A scientific statement

Head lice products used as a single application must be 100% effective against all developmental stages of the head louse (adult lice, nymphs and eggs/nits). Only possessing this high pediculicidal as well as ovicidal efficacy they are able to interrupt the life cycle of the head louse and to eradicate the infestation and already after one single treatment. The physical mode of action as well as the high creeping and spreading properties of NYDA® are causal for the high effectiveness of NYDA®. Due to its special formula, NYDA® rapidly enters the whole tracheal system of the lice and the aeropyles of the eggs. Experiments using a visualisation of the tracheal system of lice showed a rapid and irreversible complete filling of the tracheae with NYDA® even into the finest branches. Thereby oxygen is displaced inside the insects. Lice treated with NYDA® are immobilised within less than one minute ("no major vital signs"), the death follows irreversibly [Richling and Böckeler, 2008].

Various in vitro studies could show that the special dimeticone solution NYDA® has the capability to effectively kill all developmental head louse stages already after one treatment:

Pediculicidal effect

Standardized bioassays using NYDA® document a fast and 100 % lethal effect after a single treatment on head lice ex vivo [Oliveira et al., 2007; Heukelbach et al., 2009]. The studies were carried out by Prof. Dr. Jörg Heukelbach (Federal University of Ceará, Fortaleza, Brazil). In these studies the pediculicidal action of NYDA® and other head lice preparations (based on dimeticone, herbal ingredients or classical insecticides with a neurotoxic mode of action) was investigated in vitro on vital head lice freshly harvested from infested subjects. Lice adhering to strands of hair were completely submerged in the test preparations for 3 minutes (dip test) and subsequently placed on wet filter papers for 20 minutes. After this incubation time the test preparations were rinsed off and the head lice again placed on wet filter paper to avoid dehydration. Lice were examined for vitality for up to 24 hours (5, 10, 20, 30, 60, 120, 180 minutes as well as after 6 and 24 hours after treatment). The criterion for the pediculicidal efficacy of the test preparations was the mortality rate within each group of parasites – defined by strictly defined criteria for vitality. Only when there was a total absence of vital signs or when there were only minimal vital signs such as gut movements or movements of the antennae ("minor vital signs") the parasites were declared to be dead. NYDA® achieved a mortality rate of 100 % already after only 5 minutes. The mortality rate also remained constant at 100 % at all other control points. Except of one product based on 1 % malathion NYDA® performed better than all other tested products.

Ovicidal effect

In vitro studies on lice eggs showed that NYDA® has a 100 % ovicidal action after a single application with the recommended incubation period of at least eight hours [data on file, 2007]. A recently performed laboratory study at the University of Massachusetts confirmed these results. In this study NYDA® was 100 % effective in killing eggs from a permethrin-resistant head louse population after an incubation time of eight hours (Clark, 2010). But already after one hour product treatment the ovicidal action of NYDA® is very high, this was shown by Sonnberg et al., 2008. To produce a sufficient number of fertile eggs with age exactly known, head lice attached to hair strands were exposed in a plastic chamber 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 embryonpal movements. Eggs were immersed into the undiluted products (NYDA® and other pediculicides) for 3 min and washed with shampoo after an incubation period of 60 min. Hatch rates were assessed 14 days after oviposition. In the young eggs, the highest ovicidal action was observed for NYDA®. The hatch rate in the NYDA® group was 0%. Similarly, in the mature eggs best ovicidal action was observed for NYDA®. It reduced the hatch rate to 3.9 %.
Efficacy in a randomised, controlled, observer-blinded clinical trial

The results of the above mentioned in vitro studies are also confirmed by a clinical trial with NYDA®. Although designed for two treatments, the study results demonstrate that NYDA® is effective already after one treatment – even in conditions of high parasitic infestation [Heukelbach et al., 2008]. In this study efficacy and tolerability of NYDA® and a pediculicide on the basis of 1% aqueous solution of permethrin (Kwell®) were compared. Participants between 5 and 15 years of age from a Brazilian area with a high prevalence of head lice (without a known resistance to permethrin) were randomised and treated with one of the test preparations on day 1 and day 8. 145 children partly highly infested participated (73 in the dimeticone group; 72 in the permethrin group). A visual inspection was carried out to determine the intensity of the head lice infestation before the start of treatment. Combing as a diagnostic and therapeutic means was excluded during scanning for inclusion into the study as well as during the treatment. The conditions represented hard test conditions for NYDA®. Whilst in countries such as Germany, people with head lice infestations have on average 10–20 lice on the head, the study participants showed a much higher parasite count. On days 2, 7 and 9 the participants were wet-combed to test the success of the treatment. Major outcome measures were the absence of viable head lice on days 2, 7 and 9 and the reduction in clinical morbidity. The cure rates (defined as a complete absence of active lice and lice with major vital signs) were: Day 2 – NYDA® 94.5 % and 1% Permethrin 66.7 % (p<0.0001); Day 7 – NYDA® 64.4 % and Permethrin 59.7 %; Day 9 – NYDA® 97.2 % and 1% Permethrin 67.6 % (p<0.0001). The investigators could show, that already after one treatment the efficacy of NYDA® was very high even under these hard conditions (no combing in the scope of the treatment in contrast to the instruction for use and very high intensity of infestation). 95 % of the children were free of lice. The considerably lower cure rates on day 7 in the dimeticone group was especially caused by reinfestations by uncured children from the permethrin group and not by a low ovicidal action.

Conclusion

Because of its very high pediculicidal as well as ovicidal efficacy in vitro as evidenced in the clinical trial data, head lice experts like Prof. Feldmeier (M.D., Ph.D.) in his German review “Dimeticon-Präparate gegen Kopflausbefall” (translated: dimeticone products against head lice infestations) [Feldmeier 2009] also attest to the efficacy of a single treatment for NYDA®. At the end of his review Prof. Feldmeier states (translated from the original German text): “Topical administered dimeticones kill head lice, however the efficacy of the different products depends on the dimeticone concentration and other composition. Therefore appropriate evidence of efficacy must be required. Only for Etopril® [comment: This is the German trade name of Hedrin®, Thornton & Ross] and NYDA® valid data from clinical studies are available, showing their high efficacy in comparison with neurotoxic acting pediculicides. For the treatment of a severe infestation NYDA® is to be preferred, since the effect of this product is independent from the quantity of lice. Solely for NYDA® a secured ovicidal effect in vitro has been proven, so that in theory a second application could be abandoned.” To understand the statement “so that in theory a second application could be abandoned” of Prof. Feldmeier, it is important to know that in Germany authorities like the Robert Koch-Institut (RKI) as well as the Federal Environmental Agency generally postulate a second application after 8–10 days for all pediculicides. Therefore in Germany NYDA® has to be applied twice to comply with this recommendation. But also after a single treatment we also recommend the patients to re-check the result of the treatment after 8–10 days. In contrast to in vitro studies treatment failures due to reinfestation or incorrect treatment might occur and can not be ruled out in real clinical praxis.

Literature: