,1	72,2
	Visit 3	4,0	8,0	12,0	16,5	22,1
	Absolute reduction	-2,0	3,8	8,0	13,0	16,2
	% reduction	-9,1	16,5	41,9	60,0	80,0
	Visit 4	,0	4,8	8,0	15,3	22,1
	Absolute reduction	-2,0	5,8	11,0	16,3	21,0
	% reduction	-9,2	28,9	60,2	76,5	100,0
Placebo	Visit 1	16,0	18,0	20,0	22,0	24,0
	Visit 2	6,0	13,0	17,0	19,0	23,6
	Absolute reduction	-,6	1,0	3,0	6,0	11,6
	% reduction	-2,9	5,0	14,3	29,2	65,0
	Visit 3	4,8	9,0	16,0	18,0	21,0
	Absolute reduction	,0	2,0	5,0	10,0	15,0

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
	% reduction	,0	8,7	25,0	50,0	75,9
	Visit 4	2,0	6,0	15,0	18,0	21,6
	Absolute reduction	-,6	2,0	6,0	14,0	18,0
	% reduction	-3,8	9,5	26,3	68,4	90,3

Center effects

The study protocol did not provide the assessment of center effects in the biometric analysis. Further, center effects were minimised by distributing the patients, randomised in blocks of four, to as many centers as possible. 14 of the 23 trial centers had enrolled more than 8 patients into the study, when regarding both treatment collectives (cSTP and cBP). Center effects were calculated for the reduction in pain sum score as the basic variable for the main target criterion for both collectives in a separate manner.

Chronic Soft Tissue Pain

For the cSTP collective, a more pronounced reduction in pain sum score (mean > 50 %) on capsicum treatment was found at 10 centers, a less pronounced one (mean < 50 %) at 8 centers. Centers with less than 4 recruited patients were not considered. Practically no difference between verum and placebo treatment or superiority of placebo treatment was found at 6 centers. If the evaluation is restricted to the 13 centers with at least 4 enrolled patients – 2 per medication - a more marked effect on pain sum score was documented for capsicum at 8 centers and for placebo at 5 centers.

Pain sum score at the individual test centers (ITT, locf)

		Capsicum			Placebo		
Investigator		Mean	Median	N	Mean	Median	N
Dieter	Visit 1	18,00	18,00	1	,	,	
	Visit 4	3,00	3,00	1	,	,	
	% reduction	83,33	83,33	1	,	,	
Nadjar	Visit 1	24,33	25,00	3	24,00	23,50	4
	Visit 4	21,33	22,00	3	20,00	20,00	4
	% reduction	11,90	7,69	3	15,96	17,93	4

		Capsicum			Placebo		
Investigator		Mean	Median	N	Mean	Median	N
Mahla	Visit 1	19,00	19,00	5	22,25	21,00	4
	Visit 4	8,60	8,00	5	11,00	11,00	4
	% reduction	54,82	57,89	5	47,92	42,45	4
Mahner	Visit 1	,	,		,	,	
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	
Hertzberg	Visit 1	23,67	23,00	3	23,00	23,00	3
	Visit 4	13,33	12,00	3	10,33	10,00	3
	% reduction	44,46	47,83	3	55,08	54,55	3
Freise	Visit 1	,	,		22,00	22,00	3
	Visit 4	,	,		14,00	19,00	3
	% reduction	,	,		36,24	17,39	3
Neugart	Visit 1	22,50	22,00	4	22,33	22,00	3
	Visit 4	3,75	4,00	4	13,33	19,00	3
	% reduction	83,33	82,58	4	40,42	20,83	3
Gnisa	Visit 1	20,75	21,00	4	19,33	19,50	6
	Visit 4	8,75	7,50	4	16,00	17,50	6
	% reduction	60,04	64,32	4	16,89	10,26	6
Judaschke	Visit 1	,	,		,	,	
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	
Poswiat, Ch.	Visit 1	20,50	20,50	2	21,67	21,00	3
	Visit 4	4,50	4,50	2	14,33	17,00	3
	% reduction	79,55	79,55	2	33,98	20,00	3
Poswiat, W.	Visit 1	20,00	20,00	1	,	,	
	Visit 4	13,00	13,00	1	,	,	
	% reduction	35,00	35,00	1	,	,	
Spenke	Visit 1	20,50	20,50	2	20,33	20,00	3
	Visit 4	11,50	11,50	2	18,67	19,00	3
	% reduction	43,06	43,06	2	7,97	5,26	3
Stephan	Visit 1	20,67	20,00	3	,	,	
	Visit 4	1,67	2,00	3	,	,	
	% reduction	91,97	90,91	3	,	,	

		Capsicum			Placebo		
Investigator		Mean	Median	N	Mean	Median	N
Stähr	Visit 1	20,50	20,50	2	22,00	22,00	3
	Visit 4	8,00	8,00	2	16,33	18,00	3
	% reduction	60,83	60,83	2	27,17	18,18	3
Alt, H.	Visit 1	,	,		19,33	20,00	3
	Visit 4	,	,		13,67	13,00	3
	% reduction	,	,		27,91	35,00	3
Alt, U.	Visit 1	16,00	16,00	1	19,00	19,00	1
	Visit 4	15,00	15,00	1	12,00	12,00	1
	% reduction	6,25	6,25	1	36,84	36,84	1
Englert	Visit 1	18,50	18,50	2	,	,	
	Visit 4	4,50	4,50	2	,	,	
	% reduction	75,44	75,44	2	,	,	
Barth	Visit 1	26,00	28,00	3	27,00	27,50	4
	Visit 4	15,00	15,00	3	9,75	11,50	4
	% reduction	42,21	40,91	3	64,58	58,93	4
Schnapp	Visit 1	20,50	19,50	4	19,25	19,50	4
	Visit 4	8,00	7,00	4	6,25	5,50	4
	% reduction	59,47	68,50	4	67,76	72,50	4
Sommer	Visit 1	21,88	22,00	8	22,50	22,50	8
	Visit 4	12,63	12,50	8	16,00	16,50	8
	% reduction	42,33	42,68	8	30,19	25,00	8
Schmitz	Visit 1	19,67	21,50	6	21,25	21,00	4
	Visit 4	16,33	17,00	6	12,00	15,50	4
	% reduction	14,44	4,76	6	44,62	29,71	4
Reifferscheid	Visit 1	,	,		,	,	
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	
Ulbrich	Visit 1	18,70	19,00	10	17,40	17,50	10
	Visit 4	9,30	9,50	10	15,10	15,50	10
	% reduction	51,18	46,88	10	12,90	10,48	10

Chronic Pack Pain

For the cBP collective, a more pronounced reduction in the pain sum score (mean > 50 %) on capsicum treatment was found at 6 centers, a less pronounced one (mean < 50 %) at 9 centers. Centers with less than 4 recruited patients were not considered. Practically no difference between verum and placebo treatment or superiority of placebo treatment was found at 6 centers. If the evaluation is restricted to the 13 centers with at least 4 enrolled patients – 2 per medication - a more marked effect on pain sum score was documented for capsicum at 9 centers and for placebo at 1 center (no difference at 3 centers).

Pain sum score at the individual test centers (ITT, locf)

		Capsicum			Placebo		
Investigator		Mean	Median	N	Mean	Median	N
Dieter	Visit 1	22,00	22,00	1	18,00	18,00	2
	Visit 4	,00	,00	1	1,00	1,00	2
	% reduction	100,00	100,00	1	94,44	94,44	2
Nadjar	Visit 1	21,60	22,00	5	22,25	22,00	4
	Visit 4	18,40	19,00	5	19,75	20,00	4
	% reduction	15,36	17,39	5	11,25	11,01	4
Mahla	Visit 1	19,33	19,00	3	17,50	17,50	4
	Visit 4	12,33	12,00	3	16,50	17,50	4
	% reduction	38,39	36,84	3	4,28	0,49	4
Mahner	Visit 1	19,00	19,00	8	18,88	18,00	8
	Visit 4	12,75	12,00	8	16,88	15,50	8
	% reduction	34,15	36,94	8	11,33	8,68	8
Hertzberg	Visit 1	22,00	22,00	1	24,00	24,00	1
	Visit 4	7,00	7,00	1	18,00	18,00	1
	% reduction	68,18	68,18	1	25,00	25,00	1
Freise	Visit 1	21,50	22,00	4	25,00	25,00	1
	Visit 4	14,25	15,50	4	17,00	17,00	1
	% reduction	32,84	27,27	4	32,00	32,00	1
Neugart	Visit 1	23,50	24,00	8	23,00	24,00	9
	Visit 4	7,63	7,00	8	14,56	17,00	9
	% reduction	67,54	71,13	8	37,36	29,17	9
Gnisa	Visit 1	20,33	22,00	3	20,00	20,00	2

		Capsicum			Placebo		
Investigator		Mean	Median	N	Mean	Median	N
	Visit 4	12,33	15,00	3	16,50	16,50	2
	% reduction	36,40	34,78	3	17,50	17,50	2
Judaschke	Visit 1	18,25	18,00	4	18,33	18,00	3
	Visit 4	4,25	4,00	4	4,00	3,00	3
	% reduction	76,59	79,17	4	78,36	83,33	3
Poswiat, Ch.	Visit 1	18,75	18,00	4	20,00	20,00	2
	Visit 4	2,75	3,00	4	10,00	10,00	2
	% reduction	85,32	84,52	4	49,12	49,12	2
Poswiat, W.	Visit 1	20,60	21,00	5	21,20	21,00	5
	Visit 4	4,80	4,00	5	10,80	11,00	5
	% reduction	76,32	80,95	5	49,31	47,62	5
Spenske	Visit 1	20,00	20,00	1	18,33	19,00	3
	Visit 4	19,00	19,00	1	17,00	16,00	3
	% reduction	5,00	5,00	1	6,93	5,00	3
Stephan	Visit 1	20,60	20,00	5	20,75	20,50	8
	Visit 4	4,40	3,00	5	12,25	15,00	8
	% reduction	79,01	85,00	5	40,78	31,25	8
Stähr	Visit 1	20,33	20,50	6	18,60	19,00	5
	Visit 4	11,83	11,50	6	8,60	4,00	5
	% reduction	42,15	43,05	6	57,01	75,00	5
Alt, H.	Visit 1	21,00	21,50	6	19,00	18,00	3
	Visit 4	10,50	9,50	6	15,33	16,00	3
	% reduction	46,58	53,95	6	17,79	11,11	3
Alt, U.	Visit 1	17,33	17,00	3	21,33	23,00	3
	Visit 4	12,00	12,00	3	16,33	19,00	3
	% reduction	30,28	29,41	3	29,08	17,39	3
Englert	Visit 1	22,50	22,50	2	22,25	22,50	4
	Visit 4	4,00	4,00	2	4,00	4,00	4
	% reduction	81,82	81,82	2	81,90	80,48	4
Barth	Visit 1	,	,		,	,	
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	
Schnapp	Visit 1	,	,		,	,	

		Capsicum			Placebo		
Investigator		Mean	Median	N	Mean	Median	N
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	
Sommer	Visit 1	,	,		,	,	
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	
Schmitz	Visit 1	22,00	22,00	1	21,00	21,00	2
	Visit 4	24,00	24,00	1	10,50	10,50	2
	% reduction	-9,09	-9,09	1	50,00	50,00	2
Reifferscheid	Visit 1	19,00	19,00	1	23,00	23,00	2
	Visit 4	19,00	19,00	1	9,00	9,00	2
	% reduction	,00	,00	1	60,87	60,87	2
Ulbrich	Visit 1	,	,		,	,	
	Visit 4	,	,		,	,	
	% reduction	,	,		,	,	

Responder analysis (ITT, locf)

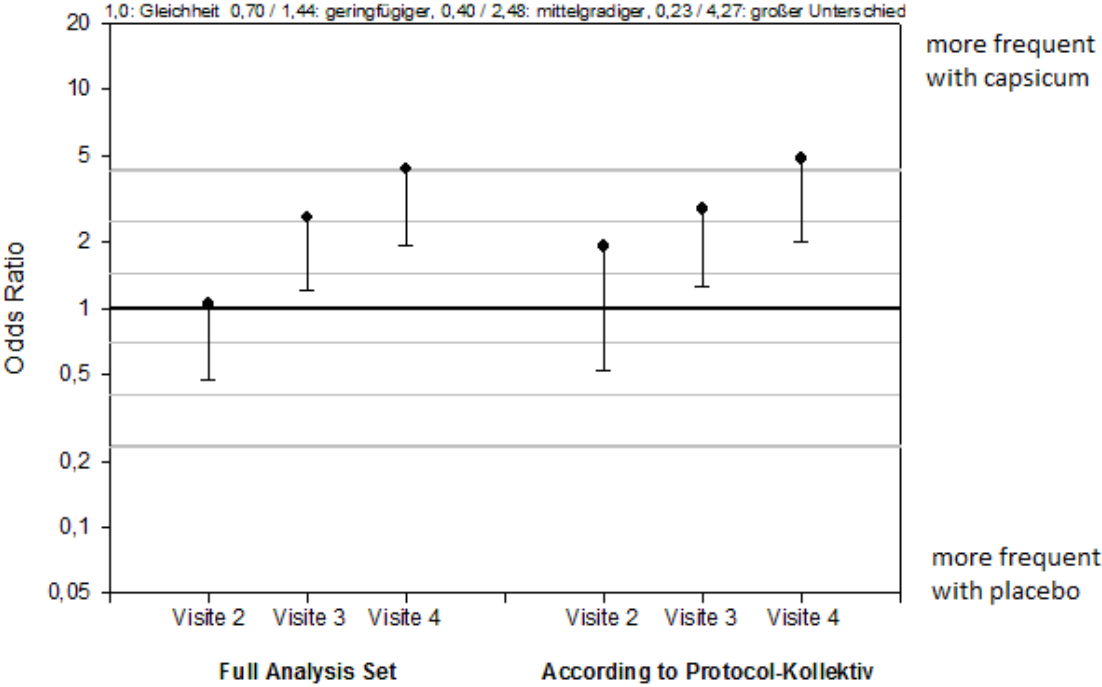
		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Responders		N	%	N	%	N	%	N	%	N	%	N	%
(30%) Visit 2	yes	22	34,4%	22	33,3%	44	33,8%	34	47,9%	17	23,9%	51	35,9%
	no	42	65,6%	44	66,7%	86	66,2%	37	52,1%	54	76,1%	91	64,1%
Visit 3	yes	42	65,6%	28	42,4%	70	53,8%	43	60,6%	32	45,1%	75	52,8%
	no	22	34,4%	38	57,6%	60	46,2%	28	39,4%	39	54,9%	67	47,2%
Visit 4	yes	48	75,0%	27	40,9%	75	57,7%	52	73,2%	35	49,3%	87	61,3%
	no	16	25,0%	39	59,1%	55	42,3%	19	26,8%	36	50,7%	55	38,7%
(50%) Visit 2	yes	5	7,8%	9	13,6%	14	10,8%	13	18,3%	6	8,5%	19	13,4%
	no	59	92,2%	57	86,4%	116	89,2%	58	81,7%	65	91,5%	123	86,6%
Visit 3	yes	23	35,9%	15	22,7%	38	29,2%	29	40,8%	21	29,6%	50	35,2%
	no	41	64,1%	51	77,3%	92	70,8%	42	59,2%	50	70,4%	92	64,8%
Visit 4	yes	32	50,0%	19	28,8%	51	39,2%	42	59,2%	24	33,8%	66	46,5%
	no	32	50,0%	47	71,2%	79	60,8%	29	40,8%	47	66,2%	76	53,5%

Exploratory between-group comparison of responder rate by means of Odds Ratio
 – (Fisher’s Exact Test) (ITT, locf)

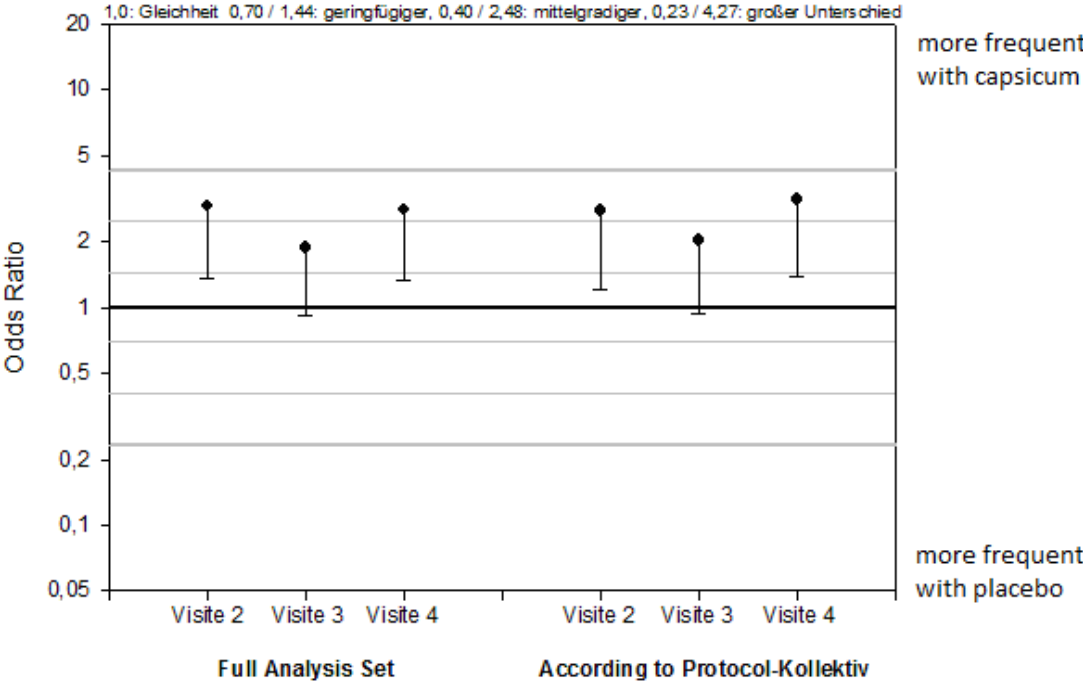
Higher Odds Ratio values correspond to a superiority of the capsicum group
 (1,000 – equality, 1,438 – small, 2,477 – moderate, 4,270 – high superiority)

Responders		Odds Ratio	97,5% Confidence interval Lower limit only		P value (one-tailed)	
Chronic soft tissue pain	30%: Visit 2 Visit 3 Visit 4	1,0476	0,475	-	0,5237	
		2,5909	1,202	-	0,0065	*
		4,3333	1,929	-	< 0,0001	***
	50%: Visit 2 Visit 3 Visit 4	0,5367	0,134	-	0,9130	
		1,9073	0,827	-	0,0716	
		2,4737	1,131	-	0,0106	*
Chronic back pain	30%: Visit 2 Visit 3 Visit 4	2,9189	1,348	-	0,0024	**
		1,8717	0,912	-	0,0462	+
		2,8150	1,321	-	0,0028	**
	50%: Visit 2 Visit 3 Visit 4	2,4282	0,793	-	0,0688	
		1,6440	0,776	-	0,1093	
		2,8362	1,359	-	0,0020	**

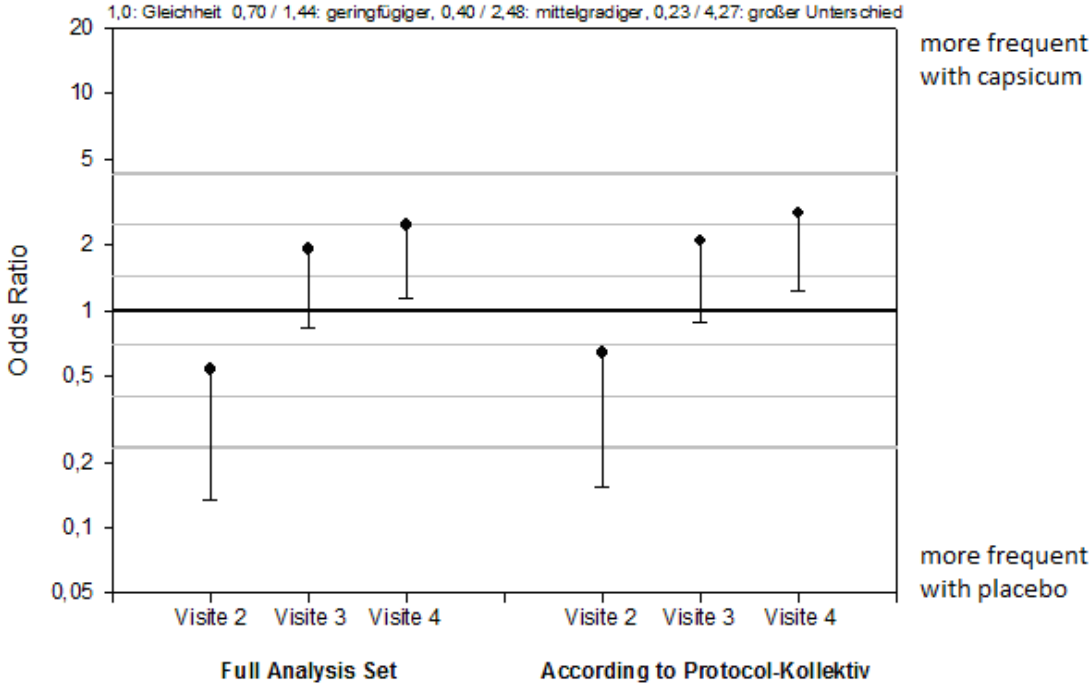
Responder rates (pain sum score reduction >- 30%) of patients suffering from chronic soft tissue pain
 - Odds ratio with 97,5% confidence interval



Responder rates (pain sum score reduction >- 30%) of patients suffering from chronic back pain
 - Odds ratio with 97,5% confidence interval



Responder rates (pain sum score reduction >- 50%) of patients suffering from chronic soft tissue pain
 - Odds ratio with 97,5% confidence interval



Exploratory between-group comparison of responder rate by means of Odds Ratio –
(Fisher's Exact Test) (PP, locf)

Higher Odds Ratio values correspond to a superiority of the capsicum group (1,000 – equality, 1,438 – small, 2,477 – moderate, 4,270 – high superiority)

Responder		Odds Ratio	97,5% Confidence interval Lower limit only		P value (one-tailed)
Soft tissue rheumatic pain	30%:	Visit 2	1,1919	0,523 -	0,3961
		Visit 3	2,8421	1,267 -	0,0053 *
		Visit 4	4,7929	2,023 -	< 0,0001 ***
	50%:	Visit 2	0,6368	0,154 -	0,8527
		Visit 3	2,0952	0,880 -	0,0509
		Visit 4	2,8066	1,240 -	0,0055 *
Back pains of other origin	30%:	Visit 2	2,7762	1,214 -	0,0066 *
		Visit 3	2,0182	0,929 -	0,0397 +
		Visit 4	3,1354	1,382 -	0,0022 **
	50%:	Visit 2	2,3794	0,737 -	0,0859
		Visit 3	1,9139	0,854 -	0,0625
		Visit 4	2,9112	1,322 -	0,0031 **

Pain subscores

Average pain within the past 24 hours

With a comparable baseline intensity (cSTP collective: $p = 0.8764$; cBP collective: $p = 0.8143$) of pain, the mean reduction of the average pain within the past 24 hours achieved was 52.8 % in the capsicum group versus 34.0 % in the placebo group of the cSTP collective, and 53.3 % in the capsicum group versus 38.1 % in the placebo group of the cBP collective

In cSTP collective, the reduction in pain became clearly more pronounced in the capsicum group compared to placebo during the course of the trial. Similarly, the between-group comparison demonstrated a stronger proof of superiority for capsicum at visit 4 than at the visits before.

In cBP collective, the groups differed clearly at visits 2 and 4. The group difference was less pronounced at visit 3.

A decrease in average pain (median) within the past 24 hours was reported for capsicum groups with 57.1 % and 62.5 % versus placebo groups with 23.6 % and 28.6 % for the cSTP and the cBP collective, respectively. A reduction by ≥ 3 points in average pain was observed in 73.5 % and 70.4 % of the capsicum groups versus 39.4 % and 45.1 % of the placebo groups for the cSTP and the cBP collective, respectively.

Group chronic soft tissue pain:

Average pain within the past 24 hours: Absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	6,81	1,18	5	10	64
	Visit 2	4,95	1,69	1	10	64
	Absolute reduction	1,86	1,40	-1	5	64
	% reduction	27,48	21,30	-20	83	64
	Visit 3	3,97	2,11	0	10	64
	Absolute reduction	2,84	1,82	-2	8	64
	% reduction	42,67	27,54	-29	100	64
	Visit 4	3,25	2,30	0	9	64
	Absolute reduction	3,56	2,16	-2	8	64
% reduction	52,84	32,22	-29	100	64	
Placebo	Visit 1	6,82	1,19	5	10	66
	Visit 2	5,18	2,01	0	9	66

	Absolute reduction	1,64	2,03	-2	9	66
	% reduction	23,24	28,56	-33	100	66
	Visit 3	4,74	1,98	0	9	66
	Absolute reduction	2,08	2,19	-1	9	66
	% reduction	29,01	29,67	-17	100	66
	Visit 4	4,41	2,13	0	9	66
	Absolute reduction	2,41	2,32	-1	8	66
	% reduction	34,04	32,08	-20	100	66

Exploratory between-group comparison of subscore average pain within the past 24 hours (ITT, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group
(0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,4922	0,412	0,572	0,8764
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,5678	0,471	-	0,0881
Absolute reduction	0,5806	0,486	-	0,0529
% reduction	0,5913	0,494	-	0,0363 +
Visit 3	0,6293	0,532	-	0,0049 **
Absolute reduction	0,6349	0,538	-	0,0035 **
% reduction	0,6476	0,548	-	0,0021 **
Visit 4	0,6609	0,562	-	0,0006 **
Absolute reduction	0,6538	0,556	-	0,0011 **
% reduction	0,6695	0,569	-	0,0005 ***

Average pain within the past 24 hours: absolute scores and reduction since visit 1 - percentiles (ITT, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	5,0	6,0	7,0	8,0	9,0
	Visit 2	2,3	4,0	5,0	6,0	8,0
	Absolute reduction	,0	1,0	2,0	3,0	4,8
	% reduction	,0	12,9	28,6	42,9	62,5
	Visit 3	,3	2,3	4,0	5,0	7,8
	Absolute reduction	,0	2,0	3,0	4,0	6,0

	% reduction	,0	25,9	42,9	61,9	95,8
	Visit 4	,0	1,3	3,0	5,0	8,0
	Absolute reduction	,0	2,0	4,0	5,0	7,0
	% reduction	,0	34,4	57,1	78,8	100,0
Placebo	Visit 1	5,0	6,0	7,0	8,0	9,0
	Visit 2	,4	4,0	5,5	6,0	8,0
	Absolute reduction	-,6	,0	1,0	3,0	5,6
	% reduction	-8,1	,0	16,7	37,5	96,5
	Visit 3	1,0	3,0	5,0	6,0	7,0
	Absolute reduction	,0	,0	1,5	3,0	6,0
	% reduction	,0	,0	21,1	50,0	88,5
	Visit 4	,0	3,0	5,0	6,0	7,0
	Absolute reduction	,0	1,0	2,0	4,0	7,0
	% reduction	,0	12,5	23,6	58,5	100,0

Group chronic back pain:

Average pain within the past 24 hours: Absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	6,59	,99	5	9	71
	Visit 2	4,73	1,66	1	8	71
	Absolute reduction	1,86	1,68	-3	5	71
	% reduction	27,45	26,47	-60	83	71
	Visit 3	3,97	1,90	0	8	71
	Absolute reduction	2,62	2,11	-2	7	71
	% reduction	38,40	31,63	-40	100	71
	Visit 4	3,00	2,27	0	8	71
	Absolute reduction	3,59	2,49	-3	8	71
	% reduction	53,25	36,11	-60	100	71
Placebo	Visit 1	6,62	,99	5	8	71
	Visit 2	5,34	1,67	0	9	71
	Absolute reduction	1,28	1,45	-2	6	71
	% reduction	19,43	23,33	-29	100	71
	Visit 3	4,48	1,79	0	9	71

	Absolute reduction	2,14	1,77	-2	6	71
	% reduction	31,99	26,76	-29	100	71
	Visit 4	4,07	2,30	0	9	71
	Absolute reduction	2,55	2,31	-2	7	71
	% reduction	38,12	35,52	-40	100	71

Exploratory between-group comparison of subscore average pain within the past 24 hours (ITT, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,5109	0,434	0,587	0,8143
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,6216	0,529	-	0,0052 *
Absolute reduction	0,6194	0,527	-	0,0060 *
% reduction	0,6197	0,525	-	0,0072 *
Visit 3	0,5814	0,491	-	0,0400 +
Absolute reduction	0,5793	0,487	-	0,0497 +
% reduction	0,5815	0,488	-	0,0474 +
Visit 4	0,6284	0,535	-	0,0037 **
Absolute reduction	0,6190	0,525	-	0,0067 *
% reduction	0,6175	0,522	-	0,0083 *

Average pain within the past 24 hours: absolute scores and reduction since visit 1 - percentiles (ITT, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	5,0	6,0	7,0	7,0	8,0
	Visit 2	2,0	4,0	5,0	6,0	8,0
	Absolute reduction	-1,0	1,0	2,0	3,0	4,4
	% reduction	-16,6	12,5	28,6	42,9	71,4
	Visit 3	1,0	2,0	4,0	6,0	7,0
	Absolute reduction	-1,0	1,0	3,0	5,0	5,0
	% reduction	-18,0	14,3	42,9	62,5	83,3
	Visit 4	,0	1,0	2,0	5,0	7,4
	Absolute reduction	,0	1,0	4,0	5,0	7,0

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
	% reduction	,0	20,0	62,5	83,3	100,0
Placebo	Visit 1	5,0	6,0	7,0	7,0	8,0
	Visit 2	2,0	4,0	6,0	6,0	8,0
	Absolute reduction	-1,0	,0	1,0	2,0	4,0
	% reduction	-16,6	,0	14,3	28,6	62,7
	Visit 3	1,0	3,0	5,0	6,0	7,0
	Absolute reduction	,0	1,0	2,0	3,0	5,4
	% reduction	,0	14,3	28,6	50,0	84,3
	Visit 4	,0	2,0	5,0	6,0	7,0
	Absolute reduction	-1,0	1,0	2,0	5,0	6,0
	% reduction	-15,5	14,3	28,6	71,4	100,0

Change in average pain within the past 24 hours from visit 1 to visit 4 (ITT, locf)

		Capsicum		Placebo		Total	
Change		N	%	N	%	N	%
Chronic soft tissue pain	Reduction by more than 5 points	12	18,8%	8	12,1%	20	15,4%
	Reduction by 3-5 points	35	54,7%	18	27,3%	53	40,8%
	Reduction by 1-2 points	8	12,5%	25	37,9%	33	25,4%
	No change	8	12,5%	14	21,2%	22	16,9%
	Increase by 1-2 points	1	1,6%	1	1,5%	2	1,5%
Chronic back pain	Reduction by more than 5 points	17	23,9%	10	14,1%	27	19,0%
	Reduction by 3-5 points	33	46,5%	22	31,0%	55	38,7%
	Reduction by 1-2 points	9	12,7%	25	35,2%	34	23,9%
	No change	10	14,1%	10	14,1%	20	14,1%
	Increase by 1-2 points	1	1,4%	4	5,6%	5	3,5%
	Increase by 3-5 points	1	1,4%			1	,7%

Worst pain within the past 3 days

In the cSTP collective, the worst pain decreased by a mean of 49.4 % in the capsicum group, versus a mean of 32.3 % in the placebo group. The corresponding median values were 50.0

% and 25.0 %.

In the cBP collective, the worst pain decreased by a mean of 49.0 % in the capsicum group, versus a mean of 37.4 % in the placebo group. The corresponding median values were 57.1 % and 28.6 %.

In the cSTP collective, a reduction by ≥ 3 points was achieved in 65.6 % of the capsicum and 43.9 % of the placebo patients. In the cBP collective, a reduction by ≥ 3 points was achieved in 69.1 % of the capsicum and 46.5 % of the placebo patients.

The Mann Whitney statistic showed for both treatment collectives a more than small superiority at visits 2+3 and a moderate one at visit 4. On visit 4, group differences were highly significant.

Chronic soft tissue pain

Worst pain within the past 3 days: Absolute scores and decrease since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	7,59	1,18	5	10	64
	Visit 2	5,88	1,55	3	10	64
	Abs. reduction	1,72	1,47	-2	5	64
	% reduction	22,02	19,47	-40	63	64
	Visit 3	4,72	1,96	1	9	64
	Abs. reduction	2,88	1,83	-1	7	64
	% reduction	38,08	24,00	-13	86	64
	Visit 4	3,84	2,25	0	9	64
	Abs. reduction	3,75	2,24	-1	9	64
	% reduction	49,42	28,68	-13	100	64
Placebo	Visit 1	7,79	1,12	5	10	66
	Visit 2	6,05	1,79	2	9	66
	Abs. reduction	1,74	1,96	-2	8	66
	% reduction	21,14	24,27	-40	80	66
	Visit 3	5,50	1,72	1	9	66
	Abs. reduction	2,29	1,99	-1	9	66
	% reduction	27,97	24,06	-20	90	66
	Visit 4	5,15	1,96	0	8	66
	Abs. reduction	2,64	2,28	-1	9	66
	% reduction	32,27	27,03	-20	100	66

Exploratory between-group comparison of subscore worst pain within the past 3 days (ITT, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,5408	0,462	0,620	0,4002
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,5588	0,462	-	0,1201
Absolute reduction	0,5334	0,437	-	0,2528
% reduction	0,5484	0,450	-	0,1696
Visit 3	0,6319	0,535	-	0,0041 **
Absolute reduction	0,5960	0,498	-	0,0280 +
% reduction	0,6188	0,520	-	0,0103 *
Visit 4	0,6916	0,594	-	< 0,0001 ***
Absolute reduction	0,6522	0,554	-	0,0012 **
% reduction	0,6781	0,578	-	0,0003 ***

Worst pain within the past 3 days: Absolute scores and reduction since visit 1 – percentiles (ITT, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	5,3	7,0	8,0	8,0	9,8
	Visit 2	3,0	5,0	6,0	7,0	9,0
	Abs. reduction	-1,0	1,0	2,0	3,0	4,0
	% reduction	-12,2	12,5	25,0	37,5	50,0
	Visit 3	1,3	4,0	5,0	6,0	8,8
	Abs. reduction	,0	1,3	3,0	4,0	6,0
	% reduction	,0	20,6	37,5	54,2	78,8
	Visit 4	,3	2,0	4,0	5,0	8,0
	Abs. reduction	,0	2,0	4,0	5,0	7,0
	% reduction	,0	28,6	50,0	72,9	97,5
Placebo	Visit 1	5,4	7,0	8,0	8,0	10,0
	Visit 2	2,0	5,0	6,0	7,0	9,0
	Abs. reduction	,0	,0	1,0	3,0	5,6
	% reduction	,0	,0	13,4	37,5	73,8
	Visit 3	2,0	4,0	6,0	7,0	8,0
	Abs. reduction	-,6	1,0	2,0	4,0	5,6
	% reduction	-9,3	12,5	25,0	44,4	72,1

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
	Visit 4	1,0	4,0	6,0	6,0	8,0
	Abs. reduction	,0	1,0	2,0	4,0	7,6
	% reduction	,0	14,3	25,0	50,0	88,4

Chronic back pain

Worst pain within the past 3 days: Absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	7,61	,92	6	10	71
	Visit 2	5,68	1,65	2	9	71
	Abs. reduction	1,93	1,60	-1	6	71
	% reduction	25,19	20,05	-14	75	71
	Visit 3	4,89	2,03	0	9	71
	Abs. reduction	2,72	2,04	-1	8	71
	% reduction	35,61	25,43	-13	100	71
	Visit 4	3,87	2,40	0	10	71
	Abs. reduction	3,73	2,44	-2	9	71
	% reduction	48,99	31,07	-25	100	71
Placebo	Visit 1	7,59	1,17	6	10	71
	Visit 2	6,08	1,69	2	10	71
	Abs. reduction	1,51	1,41	-1	5	71
	% reduction	19,90	19,95	-14	71	71
	Visit 3	5,27	1,79	1	9	71
	Abs. reduction	2,32	1,76	0	7	71
	% reduction	30,32	22,84	0	83	71
	Visit 4	4,76	2,28	0	9	71
	Abs. reduction	2,83	2,16	-1	7	71
	% reduction	37,40	29,99	-17	100	71

Exploratory between-group comparison of subscore worst pain within the past 3 days (ITT, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,4814	0,405	0,557	0,6895
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,5864	0,494	-	0,0351 +
Absolute reduction	0,5734	0,480	-	0,0617
% reduction	0,5888	0,496	-	0,0341 +

Visit 3		0,5651	0,472	-	0,0882
	Absolute reduction	0,5590	0,466	-	0,1100
	% reduction	0,5580	0,464	-	0,1166
Visit 4		0,6122	0,520	-	0,0098 *
	Absolute reduction	0,6107	0,516	-	0,0107 *
	% reduction	0,6146	0,520	-	0,0098 *

Worst pain within the past 3 days: Absolute scores and reduction since visit 1 – percentiles (ITT, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	6,0	7,0	8,0	8,0	9,0
	Visit 2	3,0	4,0	6,0	7,0	8,0
	Abs. reduction	,0	1,0	2,0	3,0	5,0
	% reduction	,0	12,5	25,0	37,5	62,5
	Visit 3	2,0	3,0	5,0	6,0	8,4
	Abs. reduction	,0	1,0	3,0	4,0	6,0
	% reduction	,0	12,5	37,5	55,6	75,0
	Visit 4	,0	2,0	3,0	6,0	8,0
	Abs. reduction	-,4	2,0	4,0	6,0	8,0
	% reduction	-5,0	28,6	57,1	71,4	100,0
Placebo	Visit 1	6,0	7,0	8,0	8,0	10,0
	Visit 2	2,0	5,0	6,0	7,0	8,4
	Abs. reduction	,0	,0	1,0	2,0	4,0
	% reduction	,0	,0	16,7	28,6	66,7
	Visit 3	2,0	4,0	6,0	7,0	7,4
	Abs. reduction	,0	1,0	2,0	4,0	6,0
	% reduction	,0	14,3	25,0	50,0	70,6
	Visit 4	1,0	3,0	5,0	6,0	7,4
	Abs. reduction	,0	1,0	2,0	5,0	6,0
	% reduction	,0	14,3	28,6	62,5	86,4

Change in worst pain within the past 3 days from visit 1 to visit 4 (ITT, locf)

		Capsicum		Placebo		Gesamt	
Change		N	%	N	%	N	%
Chronic soft tissue pain	Reduction by more than 5 points	15	23,4%	9	13,6%	24	18,5%
	Reduction by 3-5 points	27	42,2%	20	30,3%	47	36,2%
	Reduction by 1-2 points	17	26,6%	28	42,4%	45	34,6%
	No change	4	6,3%	8	12,1%	12	9,2%
	Increase by 1-2 points	1	1,6%	1	1,5%	2	1,5%
Chronic back pain	Reduction by more than 5 points	18	25,4%	10	14,1%	28	19,7%
	Reduction by 3-5 points	31	43,7%	23	32,4%	54	38,0%
	Reduction by 1-2 points	14	19,7%	28	39,4%	42	29,6%
	No change	5	7,0%	9	12,7%	14	9,9%
	Increase by 1-2 points	3	4,2%	1	1,4%	4	2,8%

Average pain intensity within the past 3 days

In the cSTP collective, the average pain intensity decreased by 47.5 % in the capsicum group and by 30 % in the placebo group. The corresponding median values were 50.0 % and 21.1 %.

In the cBP collective, the average pain intensity decreased by 50.2 % in the capsicum group and by 36.3 % in the placebo group. The corresponding median values were 57.1 % and 28.6 %.

In the cSTP collective, a reduction by ≥ 3 points was achieved in 67.2 % of the capsicum and 36.4 % of the placebo patients. In the cBP collective, a reduction by ≥ 3 points was achieved in 62 % of the capsicum and 39.5 % of the placebo patients.

The Mann Whitney statistic revealed for both treatment collectives a more than small superiority at all follow-up visits and even a moderate one at visit 4 in cSTP collective. On visit 4, the group differences were significant.

Chronic soft tissue pain

Average pain within the past 3 days.

Absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	6,34	1,18	2	9	64
	Visit 2	4,78	1,40	1	8	64
	Abs. reduction	1,56	1,45	-2	5	64
	% reduction	22,49	26,42	-100	83	64
	Visit 3	3,89	1,83	1	9	64
	Abs. reduction	2,45	1,82	-2	6	64
	% reduction	37,56	30,13	-50	86	64
	Visit 4	3,20	2,12	0	8	64
	Abs. reduction	3,14	2,22	-2	7	64
	% reduction	47,49	38,45	-100	100	64
Placebo	Visit 1	6,55	1,23	3	9	66
	Visit 2	5,20	1,78	1	9	66
	Abs. reduction	1,35	1,74	-3	7	66
	% reduction	19,48	27,21	-60	88	66
	Visit 3	4,76	1,83	1	8	66
	Abs. reduction	1,79	2,01	-2	7	66
	% reduction	25,28	30,61	-50	88	66
	Visit 4	4,45	1,95	0	7	66
	Abs. reduction	2,09	2,17	-2	8	66
	% reduction	29,97	32,70	-50	100	66

Exploratory between-group comparison of subscore average pain within the past 3 days (ITT, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,5393	0,4599	0,6187	0,4211
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,6023	0,507	-	0,0197 *
Absolute reduction	0,5549	0,458	-	0,1359
% reduction	0,5724	0,475	-	0,0768

Visit 3		0,6455	0,548	-	0,0018 **
	Absolute reduction	0,6094	0,512	-	0,0146 *
	% reduction	0,6237	0,524	-	0,0080 *
Visit 4		0,6750	0,577	-	0,0002 ***
	Absolute reduction	0,6400	0,542	-	0,0026 **
	% reduction	0,6542	0,554	-	0,0014 **

Average pain within the past 3 days: Absolute scores and reductions since visit 1 - percentiles (ITT, locf)

Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	4,0	6,0	6,0	7,0	8,0
	Visit 2	3,0	4,0	5,0	5,0	7,0
	Abs. reduction	-1,0	1,0	2,0	2,8	4,0
	% reduction	-22,3	12,5	26,8	37,5	57,1
	Visit 3	1,0	3,0	4,0	5,0	7,0
	Abs. reduction	-1,0	1,0	3,0	4,0	5,0
	% reduction	-22,9	16,7	42,9	57,1	83,3
	Visit 4	,0	1,0	3,0	5,0	6,8
	Abs. reduction	-1,0	2,0	3,0	5,0	6,0
	% reduction	-14,3	25,0	50,0	78,8	100,0
Placebo	Visit 1	4,4	6,0	6,5	7,0	9,0
	Visit 2	1,0	4,0	5,5	6,0	8,0
	Abs. reduction	-1,0	,0	1,0	2,3	4,6
	% reduction	-22,1	,0	14,3	33,3	82,2
	Visit 3	1,0	3,0	5,0	6,0	7,6
	Abs. reduction	-1,0	,0	1,0	3,3	5,6
	% reduction	-23,3	,0	20,0	50,0	82,2
	Visit 4	,4	3,0	5,0	6,0	7,0
	Abs. reduction	-1,0	,0	1,5	4,0	6,0
	% reduction	-18,8	,0	21,1	56,0	95,6

Chronic back pain

Average pain within the past 3 days.

Absolute scores and reduction since visit 1 - basic statistics (ITT, locf)

Statistics		M	S	Min	Max	N
Capsicum	Visit 1	6,32	,84	5	8	71
	Visit 2	4,63	1,68	1	8	71
	Abs. reduction	1,69	1,70	-2	5	71
	% reduction	26,22	26,40	-33	83	71
	Visit 3	3,89	1,82	0	8	71
	Abs. reduction	2,44	1,99	-1	7	71
	% reduction	37,54	29,64	-20	100	71
	Visit 4	3,08	2,16	0	8	71
	Abs. reduction	3,24	2,34	-1	7	71
	% reduction	50,20	35,13	-20	100	71
Placebo	Visit 1	6,28	,93	4	8	71
	Visit 2	5,07	1,62	0	9	71
	Abs. reduction	1,21	1,49	-2	7	71
	% reduction	19,02	23,39	-29	100	71
	Visit 3	4,41	1,75	0	9	71
	Abs. reduction	1,87	1,80	-2	7	71
	% reduction	29,08	27,47	-29	100	71
	Visit 4	3,97	2,15	0	9	71
	Abs. reduction	2,31	2,17	-2	7	71
	% reduction	36,29	33,69	-29	100	71

Exploratory between-group comparison of subscore average pain within the past 3 days (ITT, locf)

Higher Mann Whitney values correspond to lower scores or more marked reductions in score in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Visit	Mann-Whitney statistic	90% Confidence interval		p value (two-tailed)
Visit 1	0,4859	0,411	0,561	0,7615
		97,5% Confidence interval lower limit only		p value (one-tailed)
Visit 2	0,5843	0,492	-	0,0386 +
Absolute reduction	0,5927	0,500	-	0,0256 +
% reduction	0,5931	0,499	-	0,0273 +

Visit 3		0,5847	0,492	-	0,0385 +
	Absolute reduction	0,5862	0,493	-	0,0364 +
	% reduction	0,5885	0,494	-	0,0349 +
Visit 4		0,6092	0,516	-	0,0115 *
	Absolute reduction	0,6159	0,522	-	0,0079 *
	% reduction	0,6119	0,517	-	0,0112 *

Average pain within the past 3 days, absolute scores and reductions since visit 1 - percentiles (ITT, locf)

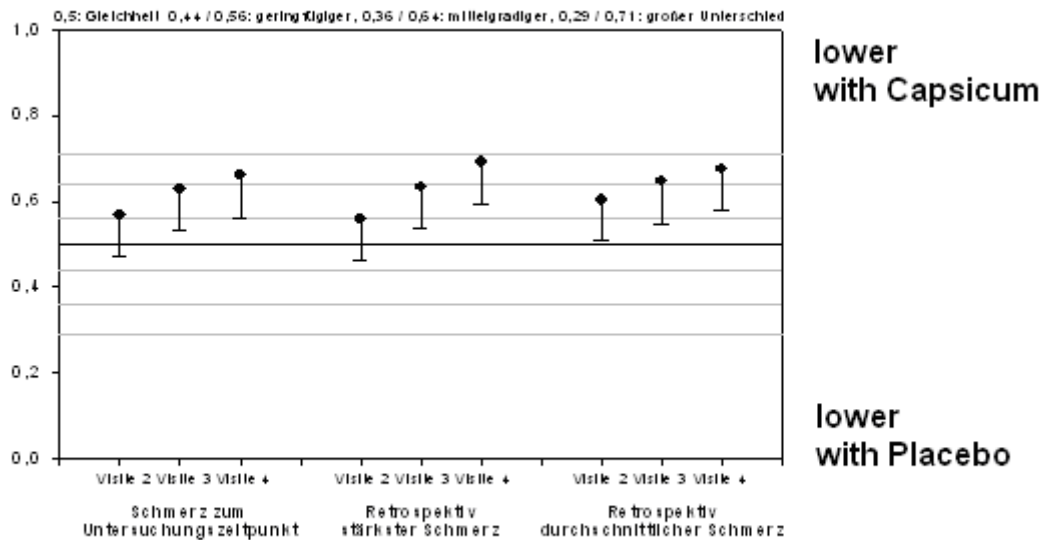
Percentiles		5 %	25 % (I. Q)	50 % (Median)	75 % (III. Q)	95%
Capsicum	Visit 1	5,0	6,0	6,0	7,0	8,0
	Visit 2	2,0	3,0	5,0	6,0	8,0
	Abs. reduction	-1,0	,0	2,0	3,0	5,0
	% reduction	-18,0	,0	28,6	50,0	68,6
	Visit 3	1,0	3,0	4,0	5,0	7,0
	Abs. reduction	-1,0	1,0	2,0	4,0	5,0
	% reduction	-16,7	14,3	40,0	60,0	83,3
	Visit 4	,0	1,0	3,0	5,0	7,0
	Abs. reduction	-1,0	2,0	3,0	5,0	7,0
	% reduction	-15,2	25,0	57,1	83,3	100,0
Placebo	Visit 1	5,0	6,0	6,0	7,0	8,0
	Visit 2	2,0	4,0	5,0	6,0	7,4
	Abs. reduction	,0	,0	1,0	2,0	4,0
	% reduction	,0	,0	14,3	33,3	62,7
	Visit 3	1,6	3,0	5,0	6,0	7,0
	Abs. reduction	,0	,0	1,0	3,0	5,0
	% reduction	,0	,0	25,0	50,0	78,3
	Visit 4	,6	2,0	5,0	6,0	7,0
	Abs. reduction	,0	1,0	2,0	4,0	6,4
	% reduction	,0	14,3	28,6	66,7	92,5

Average pain within the past 3 days, change from visit 1 to 4 (ITT, locf)

		Capsicum		Placebo		Total	
Change		N	%	N	%	N	%
Chronic soft tissue pain	Reduction by more than 5 points	10	15,6%	5	7,6%	15	11,5%
	Reduction by 3-5 points	33	51,6%	19	28,8%	52	40,0%
	Reduction by 1-2 points	8	12,5%	25	37,9%	33	25,4%
	No change	9	14,1%	13	19,7%	22	16,9%
	Increase by 1-2 points	4	6,3%	4	6,1%	8	6,2%
Chronic back pain	Reduction by more than 5 points	14	19,7%	7	9,9%	21	14,8%
	Reduction by 3-5 points	30	42,3%	21	29,6%	51	35,9%
	Reduction by 1-2 points	13	18,3%	28	39,4%	41	28,9%
	No change	10	14,1%	13	18,3%	23	16,2%
	Increase by 1-2 points	4	5,6%	2	2,8%	6	4,2%

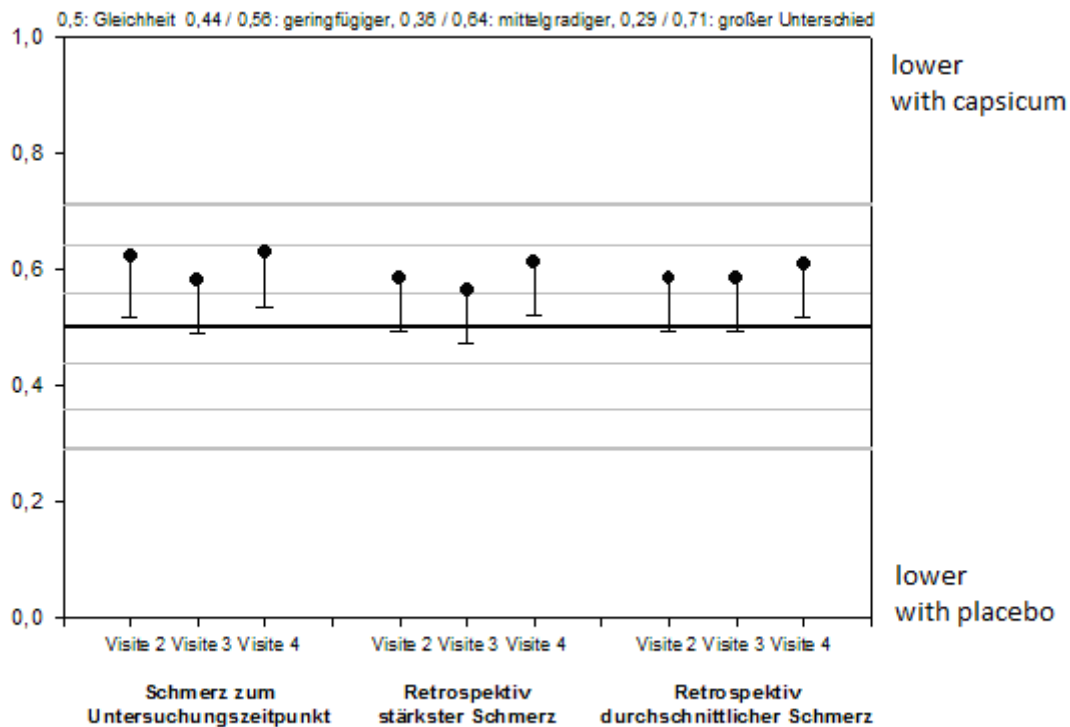
Chronic soft tissue pain

Pain sub-scores (ITT, locf): Mann-Whitney statistic with 97.5% confidence interval.



Chronic back pain

Pain sub-scores (ITT, locf): Mann-Whitney statistic with 97.5% confidence interval.



Development of pain sum score after stop of treatment

At the end of the optional two weeks follow-up phase after completion of the 3 weeks treatment phase, 46 patients of the capsicum group and 47 of the placebo group of the cSTP collective; and 49 patients of the capsicum group and 46 of the placebo group of the cBP collective, respectively, were available for an additional evaluation of the pain score. No relevant between group difference was observed in pain development within 2 weeks after stopping cream application.

In the cBP collective, a further decrease was documented in 61.2 % of patients of the capsicum group compared to 60.9 % of those of the placebo group. In contrast, in the cSTP collective, a decrease was documented in 45.6 % of patients of the capsicum group compared to 29.8 % of those of the placebo group.

Chronic soft tissue pain

Percent change of pain sum score from visit 4 to visit 5 (ITT patients with follow-up phase)

Change	Capsicum		Placebo		Total	
	N	%	N	%	N	%
Increase by > 100 %	1	2,2%	2	4,3%	3	3,2%
Increase by > 60 bis 70%	1	2,2%			1	1,1%
Increase by > 40 bis 50%	2	4,3%	1	2,1%	3	3,2%
Increase by > 30 bis 40%						
Increase by > 20 bis 30%	2	4,3%	1	2,1%	3	3,2%
Increase by > 10 bis 20%	4	8,7%	4	8,5%	8	8,6%
Unchanged / increase by up to 10%	15	32,6%	25	53,2%	40	43,0%
Reduction by up to 10%	5	10,9%	7	14,9%	12	12,9%
Reduction by > 10 bis 20%	3	6,5%	2	4,3%	5	5,4%
Reduction by > 20 bis 30%	6	13,0%	1	2,1%	7	7,5%
Reduction by > 30 bis 40%			3	6,4%	3	3,2%
Reduction by > 40 bis 50%	2	4,3%			2	2,2%
Reduction by > 60 bis 70%			1	2,1%	1	1,1%
Reduction by > 70 bis 80%	1	2,2%			1	1,1%
Reduction by > 80 bis 90%	1	2,2%			1	1,1%
Reduction by > 90 bis 100%	3	6,5%			3	3,2%

Chronic back pain

Percent change of pain sum score from visit 4 to visit 5 (ITT patients with follow-up phase)

Change	Capsicum		Placebo		Total	
	N	%	N	%	N	%
Increase by > 100 %	1	2,0%	1	2,2%	2	2,1%
Increase by > 60 bis 70%						
Increase by > 40 bis 50%	1	2,0%	1	2,2%	2	2,1%
Increase by > 30 bis 40%	1	2,0%	1	2,2%	2	2,1%
Increase by > 20 bis 30%	1	2,0%	2	4,3%	3	3,2%
Increase by > 10 bis 20%	2	4,1%	4	8,7%	6	6,3%
Unchanged / increase by up to 10%	13	26,5%	9	19,6%	22	23,2%

	Capsicum		Placebo		Total	
Reduction by up to 10%	6	12,2%	7	15,2%	13	13,7%
Reduction by > 10 bis 20%	6	12,2%	10	21,7%	16	16,8%
Reduction by > 20 bis 30%	4	8,2%	8	17,4%	12	12,6%
Reduction by > 30 bis 40%	2	4,1%	1	2,2%	3	3,2%
Reduction by > 40 bis 50%	7	14,3%			7	7,4%
Reduction by > 60 bis 70%	3	6,1%	1	2,2%	4	4,2%
Reduction by > 70 bis 80%						
Reduction by > 80 bis 90%			1	2,2%	1	1,1%
Reduction by > 90 bis 100%	2	4,1%			2	2,1%

Efficacy evaluation by investigators and patients

At the final evaluation, the capsicum treatment was rated by the investigators as excellent to good in 59.3 % and 63.4 % of the cases, compared with only 24.3 % and 29.6 % for the placebo treatments, in the cSTP and cBP collective, respectively. The treatment was rated as unsatisfactory in 28.1 % and 19.7 % of capsicum groups compared to 57.6 % and 52.1 % of placebo groups.

Efficacy assessment by investigator (ITT, locf)

		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Assessment		N	%	N	%	N	%	N	%	N	%	N	%
Visit 2	Excellent			2	3,0%	2	1,5%	2	2,8%	2	2,8%	4	2,8%
	Good	28	43,8%	12	18,2%	40	30,8%	28	39,4%	12	16,9%	40	28,2%
	Satisfactory	16	25,0%	13	19,7%	29	22,3%	21	29,6%	13	18,3%	34	23,9%
	Unsatisfactory	19	29,7%	39	59,1%	58	44,6%	20	28,2%	44	62,0%	64	45,1%
	Not evaluable	1	1,6%			1	,8%						
Visit 3	Excellent	1	1,6%	2	3,0%	3	2,3%	5	7,0%	2	2,8%	7	4,9%
	Good	33	51,6%	16	24,2%	49	37,7%	33	46,5%	20	28,2%	53	37,3%
	Satisfactory	14	21,9%	7	10,6%	21	16,2%	16	22,5%	7	9,9%	23	16,2%
	Unsatisfactory	15	23,4%	41	62,1%	56	43,1%	17	23,9%	42	59,2%	59	41,5%
	Not evaluable	1	1,6%			1	,8%						

Visit 4	Excellent	7	10,9%	5	7,6%	12	9,2%	9	12,7%	8	11,3%	17	12,0%
	Good	31	48,4%	11	16,7%	42	32,3%	36	50,7%	13	18,3%	49	34,5%
	Satisfactory	7	10,9%	12	18,2%	19	14,6%	12	16,9%	13	18,3%	25	17,6%
	Unsatisfactory	18	28,1%	38	57,6%	56	43,1%	14	19,7%	37	52,1%	51	35,9%
	Not evaluable	1	1,6%			1	,8%						

In the cSTP collective, 21.9 % of the capsicum patients but 51.5 % of the placebo patients complained of symptoms which were unchanged or worsened at the end of treatment. In the cBP collective, 19.7 % of the capsicum patients but 52.1 % of the placebo patients complained of symptoms which were unchanged or worsened at the end of treatment. In contrast, 76.6 % and 80.3 % of active drug patients reported improvement or resolution of symptoms, compared with 48.5 % and 47.9 % of the placebo patients of the cSTP and cBP collective, respectively.

The Mann Whitney statistic showed a moderate superiority of the capsicum cream from visit 2 on, combined with high statistical significance.

Efficacy assessment by the patients (ITT, locf)

		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Assessment		N	%	N	%	N	%	N	%	N	%	N	%
Visit 2	Free of complaints			2	3,0%	2	1,5%			1	1,4%	1	,7%
	Improved	46	71,9%	24	36,4%	70	53,8%	48	67,6%	23	32,4%	71	50,0%
	Unchanged	15	23,4%	38	57,6%	53	40,8%	22	31,0%	46	64,8%	68	47,9%
	worsened	2	3,1%	2	3,0%	4	3,1%	1	1,4%	1	1,4%	2	1,4%
	Not evaluable	1	1,6%			1	,8%						
Visit 3	Free of complaints	1	1,6%	2	3,0%	3	2,3%	1	1,4%	1	1,4%	2	1,4%
	Improved	45	70,3%	24	36,4%	69	53,1%	50	70,4%	28	39,4%	78	54,9%
	Unchanged	15	23,4%	39	59,1%	54	41,5%	17	23,9%	41	57,7%	58	40,8%
	worsened	2	3,1%	1	1,5%	3	2,3%	3	4,2%	1	1,4%	4	2,8%
	Not evaluable	1	1,6%			1	,8%						
Visit 4	Free of complaints	9	14,1%	5	7,6%	14	10,8%	15	21,1%	8	11,3%	23	16,2%
	Improved	40	62,5%	27	40,9%	67	51,5%	42	59,2%	26	36,6%	68	47,9%
	Unchanged	10	15,6%	33	50,0%	43	33,1%	11	15,5%	36	50,7%	47	33,1%

	worsened	4	6,3%	1	1,5%	5	3,8%	3	4,2%	1	1,4%	4	2,8%
	Not evaluable	1	1,6%			1	,8%						

Exploratory between-group comparison of global evaluation of efficacy (ITT, locf)

Higher Mann Whitney values correspond to better ratings in the capsicum group (0,50 – equality, 0,56 – small, 0,64 – moderate, 0,71 – high superiority)

Assessment		Visit	Mann-Whitney statistic	97,5% Confidence interval lower limit only			p value (one-tailed)
Chronic soft tissue pain	Investigator	Visit 2	0,6548	0,565	-	0,0005	***
		Visit 3	0,6839	0,595	-	< 0,0001	***
		Visit 4	0,6770	0,588	-	< 0,0001	***
	Patient	Visit 2	0,6515	0,569	-	0,0004	***
		Visit 3	0,6526	0,570	-	0,0004	***
		Visit 4	0,6370	0,549	-	0,0015	**
Chronic back pain	Investigator	Visit 2	0,6754	0,589	-	< 0,0001	***
		Visit 3	0,6709	0,584	-	< 0,0001	***
		Visit 4	0,6780	0,592	-	< 0,0001	***
	Patient	Visit 2	0,6619	0,584	-	< 0,0001	***
		Visit 3	0,6422	0,563	-	0,0004	***
		Visit 4	0,6577	0,573	-	0,0002	***

Pain score from Diary

Pain score prior to first daily application - basic statistics
(ITT, data as far as available. up to 7 days per patient)

Statistics			M	S	Min	Max	Days of application
Chronic soft tissue pain	Capsicum	Week 1	5,74	1,57	1	10	422
		Week 2	4,51	1,89	0	10	407
		Week 3	3,86	2,02	0	10	383
	Placebo	Week 1	5,70	1,75	0	10	429
		Week 2	5,16	1,79	0	9	421
		Week 3	4,89	1,78	0	9	398
Chronic back pain	Capsicum	Week 1	5,64	1,49	2	9	479
		Week 2	4,72	1,78	0	9	469
		Week 3	3,58	1,99	0	10	430
	Placebo	Week 1	5,81	1,52	1	9	488
		Week 2	5,03	1,67	1	9	477
		Week 3	4,54	1,89	0	9	454

Chronic soft tissue pain

Pain score 1. week - basic statistics (ITT)

(up to 7 days/patient. exclusion of patients with missing data on a daily basis)

Statistics		M	S	Min	Max	Days of application
Capsicum	Prior to 1. application/day	5,86	1,49	1	10	339
	After 1. application/day	5,20	1,59	1	10	339
	% reduction since beginning of the day	10,81	18,43	-100	67	339
	After 2. application/day	5,11	1,62	1	9	339
	% reduction since beginning of the day	12,12	21,97	-100	71	339
	After 3. application/day	4,99	1,62	0	9	339
	% reduction since beginning of the day	14,26	22,54	-150	100	339
Placebo	Prior to 1. application/day	5,65	1,82	0	10	255
	After 1. application/day	5,35	1,92	0	10	255
	% reduction since beginning of the day	6,00	21,57	-200	100	252
Placebo	After 2. application/day	5,24	1,91	0	9	255
	% reduction since beginning of the day	6,57	27,89	-300	100	252
	After 3. application/day	5,33	2,03	0	9	255
	% reduction since beginning of the day	6,18	28,68	-300	100	252

Pain score 2. week - basic statistics (ITT)

(up to 7 days/patient. exclusion of patients with missing data on a daily basis)

Statistics		M	S	Min	Max	Days of application
Capsicum	Prior to 1. application/day	4,62	1,83	0	10	320
	After 1. application/day	4,11	1,98	0	10	320
	% reduction since beginning of the day	13,05	24,34	-67	100	319
	After 2. application/day	4,00	1,96	0	9	320
	% reduction since beginning of the day	14,86	27,47	-100	100	319
	After 3. application/day	3,97	2,02	0	10	320
	% reduction since beginning of the day	15,03	27,43	-75	100	319
Placebo	Prior to 1. application/day	4,76	1,79	0	9	243
	After 1. application/day	4,58	1,84	0	8	243
	% reduction since beginning of the day	3,31	25,06	-300	75	235
	After 2. application/day	4,60	1,82	0	9	243
	% reduction since beginning of the day	3,03	21,64	-200	100	235

	After 3. application/day	4,52	1,96	0	9	243
	% reduction since beginning of the day	5,85	25,39	-200	100	235

Pain score 3. week - basic statistics (ITT)

(up to 7 days/patient. exclusion of patients with missing data on a daily basis)

Statistics		M	S	Min	Max	Days of application
Capsicum	Prior to 1. application/day	3,70	1,98	0	9	282
	After 1. application/day	3,24	1,99	0	9	282
	% reduction since beginning of the day	13,10	37,90	-200	100	270
	After 2. application/day	3,12	2,07	0	9	282
	% reduction since beginning of the day	16,86	44,74	-300	100	270
	After 3. application/day	3,12	2,03	0	9	282
	% reduction since beginning of the day	14,88	49,63	-300	100	270
Placebo	Prior to 1. application/day	4,38	1,85	0	8	224
	After 1. application/day	4,14	1,92	0	7	224
	% reduction since beginning of the day	6,84	18,99	-50	100	213
	After 2. application/day	4,19	1,96	0	8	224
	% reduction since beginning of the day	5,57	23,14	-100	100	213
	After 3. application/day	4,12	2,02	0	8	224
	% reduction since beginning of the day	8,86	25,42	-67	100	213

Chronic back pain

Pain score 1. week - basic statistics (ITT)

(up to 7 days/patient. exclusion of patients with missing data on a daily basis)

Statistics		M	S	Min	Max	Days of application
Capsicum	Prior to 1. application/day	5,51	1,50	2	9	392
	After 1. application/day	4,56	1,79	1	9	392
	% reduction since beginning of the day	17,54	22,32	-50	83	392
	After 2. application/day	4,37	1,75	1	9	392
	% reduction since beginning of the day	20,83	22,17	-50	88	392
	After 3. application/day	4,19	1,83	0	9	392
	% reduction since beginning of the day	24,42	24,38	-50	100	392
Placebo	Prior to 1. application/day	5,66	1,53	1	9	364
	After 1. application/day	5,23	1,64	0	9	364
	% reduction since beginning of the day	7,49	17,19	-50	100	364
	After 2. application/day	5,13	1,64	0	9	364
	% reduction since beginning of the day	9,15	18,56	-67	100	364
	After 3. application/day	5,07	1,70	0	9	364
	% reduction since beginning of the day	10,25	22,47	-100	100	364

Pain score 2. week - basic statistics (ITT)
 (up to 7 days/patient. exclusion of patients with missing data on a daily basis)

Statistics		M	S	Min	Max	Days of application
Capsicum	Prior to 1. application/day	4,53	1,75	0	9	367
	After 1. application/day	3,72	1,96	0	9	367
	% reduction since beginning of the day	18,57	28,44	-67	100	362
	After 2. application/day	3,56	1,97	0	9	367
	% reduction since beginning of the day	22,29	30,52	-67	100	362
	After 3. application/day	3,48	1,99	0	9	367
	% reduction since beginning of the day	24,39	31,36	-100	100	362
Placebo	Prior to 1. application/day	4,94	1,69	1	9	374
	After 1. application/day	4,53	1,84	0	9	374
	% reduction since beginning of the day	8,91	20,15	-67	100	374
	After 2. application/day	4,40	1,86	0	9	374
	% reduction since beginning of the day	11,37	22,52	-50	100	374
	After 3. application/day	4,37	1,93	0	9	374
	% reduction since beginning of the day	11,85	26,91	-100	100	374

Pain score 3. week - basic statistics (ITT)
 (up to 7 days/patient. exclusion of patients with missing data on a daily basis)

Statistics		M	S	Min	Max	Days of application
Capsicum	Prior to 1. application/day	3,40	1,97	0	10	364
	After 1. application/day	2,95	2,11	0	10	364
	% reduction since beginning of the day	16,48	45,84	-300	100	352
	After 2. application/day	2,87	2,17	0	10	364
	% reduction since beginning of the day	20,66	48,64	-300	100	352
	After 3. application/day	2,80	2,18	0	10	364
	% reduction since beginning of the day	22,87	49,99	-300	100	352
Placebo	Prior to 1. application/day	4,44	1,96	0	9	356
	After 1. application/day	4,11	2,10	0	9	356
	% reduction since beginning of the day	10,21	23,62	-100	100	348
	After 2. application/day	4,00	2,16	0	9	356
	% reduction since beginning of the day	13,07	31,49	-200	100	348
	After 3. application/day	3,94	2,21	0	9	356

Statistics		M	S	Min	Max	Days of application
	% reduction since beginning of the day	15,10	32,23	-200	100	348

Delay until onset of analgesic effect

Patients suffering from chronic soft tissue pain

1. week (ITT, data as far as available. up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. application/day	0-1 hour	220	53,7%	86	20,2%	306	36,6%
	1-2 hours	50	12,2%	39	9,2%	89	10,7%
	2-4 hours	27	6,6%	10	2,4%	37	4,4%
	no effect	113	27,6%	290	68,2%	403	48,3%
Total		410	100,0%	425	100,0%	835	100,0%
2. application/day	0-1 hour	206	50,7%	81	19,4%	287	34,9%
	1-2 hours	64	15,8%	43	10,3%	107	13,0%
	2-4 hours	28	6,9%	8	1,9%	36	4,4%
	no effect	108	26,6%	285	68,3%	393	47,8%
Total		406	100,0%	417	100,0%	823	100,0%
3. application/day	0-1 hour	207	53,4%	83	21,3%	290	37,3%
	1-2 hours	62	16,0%	39	10,0%	101	13,0%
	2-4 hours	23	5,9%	6	1,5%	29	3,7%
	no effect	96	24,7%	262	67,2%	358	46,0%
Total		388	100,0%	390	100,0%	778	100,0%

2. week (ITT, data as far as available. up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. application/day	0-1 hour	225	57,5%	85	20,6%	310	38,6%
	1-2 hours	61	15,6%	41	9,9%	102	12,7%
	2-4 hours	21	5,4%	7	1,7%	28	3,5%

	no effect	84	21,5%	280	67,8%	364	45,3%
Total		391	100,0%	413	100,0%	804	100,0%
2. application/day	0-1 hour	224	57,4%	74	18,4%	298	37,6%
	1-2 hours	57	14,6%	43	10,7%	100	12,6%
	2-4 hours	21	5,4%	6	1,5%	27	3,4%
	no effect	88	22,6%	280	69,5%	368	46,4%
Total		390	100,0%	403	100,0%	793	100,0%
3. application/day	0-1 hour	222	58,7%	89	23,2%	311	40,8%
	1-2 hours	53	14,0%	37	9,6%	90	11,8%
	2-4 hours	24	6,3%	4	1,0%	28	3,7%
	no effect	79	20,9%	254	66,1%	333	43,7%
Total		378	100,0%	384	100,0%	762	100,0%

3. week (ITT, data as far as available. up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	199	52,8%	74	19,1%	273	35,7%
	1-2 hours	58	15,4%	32	8,3%	90	11,8%
	2-4 hours	17	4,5%	6	1,6%	23	3,0%
	no effect	103	27,3%	275	71,1%	378	49,5%
Total		377	100,0%	387	100,0%	764	100,0%
2. Application/day	0-1 hour	202	54,6%	76	20,2%	278	37,2%
	1-2 hours	62	16,8%	29	7,7%	91	12,2%
	2-4 hours	16	4,3%	7	1,9%	23	3,1%
	no effect	90	24,3%	265	70,3%	355	47,5%
Total		370	100,0%	377	100,0%	747	100,0%
3. Application/day	0-1 hour	211	56,7%	86	22,8%	297	39,7%
	1-2 hours	52	14,0%	23	6,1%	75	10,0%
	2-4 hours	17	4,6%	4	1,1%	21	2,8%
	no effect	92	24,7%	264	70,0%	356	47,5%
Total		372	100,0%	377	100,0%	749	100,0%

Patients suffering from chronic back pain

1. week (ITT, data as far as available. up to 7 days/patient)

		Capsicum		Placebo		Gesamt	
Delay		Days	%	Days	%	Days	%
1. application/day	0-1 hour	279	59,4%	151	31,5%	430	45,3%
	1-2 hours	71	15,1%	48	10,0%	119	12,5%
	2-4 hours	16	3,4%	15	3,1%	31	3,3%
	no effect	104	22,1%	265	55,3%	369	38,9%
Total		470	100,0%	479	100,0%	949	100,0%
2. application/day	0-1 hour	272	58,4%	139	29,2%	411	43,6%
	1-2 hours	69	14,8%	65	13,7%	134	14,2%
	2-4 hours	20	4,3%	17	3,6%	37	3,9%
	no effect	105	22,5%	255	53,6%	360	38,2%
Total		466	100,0%	476	100,0%	942	100,0%
3. application/day	0-1 hour	288	63,7%	138	29,5%	426	46,3%
	1-2 hours	61	13,5%	67	14,3%	128	13,9%
	2-4 hours	11	2,4%	14	3,0%	25	2,7%
	no effect	92	20,4%	249	53,2%	341	37,1%
Total		452	100,0%	468	100,0%	920	100,0%

2. week (ITT, data as far as available. up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	263	56,3%	151	31,9%	414	44,0%
	1-2 hours	82	17,6%	74	15,6%	156	16,6%
	2-4 hours	9	1,9%	11	2,3%	20	2,1%
	no effect	113	24,2%	237	50,1%	350	37,2%
Total		467	100,0%	473	100,0%	940	100,0%
2. Application/day	0-1 hour	250	53,8%	153	32,4%	403	43,0%
	1-2 hours	81	17,4%	71	15,0%	152	16,2%
	2-4 hours	14	3,0%	16	3,4%	30	3,2%
	no effect	120	25,8%	232	49,2%	352	37,6%
Total		465	100,0%	472	100,0%	937	100,0%

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
3. Application/day	0-1 hour	262	60,2%	156	33,5%	418	46,4%
	1-2 hours	64	14,7%	64	13,8%	128	14,2%
	2-4 hours	12	2,8%	9	1,9%	21	2,3%
	no effect	97	22,3%	236	50,8%	333	37,0%
Total		435	100,0%	465	100,0%	900	100,0%

3. week (ITT, data as far as available. up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	260	61,8%	162	36,2%	422	48,6%
	1-2 hours	60	14,3%	49	10,9%	109	12,5%
	2-4 hours	5	1,2%	6	1,3%	11	1,3%
	no effect	96	22,8%	231	51,6%	327	37,6%
Total		421	100,0%	448	100,0%	869	100,0%
2. Application/day	0-1 hour	257	60,8%	163	36,7%	420	48,4%
	1-2 hours	62	14,7%	46	10,4%	108	12,5%
	2-4 hours	4	,9%	6	1,4%	10	1,2%
	no effect	100	23,6%	229	51,6%	329	37,9%
Total		423	100,0%	444	100,0%	867	100,0%
3. Application/day	0-1 hour	248	60,0%	160	36,0%	408	47,6%
	1-2 hours	64	15,5%	52	11,7%	116	13,5%
	2-4 hours	5	1,2%	6	1,4%	11	1,3%
	no effect	96	23,2%	226	50,9%	322	37,6%
Total		413	100,0%	444	100,0%	857	100,0%

Delay until maximum effect

The absolute numbers of days where the patients reported an analgetic effect (effective cases) were much higher in the capsicum group than in the placebo one. In 80% and 86% of the effective cases in cSTP and cBP collective, respectively, the maximum effect was reached within 2 hours.

Chronic soft tissue pain

Delay until maximum effect, 1. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	85	21,4%	33	8,0%	118	14,6%
	1-2 hours	144	36,2%	68	16,5%	212	26,2%
	2-4 hours	55	13,8%	15	3,6%	70	8,6%
	no effect	114	28,6%	296	71,8%	410	50,6%
Total		398	100,0%	412	100,0%	810	100,0%
2. Application/day	0-1 hour	67	17,0%	32	7,9%	99	12,4%
	1-2 hours	159	40,4%	68	16,8%	227	28,4%
	2-4 hours	60	15,2%	12	3,0%	72	9,0%
	no effect	108	27,4%	292	72,3%	400	50,1%
Total		394	100,0%	404	100,0%	798	100,0%
3. Application/day	0-1 hour	83	21,6%	41	10,8%	124	16,3%
	1-2 hours	146	37,9%	60	15,9%	206	27,0%
	2-4 hours	60	15,6%	8	2,1%	68	8,9%
	no effect	96	24,9%	269	71,2%	365	47,8%
Total		385	100,0%	378	100,0%	763	100,0%

Delay until maximum effect, 2. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	98	25,9%	49	12,2%	147	18,8%
	1-2 hours	140	36,9%	52	12,9%	192	24,6%
	2-4 hours	57	15,0%	13	3,2%	70	9,0%

	no effect	84	22,2%	288	71,6%	372	47,6%
Total		379	100,0%	402	100,0%	781	100,0%
2. Application/day	0-1 hour	98	25,9%	35	8,8%	133	17,2%
	1-2 hours	137	36,1%	59	14,9%	196	25,3%
	2-4 hours	56	14,8%	16	4,0%	72	9,3%
	no effect	88	23,2%	286	72,2%	374	48,3%
Total		379	100,0%	396	100,0%	775	100,0%
3. Application/day	0-1 hour	98	26,4%	49	13,1%	147	19,8%
	1-2 hours	144	38,8%	52	13,9%	196	26,3%
	2-4 hours	50	13,5%	12	3,2%	62	8,3%
	no effect	79	21,3%	260	69,7%	339	45,6%
Total		371	100,0%	373	100,0%	744	100,0%

Delay until maximum effect, 3. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	81	21,9%	39	10,3%	120	16,0%
	1-2 hours	145	39,2%	51	13,5%	196	26,2%
	2-4 hours	41	11,1%	5	1,3%	46	6,1%
	no effect	103	27,8%	283	74,9%	386	51,6%
Total		370	100,0%	378	100,0%	748	100,0%
2. Application/day	0-1 hour	87	24,0%	43	11,6%	130	17,7%
	1-2 hours	148	40,8%	52	14,0%	200	27,2%
	2-4 hours	38	10,5%	5	1,3%	43	5,9%
	no effect	90	24,8%	272	73,1%	362	49,3%
Total		363	100,0%	372	100,0%	735	100,0%
3. Application/day	0-1 hour	93	25,0%	41	11,1%	134	18,1%
	1-2 hours	140	37,6%	52	14,1%	192	25,9%
	2-4 hours	47	12,6%	5	1,4%	52	7,0%
	no effect	92	24,7%	270	73,4%	362	48,9%
Total		372	100,0%	368	100,0%	740	100,0%

Chronic back pain

Delay until maximum effect, 1. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	130	28,8%	64	13,6%	194	21,0%
	1-2 hours	163	36,1%	80	17,0%	243	26,4%
	2-4 hours	48	10,6%	42	8,9%	90	9,8%
	no effect	110	24,4%	285	60,5%	395	42,8%
Total		451	100,0%	471	100,0%	922	100,0%
2. Application/day	0-1 hour	116	25,3%	66	14,0%	182	19,5%
	1-2 hours	186	40,5%	81	17,2%	267	28,7%
	2-4 hours	47	10,2%	53	11,2%	100	10,7%
	no effect	110	24,0%	272	57,6%	382	41,0%
Total		459	100,0%	472	100,0%	931	100,0%
3. Application/day	0-1 hour	123	28,0%	56	12,1%	179	19,9%
	1-2 hours	170	38,7%	90	19,5%	260	28,9%
	2-4 hours	46	10,5%	47	10,2%	93	10,3%
	no effect	100	22,8%	268	58,1%	368	40,9%
Total		439	100,0%	461	100,0%	900	100,0%

Delay until maximum effect, 2. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	116	25,3%	83	17,7%	199	21,4%
	1-2 hours	178	38,8%	75	16,0%	253	27,3%
	2-4 hours	46	10,0%	53	11,3%	99	10,7%
	no effect	119	25,9%	258	55,0%	377	40,6%
Total		459	100,0%	469	100,0%	928	100,0%
2. Application/day	0-1 hour	111	24,1%	77	16,4%	188	20,2%
	1-2 hours	176	38,3%	82	17,5%	258	27,8%
	2-4 hours	48	10,4%	57	12,2%	105	11,3%

	no effect	125	27,2%	253	53,9%	378	40,7%
Total		460	100,0%	469	100,0%	929	100,0%
3. Application/day	0-1 hour	113	26,3%	88	19,0%	201	22,5%
	1-2 hours	170	39,6%	72	15,5%	242	27,1%
	2-4 hours	43	10,0%	50	10,8%	93	10,4%
	no effect	103	24,0%	254	54,7%	357	40,0%
Total		429	100,0%	464	100,0%	893	100,0%

Delay until maximum effect, 3. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Delay		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	114	27,3%	69	15,5%	183	21,2%
	1-2 hours	160	38,3%	82	18,4%	242	28,0%
	2-4 hours	39	9,3%	43	9,6%	82	9,5%
	no effect	105	25,1%	252	56,5%	357	41,3%
Total		418	100,0%	446	100,0%	864	100,0%
2. Application/day	0-1 hour	118	28,0%	67	15,2%	185	21,5%
	1-2 hours	152	36,1%	77	17,5%	229	26,6%
	2-4 hours	44	10,5%	46	10,5%	90	10,5%
	no effect	107	25,4%	250	56,8%	357	41,5%
Total		421	100,0%	440	100,0%	861	100,0%
3. Application/day	0-1 hour	116	28,4%	74	16,8%	190	22,4%
	1-2 hours	147	35,9%	70	15,9%	217	25,6%
	2-4 hours	44	10,8%	50	11,4%	94	11,1%
	no effect	102	24,9%	246	55,9%	348	41,0%
Total		409	100,0%	440	100,0%	849	100,0%

Duration of analgesia

Chronic soft tissue pain

1. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	37	9,3%	41	9,8%	78	9,5%
	1-2 hours	116	29,0%	58	13,9%	174	21,3%
	2-4 hours	137	34,3%	42	10,1%	179	21,9%
	no effect	110	27,5%	276	66,2%	386	47,2%
Total		400	100,0%	417	100,0%	817	100,0%
2. Application/day	0-1 hour	36	9,1%	39	9,6%	75	9,4%
	1-2 hours	117	29,5%	64	15,8%	181	22,6%
	2-4 hours	137	34,6%	32	7,9%	169	21,1%
	no effect	106	26,8%	271	66,7%	377	47,0%
Total		396	100,0%	406	100,0%	802	100,0%
3. Application/day	0-1 hour	40	10,4%	47	12,3%	87	11,3%
	1-2 hours	105	27,2%	47	12,3%	152	19,8%
	2-4 hours	147	38,1%	43	11,2%	190	24,7%
	no effect	94	24,4%	246	64,2%	340	44,2%
Total		386	100,0%	383	100,0%	769	100,0%

2. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	39	10,1%	36	8,8%	75	9,4%
	1-2 hours	94	24,4%	53	13,0%	147	18,5%
	2-4 hours	169	43,8%	40	9,8%	209	26,3%
	no effect	84	21,8%	280	68,5%	364	45,8%
Total		386	100,0%	409	100,0%	795	100,0%
2. Application/day	0-1 hour	29	7,6%	32	8,2%	61	7,9%
	1-2 hours	106	27,8%	40	10,2%	146	18,9%
	2-4 hours	160	42,0%	45	11,5%	205	26,5%
	no effect	86	22,6%	275	70,2%	361	46,7%

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
Total		381	100,0%	392	100,0%	773	100,0%
3. Application/day	0-1 hour	32	8,6%	42	11,1%	74	9,8%
	1-2 hours	80	21,4%	45	11,9%	125	16,6%
	2-4 hours	183	48,9%	40	10,6%	223	29,7%
	no effect	79	21,1%	251	66,4%	330	43,9%
Total		374	100,0%	378	100,0%	752	100,0%

3. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	17	4,6%	29	7,6%	46	6,1%
	1-2 hours	102	27,3%	43	11,2%	145	19,2%
	2-4 hours	151	40,5%	38	9,9%	189	25,0%
	no effect	103	27,6%	273	71,3%	376	49,7%
Total		373	100,0%	383	100,0%	756	100,0%
2. Application/day	0-1 hour	25	7,0%	26	7,0%	51	7,0%
	1-2 hours	99	27,7%	39	10,6%	138	19,0%
	2-4 hours	144	40,3%	40	10,8%	184	25,3%
	no effect	89	24,9%	264	71,5%	353	48,6%
Total		357	100,0%	369	100,0%	726	100,0%
3. Application/day	0-1 hour	28	7,6%	27	7,3%	55	7,4%
	1-2 hours	92	24,9%	38	10,3%	130	17,6%
	2-4 hours	157	42,5%	42	11,4%	199	26,9%
	no effect	92	24,9%	263	71,1%	355	48,0%
Total		369	100,0%	370	100,0%	739	100,0%

Chronic back pain

1. week (ITT, data as available, up to 7 days/patient)

	Capsicum	Placebo	Total

Duration		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	53	11,4%	84	17,8%	137	14,6%
	1-2 hours	112	24,2%	63	13,3%	175	18,7%
	2-4 hours	196	42,3%	70	14,8%	266	28,4%
	no effect	102	22,0%	256	54,1%	358	38,2%
Total		463	100,0%	473	100,0%	936	100,0%
2. Application/day	0-1 hour	57	12,6%	94	20,0%	151	16,4%
	1-2 hours	97	21,5%	55	11,7%	152	16,5%
	2-4 hours	195	43,1%	76	16,2%	271	29,4%
	no effect	103	22,8%	245	52,1%	348	37,7%
Total		452	100,0%	470	100,0%	922	100,0%
3. Application/day	0-1 hour	55	12,4%	88	19,0%	143	15,8%
	1-2 hours	90	20,3%	49	10,6%	139	15,3%
	2-4 hours	207	46,6%	84	18,1%	291	32,1%
	no effect	92	20,7%	242	52,3%	334	36,8%
Total		444	100,0%	463	100,0%	907	100,0%

2. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	54	11,7%	89	19,1%	143	15,4%
	1-2 hours	107	23,2%	38	8,2%	145	15,6%
	2-4 hours	192	41,6%	109	23,4%	301	32,5%
	no effect	108	23,4%	230	49,4%	338	36,5%
Total		461	100,0%	466	100,0%	927	100,0%
2. Application/day	0-1 hour	49	10,8%	95	20,6%	144	15,7%
	1-2 hours	108	23,8%	43	9,3%	151	16,5%
	2-4 hours	182	40,2%	100	21,6%	282	30,8%
	no effect	114	25,2%	224	48,5%	338	36,9%
Total		453	100,0%	462	100,0%	915	100,0%
3. Application/day	0-1 hour	55	12,9%	88	19,0%	143	16,1%
	1-2 hours	75	17,5%	47	10,2%	122	13,7%
	2-4 hours	202	47,2%	102	22,1%	304	34,2%

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
	no effect	96	22,4%	225	48,7%	321	36,1%
Total		428	100,0%	462	100,0%	890	100,0%

3. week (ITT, data as available, up to 7 days/patient)

		Capsicum		Placebo		Total	
Duration		Days	%	Days	%	Days	%
1. Application/day	0-1 hour	42	10,0%	75	16,9%	117	13,6%
	1-2 hours	117	28,0%	22	4,9%	139	16,1%
	2-4 hours	169	40,4%	115	25,8%	284	32,9%
	no effect	90	21,5%	233	52,4%	323	37,4%
Total		418	100,0%	445	100,0%	863	100,0%
2. Application/day	0-1 hour	39	9,5%	78	17,8%	117	13,8%
	1-2 hours	96	23,5%	29	6,6%	125	14,7%
	2-4 hours	176	43,0%	105	23,9%	281	33,1%
	no effect	98	24,0%	227	51,7%	325	38,3%
Total		409	100,0%	439	100,0%	848	100,0%
3. Application/day	0-1 hour	44	10,7%	72	16,4%	116	13,6%
	1-2 hours	85	20,6%	20	4,6%	105	12,4%
	2-4 hours	191	46,4%	120	27,4%	311	36,6%
	no effect	92	22,3%	226	51,6%	318	37,4%
Total		412	100,0%	438	100,0%	850	100,0%

Evaluation of Safety by investigators and patients

Safety. Assessment by investigator (ITT, data as available)

		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Assessment		N	%	N	%	N	%	N	%	N	%	N	%
Visit 2	Good	60	93,8%	66	100,0%	126	96,9%	69	97,2%	71	100,0%	140	98,6%
	Moderate	4	6,3%			4	3,1%	1	1,4%			1	,7%
	Unsatisfactory							1	1,4%			1	,7%
Visit 3	Missing data	2	3,1%	1	1,5%	3	2,3%	1	1,4%	1	1,4%	2	1,4%
	Good	60	93,8%	65	98,5%	125	96,2%	69	97,2%	70	98,6%	139	97,9%
	Moderate	2	3,1%			2	1,5%	1	1,4%			1	,7%
Visit 4	Missing data	5	7,8%	2	3,0%	7	5,4%	4	5,6%	2	2,8%	6	4,2%
	Good	59	92,2%	64	97,0%	123	94,6%	67	94,4%	69	97,2%	136	95,8%
Visit 5	Missing data	16	25,0%	19	28,8%	35	26,9%	20	28,2%	24	33,8%	44	31,0%
	Good	48	75,0%	47	71,2%	95	73,1%	50	70,4%	47	66,2%	97	68,3%
	Unsatisfactory							1	1,4%			1	,7%

Safety. assessment by patient (ITT, data as available)

		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Assessment		N	%	N	%	N	%	N	%	N	%	N	%
Visit 2	Good	60	93,8%	66	100,0%	126	96,9%	68	95,8%	71	100,0%	139	97,9%
	Moderate	3	4,7%			3	2,3%	2	2,8%			2	1,4%
	Unsatisfactory	1	1,6%			1	,8%	1	1,4%			1	,7%
Visit 3	Missing data	2	3,1%	1	1,5%	3	2,3%	1	1,4%	1	1,4%	2	1,4%
	Good	59	92,2%	65	98,5%	124	95,4%	67	94,4%	70	98,6%	137	96,5%
	Moderate	3	4,7%			3	2,3%	2	2,8%			2	1,4%
	Unsatisfactory							1	1,4%			1	,7%
Visit 4	Missing data	5	7,8%	2	3,0%	7	5,4%	4	5,6%	2	2,8%	6	4,2%
	Good	57	89,1%	64	97,0%	121	93,1%	67	94,4%	69	97,2%	136	95,8%
	Moderate	2	3,1%			2	1,5%						
Visit 5	Missing data	16	25,0%	19	28,8%	35	26,9%	20	28,2%	24	33,8%	44	31,0%
	Good	47	73,4%	47	71,2%	94	72,3%	50	70,4%	47	66,2%	97	68,3%

	Moderate	1	1,6%			1	,8%						
	Unsatisfactory							1	1,4%			1	,7%

Heat sensation at the application site (ITT, data as available)

			Visit 2		Visit 3		Visit 4	
Heat sensation			N	%	N	%	N	%
Chronic soft tissue pain	Capsicum	Not evaluable	1	1,6%	2	3,1%	5	7,8%
		Yes	51	79,7%	50	78,1%	47	73,4%
		No	12	18,8%	12	18,8%	12	18,8%
	Placebo	Not evaluable			1	1,5%	2	3,0%
		Yes	23	34,8%	19	28,8%	19	28,8%
		No	43	65,2%	46	69,7%	45	68,2%
Chronic back pain	Capsicum	Not evaluable			1	1,4%	4	5,6%
		Yes	62	87,3%	59	83,1%	60	84,5%
		No	9	12,7%	11	15,5%	7	9,9%
	Placebo	Not evaluable			1	1,4%	2	2,8%
		Yes	22	31,0%	25	35,2%	25	35,2%
		No	49	69,0%	45	63,4%	44	62,0%

Pruritus at the application site (ITT, data as available)

			Visit 2		Visit 3		Visit 4	
Pruritus			N	%	N	%	N	%
Soft tissue rheumatic pain	Capsicum	Not evaluable	1	1,6%	2	3,1%	5	7,8%
		Yes	12	18,8%	11	17,2%	8	12,5%
		No	51	79,7%	51	79,7%	51	79,7%
	Placebo	Not evaluable			1	1,5%	2	3,0%
		Yes	4	6,1%			1	1,5%
		No	62	93,9%	65	98,5%	63	95,5%
Back pain of other origin	Capsicum	Not evaluable			2	2,8%	4	5,6%
		Yes	14	19,7%	9	12,7%	8	11,3%
		No	57	80,3%	60	84,5%	59	83,1%
	Placebo	Not evaluable			1	1,4%	2	2,8%
		Yes	3	4,2%	6	8,5%	4	5,6%
		No	68	95,8%	64	90,1%	65	91,5%

Intensity of heat sensation (ITT, data as available)

		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Intensity		N	%	N	%	N	%	N	%	N	%	N	%
Visit 2	0 - None	12	18,8%	43	65,2%	55	42,3%	9	12,7%	49	69,0%	58	40,8%
	1	1	1,6%	4	6,1%	5	3,8%	1	1,4%	2	2,8%	3	2,1%
	2	5	7,8%	11	16,7%	16	12,3%	6	8,5%	3	4,2%	9	6,3%
	3	10	15,6%	3	4,5%	13	10,0%	9	12,7%	7	9,9%	16	11,3%
	4	7	10,9%	3	4,5%	10	7,7%	18	25,4%	5	7,0%	23	16,2%
	5	9	14,1%	1	1,5%	10	7,7%	9	12,7%	4	5,6%	13	9,2%
	6	10	15,6%	1	1,5%	11	8,5%	8	11,3%	1	1,4%	9	6,3%
	7	2	3,1%			2	1,5%	6	8,5%			6	4,2%
	8	3	4,7%			3	2,3%	3	4,2%			3	2,1%
	9	2	3,1%			2	1,5%	2	2,8%			2	1,4%
	10 - Intolerable	1	1,6%			1	,8%						
	Not evaluable	2	3,1%			2	1,5%						
Visit 3	0 - None	12	18,8%	46	69,7%	58	44,6%	11	15,5%	45	63,4%	56	39,4%
	1	3	4,7%	4	6,1%	7	5,4%	3	4,2%	1	1,4%	4	2,8%
	2	6	9,4%	10	15,2%	16	12,3%	9	12,7%	4	5,6%	13	9,2%
	3	10	15,6%	1	1,5%	11	8,5%	16	22,5%	8	11,3%	24	16,9%
	4	6	9,4%	2	3,0%	8	6,2%	13	18,3%	4	5,6%	17	12,0%
	5	12	18,8%	2	3,0%	14	10,8%	9	12,7%	4	5,6%	13	9,2%
	6	3	4,7%			3	2,3%	3	4,2%	4	5,6%	7	4,9%
	7	6	9,4%			6	4,6%	5	7,0%			5	3,5%
	8	2	3,1%			2	1,5%	1	1,4%			1	,7%
	9	2	3,1%			2	1,5%						
	Not evaluable	2	3,1%	1	1,5%	3	2,3%	1	1,4%	1	1,4%	2	1,4%
	Visit 4	0 - None	12	18,8%	45	68,2%	57	43,8%	7	9,9%	44	62,0%	51
1		2	3,1%	4	6,1%	6	4,6%	5	7,0%	3	4,2%	8	5,6%
2		7	10,9%	9	13,6%	16	12,3%	10	14,1%	5	7,0%	15	10,6%
3		11	17,2%	2	3,0%	13	10,0%	15	21,1%	7	9,9%	22	15,5%
4		7	10,9%	1	1,5%	8	6,2%	14	19,7%	4	5,6%	18	12,7%
5		8	12,5%	1	1,5%	9	6,9%	6	8,5%	2	2,8%	8	5,6%
6		4	6,3%	1	1,5%	5	3,8%	5	7,0%	3	4,2%	8	5,6%
7		5	7,8%	1	1,5%	6	4,6%	3	4,2%			3	2,1%
8		2	3,1%			2	1,5%	2	2,8%			2	1,4%
9		1	1,6%			1	,8%						

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Total		Capsicum		Placebo		Total	
	Not evaluable	5	7,8%	2	3,0%	7	5,4%	4	5,6%	3	4,2%	7

Intensity of pruritus (ITT, data as available)

Intensity		Chronic soft tissue pain						Chronic back pain					
		Capsicum		Placebo		Total		Capsicum		Placebo		Total	
		N	%	N	%	N	%	N	%	N	%	N	%
Visit 2	0 - None	51	79,7%	62	93,9%	113	86,9%	57	80,3%	68	95,8%	125	88,0%
	1	5	7,8%	3	4,5%	8	6,2%			1	1,4%	1	,7%
	2	1	1,6%	1	1,5%	2	1,5%	6	8,5%	1	1,4%	7	4,9%
	3	2	3,1%			2	1,5%	4	5,6%			4	2,8%
	4	1	1,6%			1	,8%	2	2,8%	1	1,4%	3	2,1%
	5	1	1,6%			1	,8%	1	1,4%			1	,7%
	6	1	1,6%			1	,8%	1	1,4%			1	,7%
	8	1	1,6%			1	,8%						
	Not evaluable	1	1,6%			1	,8%						
Visit 3	0 - None	51	79,7%	65	98,5%	116	89,2%	60	84,5%	64	90,1%	124	87,3%
	1	4	6,3%			4	3,1%	1	1,4%	1	1,4%	2	1,4%
	2	2	3,1%			2	1,5%	4	5,6%	1	1,4%	5	3,5%
	3	3	4,7%			3	2,3%	2	2,8%	2	2,8%	4	2,8%
	4									1	1,4%	1	,7%
	5	1	1,6%			1	,8%	1	1,4%			1	,7%
	8	1	1,6%			1	,8%			1	1,4%	1	,7%
	9							1	1,4%			1	,7%
	Not evaluable	2	3,1%	1	1,5%	3	2,3%	2	2,8%	1	1,4%	3	2,1%
Visit 4	0 - None	51	79,7%	63	95,5%	114	87,7%	59	83,1%	65	91,5%	124	87,3%
	1	4	6,3%			4	3,1%	2	2,8%	1	1,4%	3	2,1%
	2	2	3,1%			2	1,5%	2	2,8%	1	1,4%	3	2,1%
	3							3	4,2%	2	2,8%	5	3,5%
	4			1	1,5%	1	,8%	1	1,4%			1	,7%
	7	1	1,6%			1	,8%						
	8	1	1,6%			1	,8%						
	Not evaluable	5	7,8%	2	3,0%	7	5,4%	4	5,6%	2	2,8%	6	4,2%

Skin type on enrolment (ITT)

		Capsicum		Placebo		Total	
Skin type		N	%	N	%	N	%
Chronic soft tissue pain	Normal	57	89,1%	60	90,9%	117	90,0%
	Dry	6	9,4%	5	7,6%	11	8,5%
	Seborrheic	1	1,6%	1	1,5%	2	1,5%
Chronic back pain	Normal	62	87,3%	66	93,0%	128	90,1%
	Dry	9	12,7%	4	5,6%	13	9,2%
	Seborrheic			1	1,4%	1	,7%

Skin changes (ITT, data as available)

			Visit 1		Visit 2		Visit 3		Visit 4		Visit 5	
Finding			N	%	N	%	N	%	N	%	N	%
Chronic soft tissue pain	Capsicum	Not evaluable			1	1,6%	2	3,1%	5	7,8%	16	25,0%
		Negative	63	98,4%	59	92,2%	60	93,8%	58	90,6%	48	75,0%
		Doubtful	1	1,6%	4	6,3%	2	3,1%	1	1,6%		
	Placebo	Not evaluable					1	1,5%	2	3,0%	19	28,8%
		Negative	66	100,0%	66	100,0%	65	98,5%	63	95,5%	47	71,2%
		Doubtful							1	1,5%		
Chronic back pain	Capsicum	Not evaluable					1	1,4%	4	5,6%	20	28,2%
		Negative	71	100,0%	65	91,5%	67	94,4%	63	88,7%	51	71,8%
		Doubtful			4	5,6%	3	4,2%	4	5,6%		
		Positive			2	2,8%						
	Placebo	Not evaluable					1	1,4%	2	2,8%	24	33,8%
		Negative	71	100,0%	68	95,8%	65	91,5%	64	90,1%	47	66,2%
		Doubtful			3	4,2%	5	7,0%	4	5,6%		
		Positiv							1	1,4%		