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The modern standard in head lice therapy: Dimeticone

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Efficacy assessment of NYDA®

The efficacy of NYDA®, a new pediculicide containing a high concentration of dimeticone, was assessed by:

1. *in vitro* studies on head lice (pediculicidal action)
2. *in vitro* studies on head louse eggs (ovicidal action)
3. a randomized controlled observer blinded clinical trial (clinical efficacy)

1. *In vitro* studies on pediculicidal action

Seven products available on the market for head lice infestation were compared by *in vitro* assays: NYDA® (92% dimeticone; also marketed under the trade name NYDA® L); Hedrin® Lotion (4% dimeticone; in Germany marketed under the trade name EtoPril®); mosquito® LäuseShampoo (soy oil, coconut oil); Lyclear® Crème Rinse (1% permethrin; aqueous solution); Infectopedicul® (0.5% permethrin, alcoholic solution); Prioderm® Shampoo (1% malathion); and Goldgeist® forte (pyrethrum extract and pipronyl butoxide, chlorocresol, diethylenglycol). A negative control group was also included (no treatment).

Head lice were collected from heavily infested patients in a resource-poor community in northeast Brazil, where no resistance against pediculicides has been reported. In each of the eight groups, 50 adult fully active lice were tested, by immersion in the undiluted products for 3 min. The products were washed off after 20 min. Using strict mortality criteria, lice were monitored for activity at different points in time, for a period of 24 h.

No lice treated with NYDA® or Prioderm® showed major vital signs after 5 minutes, or at any other observation points. Efficacy of Infectopedicul® ranged between 76% and 96% (in evaluations after 5 min to 6 hours); Lyclear® killed between 86% and 94% of lice in this period. All lice treated with mosquito® were considered dead after 5 min, but at observation points between 60 min and 6 h, achieved only 58% - 66% mortality. Similarly, despite showing no major vital signs during the first hour, lice treated with Hedrin® recovered, with a mortality of 74% after 6 h. Goldgeist® killed only 22% - 52% of lice (5 min to 3 hours after treatment).

It is concluded that NYDA® and Prioderm® showed excellent action in killing head lice *in vitro*. The head lice tested were virtually not resistant against permethrin. A considerable number of lice treated with mosquito® and Hedrin® resurrected. Efficacy of Goldgeist® was only moderate.

2. *In vitro* studies on ovicidal action

The following products were tested for their ovicidal action *in vitro*: NYDA® (92% dimeticone); Infectopedicul® (0.5% permethrin, alcoholic solution); mosquito® LäuseShampoo (soy oil, coconut oil); and Goldgeist® forte (pyrethrum extract and pipronyl butoxide, chlorocresol, diethylenglycol). In a control group, eggs were left untreated.

To produce a sufficient number of fertile eggs with exact age known, head lice attached to hair strands were exposed in a plastic chamber (“artifical dog”) with a mesh. The plastic chamber was left for several days attached to the skin of volunteers, to allow blood feeding of lice *ad libitum*, and checked several times per day for newly laid eggs.

Ovicidal action was assessed in two groups of eggs: young eggs (treated 1-2 days after oviposition), and mature eggs with visible eyespot and embryonal movements (treated 10 days after oviposition). Eggs were immersed into the undiluted products for 3 min and washed with shampoo after incubation periods of 30 min and 60 min, respectively. Ovicidal activity of NYDA® was also tested after 10 min incubation. In each group, 50-60 eggs were tested. Hatch rates were assessed 14 days after oviposition.

In young eggs, the highest ovicidal action was observed for NYDA®. Hatch rate in the NYDA® group was 0% for all three incubation periods. Hatch rates of young eggs in the Infectopedicul® group ranged between 48.0% and 54.9%, in the mosquito® group between 19.7% and 65.6%, and in the Goldgeist® group between 56.4% and 72.5%.

Similarly, in mature eggs best ovicidal action was observed for the dimeticone-based product. NYDA® reduced hatch rates to 27.5% (10 min), 9.4% (30 min) and 3.9% (60 min). The hatch rates of mosquito®-treated eggs ranged between 38.9% and 42.3%. Permethrin and pyrethrum showed only a low ovicidal action: hatch rates ranged between 78.4% and 80.0% (Infectopedicul®) and between 72.5% and 89.5% (Goldgeist®).
Hatch rates in the control groups were 77.1% (young eggs) and 83.6% (mature eggs), respectively.
We conclude that only the dimeticone-based product NYDA® showed high ovicidal action in vitro. NYDA® performed significantly better than all other products. Hatch rates decreased with increasing incubation period, which should last at least 60 min.

3. Clinical trial
To assess the clinical efficacy of NYDA®, we conducted a randomized, controlled, observer blinded clinical trial in children (5-15 years) with high intensity of head lice infestation in Fortaleza, Brazil. Participants were recruited from a poor urban neighbourhood in Brazil, where pediculosis is highly prevalent. During the trial, study participants were transferred to a holiday resort outside the endemic area, for a period of 9 days.
NYDA® was compared to a product containing 1% permethrin (Kwell®). The participants were treated topically on days 1 and 8, and no fine tooth combing was performed on these days. Visual inspection was done to detect head lice before treatment, and diagnostic wet combing on days 2, 7 and 9. Clinical examination was performed, and degree of itching was recorded daily, based on an ordinal visual analogue scale; cosmetic acceptability was assessed using a scale including smell, irritation of scalp, cosmetic changes of hair and changes in combing. The primary outcome was defined as cure rates on days 2, 7 and 9 (complete absence of vital head lice).
In total, 145 individuals (73 in the dimeticone group; 72 in the permethrin group) were included in the study. Sex and age distribution, intensity of infestation before treatment and length of hair did not differ between both groups. Overall cure rates were: day 2 – dimeticone 94.5% and permethrin 66.7% ($p<0.0001$); day 7 – dimeticone 64.4% and permethrin 59.7% ($p=0.5$); day 9 – dimeticone 97.2% and permethrin 67.6% ($p<0.0001$). Itching was reduced similarly in both groups. Cosmetic acceptability was significantly better in the dimeticone group as compared to the permethrin group ($p=0.01$). Only one possibly related adverse event (conjunctivitis) occurred, in the permethrin group.
The observation that 7 days after the first application cure rates were considerably lower can be attributed mainly to reinfestation, as the vast majority of study participants cured on day 2, but diagnosed with pediculosis on day 7, had adult lice detected. Adults found up to one week after cure derive from reinfestation - no newly hatched nymphs can develop into adults within one week.
We conclude that NYDA® is a highly efficacious and safe pediculicide. NYDA® is a treatment option for individuals that do not want to use insecticides with a neurotoxic potential and for those who seek a high cosmetic acceptability. As efficacy of dimeticone was very high without using a head louse comb, NYDA® will also be ideal for parents who find combing nasty and time consuming. Due to its mode of action (interruption of oxygen exchange in the spiracles of lice), the development of resistance is unlikely.

Heukelbach J. et al. (2007): High efficacy of a pediculicide based on dimeticone in a population with a high intensity of infestation: a randomized controlled trial. Trop. Med. Int. Health 12, suppl. 1, 178-179.