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80/SCH001/134

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PIROCTONE OLAMINE SHAMPOO VS.  
AN INACTIVE SHAMPOO  
ANTI-DANDRUFF ACTIVITY  
USING THE HALF-HEAD TECHNIQUE

ANTI-DANDRUFF ACTIVITY SHAMPOO contains 0.75 % Piroctone Olamine

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24 April 1980

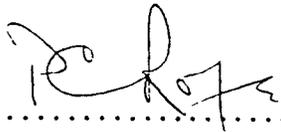


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AN INACTIVE SHAMPOO  
ANTI-DANDRUFF ACTIVITY  
USING THE HALF-HEAD TECHNIQUE

LSR Report No : 80/SCH001/134

We, the undersigned, hereby declare that the report following constitutes a true and faithful account of the procedures adopted, and the results obtained, in the performance of this study.

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.....

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.....

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## METHODS

### 1. Experimental design

Thirty-two subjects (25 women and 7 men) with moderate or severe dandruff used an inactive shampoo at home for two weeks. For the next six weeks they were treated weekly with Piroctone Olamine shampoo (Schwarzkopf) and the inactive shampoo, one shampoo to each half of the head. Assessment of dandruff was made on the day before the first treatment (Day -1), and on Days 14, 28 and 42.

### 2. Selection of subjects

Ninety-nine volunteers were examined to determine the type and extent of dandruff present. Volunteers undergoing medical treatment for a scalp condition, and those with visible inflammation of the scalp, were excluded from the trial. Forty-four volunteers with a dandruff score of at least 7 (area x severity) on each side of the head were issued with an inactive shampoo to use at home for 13 days.

On Day -1 they were again assessed. Thirty-three with moderate or severe dandruff were randomly allocated to two treatment groups such that the group mean dandruff scores (area x severity) and the numbers in the two groups were approximately equal. Seventeen volunteers received Piroctone Olamine on the right side of the head throughout the trial, and 16 received it on the left side. The inactive shampoo was applied to each head on the alternate side. Appendix 1 provides the age and sex of the 32 subjects who completed the trial.

### 3. Product coding and description

The inactive shampoo for use at home was supplied in 50 ml clear glass bottles labelled as follows:

#### Shampoo b

Wet the hair and apply shampoo. Lather and rinse. Repeat the application, then rinse again.

Caution: Not to be taken internally.  
Keep out of children's reach.  
Avoid getting shampoo into eyes. If this happens, rinse eyes with water.

Distributed by: Life Science Research,  
Stock, Essex.

The Piroctone Olamine and the inactive shampoo for the treatment period were supplied in 200 ml clear plastic bottles, labelled Seborin Shampoo A and Seborin Shampoo B respectively. (The latter was the same formulation as "Shampoo b" but subjects were not informed of this). Both shampoos were opaque creamy turquoise-blue liquids with a similar mild fresh perfume - Shampoo B appeared to be slightly bluer in colour than Shampoo A.

## RESULTS AND DISCUSSION

Individual dandruff assessments and group means are tabulated in Appendices 3 - 6 and are displayed in Figure 1. Statistical examination of these data is summarised in Tables 1 and 2.

Of the 32 subjects who completed the trial, 11 women and 5 men received Piroctone Olamine on the left side of the head and the inactive shampoo on the right side; 14 women and 2 men received the shampoos in the reverse order.

1. Antidandruff efficacy: scores for area x severity, maximum 40  
(Figure 1; Table 1; Appendix 3)

The mean dandruff scores (area x severity) taken before the first treatment were 24.4 for the sides of the head to be treated with Piroctone Olamine, and 24.3 for those to be treated with the inactive shampoo.

### Piroctone Olamine (area x severity)

After six weeks treatment the mean dandruff score associated with Piroctone Olamine had decreased from 24.4 to 11.1, a reduction of 54.5% which was highly significant ( $p < 0.001$ ). The reductions after two and four weeks treatment with Piroctone Olamine were also highly significant (11.1% reduction on Day 14,  $p < 0.01$ ; 34.0% reduction on Day 28,  $p < 0.001$ ).

### Inactive shampoo (area x severity)

After two weeks treatment, the mean dandruff score associated with the inactive shampoo had increased by 10.3%, from 24.3 to 26.8. After four weeks the mean score had risen to 27.8, an increase of 14.4% over the Day -1 mean. Both these increases were highly significant (Day 14,  $p < 0.01$ ; Day 28,  $p < 0.001$ ). After six weeks the mean had fallen back to 26.7: this still represented a 9.9% increase from the Day -1 mean score, but just missed arbitrary significance ( $p > 0.05$ ) because of the greater variation in response between subjects.

The worsening of dandruff associated with the inactive shampoo during the six weeks treatment period was also taking place during the two pre-treatment weeks, when the same shampoo was used. A comparison of the whole-head scores taken at the preliminary screening, with those taken on Day -1, showed that the mean dandruff level for the 32 subjects who completed the trial increased from 38.6 on Day -14 to 48.5 on Day -1, a rise of 10.2 (26.4%) which was highly significant ( $p < 0.001$ ).

### Piroctone Olamine shampoo vs inactive shampoo (area x severity)

The differences between the mean changes in dandruff score from Day -1 values, associated with the two shampoos, were highly significant on Days 14, 28 and 42 ( $p < 0.001$ ).

The percentage reduction in dandruff (area x severity) was greatest (63.1%) in the group with predominantly adhering dandruff, and least (31.4%) in the group whose dandruff was predominantly looser at the start of the trial (Appendix 6). However, the proportions of subjects in each group who responded well, i.e. those whose score (area x severity) for the half of the head treated with Piroctone Olamine fell below 7 after six weeks, were roughly similar:

<u>Groups by type of dandruff</u>	<u>Number of subjects in group</u>	<u>Number of subjects scoring less than 7 after 6 weeks</u>	<u>% of group</u>
A, AB	4	1	25.0
AC, B	13	3	23.1
BC, C	15	5	33.3

The proportions of subjects in each group who showed resistance to treatment (i.e. whose dandruff score (area x severity) had increased after six weeks, or had fallen by less than 30%) showed that there were proportionately fewer resistant subjects in the BC, C group.

<u>Groups by type of dandruff</u>	<u>Number of subjects in group</u>	<u>Number of subjects whose dandruff was reduced by less than 25% after 6 weeks</u>	<u>% of group</u>
A, AB	4	2	50.0
AC, B	13	3	23.0
BC, C	15	2	13.0

The inclusion of an estimate of severity in the scoring procedure thus gives an earlier discrimination between products and also suggests the tendency to a differential response to treatment according to dandruff type.

FIGURE 1

Mean half-head values for area of dandruff x severity and area only, in 32 subjects before and after receiving weekly treatments with Piroctone Olamine shampoo and an inactive shampoo

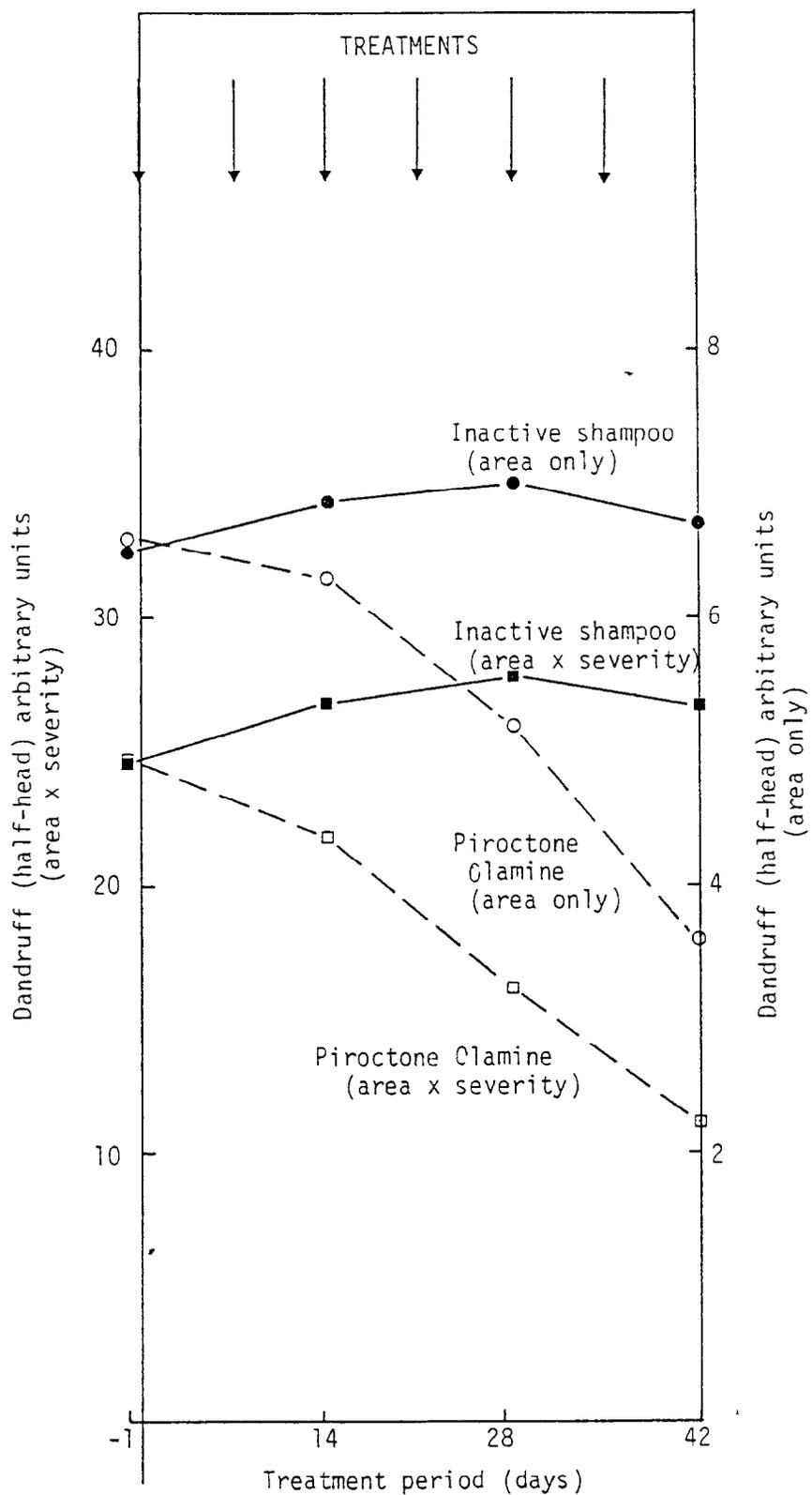


TABLE 2

Significance of differences between initial mean scores (area only) for each product and those at 14, 28 and 42 days, and comparison of means at each stage

	Days since start of half-head treatment															
	Day -1				Day 14				Day 28				Day 42			
	B	A	Δ	p	B	A	Δ	p	B	A	Δ	p	B	A	Δ	p
Mean score	6.5	6.6			6.9	6.3			7.0	5.2			6.7	3.6		
Initial score minus current score					-0.4	0.3	0.7	<0.001 <sup>**</sup>	-0.5	1.4	1.9	<0.001 <sup>**</sup>	-0.2	3.0	3.2	<0.001 <sup>**</sup>
% decrease or increase					-6.2	4.5			-7.7	21.2			-3.1	45.5		
p					NS	NS			<0.05 <sup>*</sup>	<0.01 <sup>**</sup>			NS	<0.001 <sup>**</sup>		

NS Not significant.  
 \* Significant.  
 \*\* Highly significant.

DANDRUFF GRADING FORM

Miss \_\_\_\_\_  
 Mrs \_\_\_\_\_  
 Mr \_\_\_\_\_

Initials: \_\_\_\_\_

Examination date	Days since last wash	Left back	Left front	Left total	Right back	Right front	Right total	Area total	
								Left	Right
4.2.80	6	3AC	4AC	21	2AB	4C	24	7	6
19.2.80	7	3AC	4AC	21	2AB	4C	24	7	6
4.3.80	7	3AC	2BC	17	3AC	4C	29	5	7
18.3.80	7	2BC	1AC	11	2BC	4C	28	3	6

APPENDIX 3

Half-head scores left (L) or right (R) for dandruff before and during treatment with Piroctone Olamine shampoo (A) or an inactive shampoo (B) assessed according to an arbitrary scale (area x severity, see text)

Subject number and sex	After 13 days on inactive (ie Day -1)		Days since start of half-head treatment					
			14		28		42	
	L	R	A L	B R	A L	B R	A L	B R
1♀	21	24	21	24	17	29	11	28
8♂	24	24	24	32	24	32	12	32
10♀	24	24	24	24	17	17	12	28
11♂	20	24	14	24	10	24	11	14
14♀	25	32	18	32	6	32	4	32
16♀	40	40	32	40	6	40	4	40
18♀	35	35	30	40	15	40	7	40
21♂	21	24	21	32	24	32	17	32
23♀	30	25	20	30	15	20	5	14
26♀	32	32	24	32	15	27	5	24
28♂	32	32	20	24	32	32	24	28
30♀	28	25	22	36	13	32	4	28
34♀	28	27	32	32	24	40	12	40
36♀	15	15	11	20	8	20	3	19
41♀	25	28	21	24	21	28	18	28
43♂	21	21	14	21	28	30	28	30
	R	L	R	L	R	L	R	L
2♀	20	24	16	17	3	24	7	18
4♀	35	35	30	35	30	35	15	21
5♀	40	40	40	40	25	40	19	30
7♂	24	24	32	32	18	32	10	40
9♀	21	21	28	32	24	32	14	32
12♀	24	24	24	24	24	32	12	36
17♀	10	10	5	10	5	15	0	10
20♀	14	11	16	15	20	14	12	14
22♀	9	9	12	18	14	15	15	18
24♂	28	24	28	28	15	32	7	28
27♀	24	24	24	28	21	32	21	32
31♀	32	32	28	32	12	32	12	32
33♀	18	16	8	12	5	12	4	13
37♀	21	21	21	21	8	19	9	24
38♀	20	16	20	24	12	28	18	28
40♀	21	15	15	21	3	21	3	21
Mean	24.4	24.3	21.7	26.8	16.1	27.8	11.1	26.7

APPENDIX 4

Half-head scores left (L) or right (R) for dandruff before and during treatment with Piroctone Olamine shampoo (A) or an inactive shampoo (B) assessed according to an arbitrary scale (area only, see text)

Subject number and sex	After 13 days on inactive (ie Day -1)		Days since start of half-head treatment					
	L	R	14		28		42	
			A L	B R	A L	B R	A L	B R
1♀	7	6	7	6	5	7	3	6
8♂	8	8	8	8	8	8	4	8
10♀	7	8	7	8	4	5	3	7
11♂	8	8	7	8	5	8	4	7
14♀	7	8	6	8	2	8	2	8
16♀	8	8	7	8	2	8	1	8
18♀	7	7	6	8	6	8	2	8
21♂	7	8	7	8	3	8	5	8
23♀	6	5	4	6	3	4	1	3
26♀	8	8	8	8	6	7	2	6
28♂	8	8	5	6	8	8	6	7
30♀	6	5	6	8	5	8	1	6
34♀	6	6	7	7	3	8	4	8
36♀	5	3	4	4	3	4	1	4
41♀	7	7	7	8	7	8	6	8
43♂	5	5	4	5	7	6	7	6
	R	L	R	L	R	L	R	L
2♀	5	7	4	5	1	7	2	5
4♀	7	7	6	7	6	7	3	5
5♀	8	8	8	8	5	8	4	6
7♂	6	6	8	8	6	8	3	8
9♀	7	7	8	8	8	8	4	8
12♀	8	8	8	8	8	8	4	8
17♀	2	2	1	2	1	3	0	2
20♀	4	4	6	5	8	7	6	7
22♀	4	3	6	6	7	5	6	6
24♂	7	6	7	7	5	8	3	7
27♀	8	8	8	8	7	8	7	8
31♀	8	8	3	8	6	8	6	8
33♀	7	8	4	6	3	6	4	7
37♀	5	5	5	5	2	5	3	6
38♀	8	8	8	8	4	8	7	8
40♀	7	5	5	7	1	7	1	7
Mean	6.6	6.5	6.3	6.9	5.2	7.0	3.6	6.7

APPENDIX 5

Types of dandruff for the two quadrants of the side of the head treated with Piroctone Olamine shampoo, assessed according to an arbitrary scale (see text); individual values for three groups of subjects

Group 1 (4 subjects) (Type A, AB)									Group 2 (13 subjects) (Type AC, B)								Group 3 (15 subjects) (Type BC, C)									
Subject number and sex	After 2 weeks inactive		Treatment days						Subject number and sex	After 2 weeks inactive		Treatment days						Subject number and sex	After 2 weeks inactive		Treatment days					
			14		28		42					14		28		42					14		28		42	
	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant		Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant		Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant	Back quadrant	Front quadrant
11d	AB	AC	AB	AB	AB	AB	AB	B	19	AC	AC	AC	AC	AC	BC	BC	AC	29	BC	BC	BC	BC	B	B	BC	B
209	AB	BC	AB	B	AB	B	AB	AB	7d	AC	C	AC	C	AC	AC	BC	AC	49	C	C	C	C	C	C	C	C
229	AC	AB	AB	AB	AB	AB	AC	AB	8d	AC	AC	AC	AC	AC	AC	AC	AC	59	C	C	C	C	C	C	C	BC
339	B	AB	AB	AB	AB	A	A	A	99	B	B	AC	BC	AC	AC	AC	C	109	BC	AC	BC	AC	BC	C	C	A
									129	AC	AC	AC	AC	AC	AC	AC	AC	169	C	C	BC	C	BC	AB	BC	-
									149	BC	AC	AC	AC	BC	AB	AB	AC	179	C	C	BC	C	AC	C	BC	C
									21d	B	B	B	B	B	B	BC	B	189	C	C	C	C	AB	B	BC	B
									279	AC	AC	AC	AC	AC	AC	AC	AC	239	C	C	C	C	C	C	C	C
									369	AC	AC	AB	AC	AB	AC	AC	AC	24d	BC	BC	BC	BC	B	B	AB	B
									379	AC	C	AC	C	AC	C	AC	AC	269	C	AC	AC	AC	AB	AC	AC	AB
									389	B	AB	B	AB	B	B	B	AB	28d	BC	BC	BC	BC	BC	BC	BC	BC
									409	AC	AC	AC	AC	A	AC	AC	-	309	BC	C	C	AC	AB	AC	BC	AC
									419	B	BC	B	AC	AC	B	AC	AC	319	BC	BC	BC	C	AB	AB	AB	AB
																		349	BC	C	BC	C	AC	AC	AC	AC
																		43d	AC	C	AC	BC	BC	BC	BC	BC

APPENDIX 6

Half-head scores (area x severity) for sides of head treated with Piroctone Olamine shampoo in three groups of 4, 13 and 15 subjects with differing types of dandruff, assessed according to an arbitrary scale (see text); individual values and group means

Group 1 (4 subjects) (Type A, AB)					Group 2 (13 subjects) (Type AC, B)					Group 3 (15 subjects) (Type BC, C)				
Subject number and sex	After 2 weeks inactive	Treatment days			Subject number and sex	After 2 weeks inactive	Treatment days			Subject number and sex	After 2 weeks inactive	Treatment days		
		14	28	42			14	28	42			14	28	42
11♂	20	14	10	11	1♀	21	21	17	11	2♀	20	16	3	7
20♀	14	16	20	12	7♂	24	32	18	10	4♀	35	30	30	15
22♀	9	12	14	15	8♂	24	24	24	12	5♀	40	40	25	19
33♀	18	8	5	4	9♀	21	28	24	14	10♀	24	24	17	12
					12♀	24	24	24	12	16♀	40	32	6	4
					14♀	25	18	6	4	17♀	10	5	5	0
					21♂	21	21	24	17	18♀	35	30	15	7
					27♀	24	24	21	21	23♀	30	20	15	5
					36♀	15	11	8	3	24♂	28	28	15	7
					37♀	21	21	8	9	26♀	32	24	15	5
					38♀	20	20	12	18	28♂	32	20	32	24
					40♀	21	15	3	3	30♀	28	22	13	4
					41♀	25	21	21	18	31♀	32	28	12	12
										34♀	28	32	24	12
										43♂	21	14	28	28
Mean	15.3	12.5	12.3	10.5	Mean	22.0	21.5	16.2	11.7	Mean	29.0	24.3	17.0	10.7
Δ		2.8	3.0	4.8	Δ		0.5	5.8	10.3	Δ		4.7	12.0	18.3
% reduction		18.3	19.6	31.4	% reduction		2.3	26.4	46.8	% reduction		16.2	41.4	63.1