

# A randomized, double-blind, vehicle-controlled study of the ovicidal efficacy of a new head lice therapy, abametapir lotion, 0.74%, administered for the treatment of head lice infestation

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## Introduction

- Successful treatment of head lice infestations may be hampered by limited ovicidal efficacy of current treatments and increasing resistance to commonly used treatments. Many current treatments for head lice infestation leave eggs relatively unaffected, typically necessitating a second application after 7 to 10 days to kill newly hatched lice.
- Abametapir lotion, 0.74% is a novel compound that inhibits enzymes critical for both egg development and survival of crawling lice.

## Objective

The objective of this clinical study was to assess the efficacy of abametapir lotion, 0.74% against head louse eggs following a single 10-minute application.

## Methods

- This double-blind, randomized, vehicle-controlled, single-dose study enrolled subjects aged ≥ 3 years with an active head lice infestation with both live lice and unhatched eggs.
- Prior to treatment (day 0), at least 5 viable eggs were removed to serve as a control for untreated hatch rate. Either abametapir lotion, 0.74% or vehicle lotion was applied to dry hair for 10 minutes and then rinsed with warm water with no nit combing.
- Following treatment, the random egg collection process was repeated. Eggs deemed viable were incubated for 14 days at 30°C and 60% relative humidity. Ovicidal efficacy was measured by comparing the hatch rate of eggs that were collected from the subject's hair pretreatment and posttreatment and incubated for 14 days.

## Results

- Fifty subjects were randomized to either abametapir lotion, 0.74% or vehicle.
- After 14 days of incubation, 100% of eggs from the abametapir lotion, 0.74% group remained unhatched compared with 64% of vehicle-treated eggs (Figure 1).
- Compared with the eggs from the untreated control group, the abametapir lotion, 0.74% group had a 92.9% reduction in hatch rate (95% CI: 86.5-99.4) compared with 42.3% (95% CI: 30.2-54.4) for the vehicle group. The difference in absolute reduction of hatch rates was 50.6% ( $P < .0001$ ) (Table 1).
- There were no SAEs and all TEAEs were mild except for one rash in the abametapir lotion, 0.74% group that was classified as moderate and resolved by day 4.

## Conclusions

- After a single 10-minute application of abametapir lotion, 0.74% inhibited, 100% of head lice eggs failed to hatch.
- These results in conjunction with data obtained from two pivotal phase 3 studies, demonstrate that abametapir lotion, 0.74% possesses both lousicidal and ovicidal activity following a single application.

## References

1. Mumcuoglu KY. Effective treatment of head louse with pediculicides. *J Drug Dermatol.* 2006;5:451-452.
2. Durand RS, Bouvresse Z, Berdjane A, et al. Insecticide resistance in head lice: Clinical, parasitological and genetic aspects. *Clin Microbiol Infect.* 2012;18:338-244.

Figure 1. Percent Unhatched Eggs Post-Treatment and Absolute Reduction in Egg Hatch

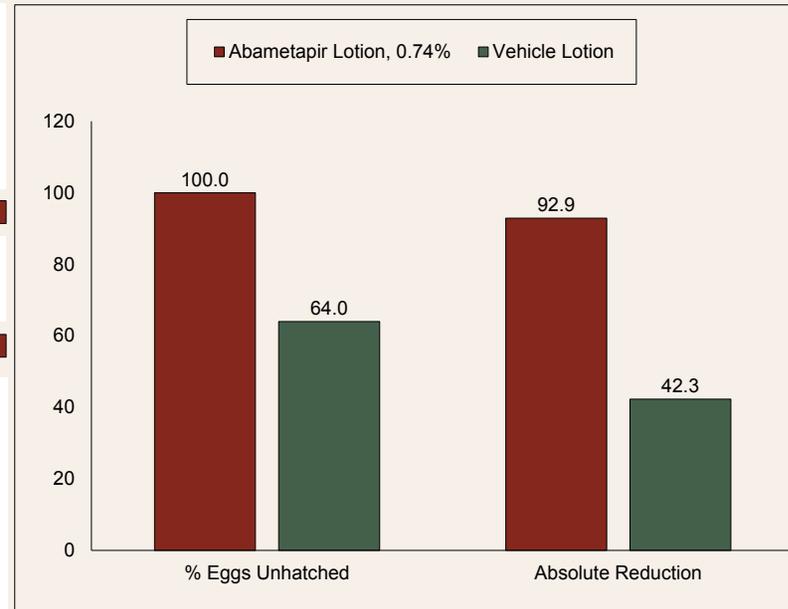


Table 1. Percent Hatched Eggs by Pre- and Post-Treatment and Absolute Reduction

Egg Hatch Status N (%)	Abametapir Lotion, 0.74% (N=25)	Vehicle Lotion (N=25)
<b>Pre-treatment eggs</b>	<b>119</b>	<b>117</b>
Counted as hatched	111 (93.3%)	93 (79.5%)
Counted as unhatched	8 (6.7%)	24 (20.5%)
<b>Post-treatment eggs</b>	<b>130</b>	<b>136</b>
Counted as hatched	0	49 (36.0%)
Counted as unhatched	130 (100.0%)	87 (64.0%)

A GEE model was applied to account for the correlation of eggs within subject and establish an absolute reduction rate

Hatched eggs % (95% CI)	Abametapir Lotion, 0.74% (N=25)	Vehicle Lotion (N=25)	Treatment Difference	P Value
Pre-treatment	93 (82.8, 97.5)	79.4 (69.4, 86.7)	13.9 (3.3, 24.5)	
Post-treatment	0.3 (0.3, 0.4)	37.1 (27.9, 47.3)	-36.7 (-46.4, -27.1)	
Change*	-92.9 (-99.4, -86.5)	-42.3 (-54.4, -30.2)	-50.6 (-64.3, -36.9)	<.0001

\*Change = post-treatment minus pre-treatment