Reviewer's report

Title: Evaluation of therapeutic potential of VB-001, a leave-on formulation, for the treatment of moderate adherent dandruff

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Reviewer: Peter Mayser

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Dandruff/seborrheic eczema is a common problem and it is worth to think about new therapeutic concepts. The study compares VB-001, an antidandruff leave-on formulation with a marketed antidandruff ZPTO shampoo in 168 patients with moderate adherent dandruff of the scalp. The efficacy of each product was evaluated by comparing proportion of subjects who have shown reduction in flaking by ASFS (adherent scalp flaking score) and pruritus by IGA (investigator global assessment) score. VB-001 imparted consistently better reduction in ASFS and enabled early reduction of Pruritus in comparison to marketed ZPTO shampoo. As mentioned by the authors the open Label Feature of the study was a limitation of the trial. It is caused by clear differences between VB-001 and the antidandruff shampoo in appearance and viscosity.

However there are further questions and limitations:

1. both formulations were used in a different way: VB-001 daily over fourteen days left overnight, the ZPT shampoo on alternate days, than rinsed off (Minutes of application not given). Furthermore two more non antidandruff products from reputed brands were included in both the study arms; a non-antidandruff shampoo for VB-001 arm and a non-antidandruff conditioner for antidandruff shampoo arm, which were used additionally. Thus we have two further variables - why?

2. the study lasted 14 days, the period of active treatment. There was no follow-up - why? It would have been interesting in terms of relapse (scaling, Pruritus).

It was also looked for hair fall, but with a treatment period of 14 days and no follow up, one would record only toxic hair loss. the period is very short to show potential effects on hair loss.
3. Figure 4/5: at the end of the study the Pruritus score and complete cure were nearly identical between both arms. However, the VB-001 arm had to face much more Intervention, i.e. application every day, leave-on over night. Is this extra time justified by the results. How did the patients accept the leave-on overnight?

4. VB-001 is not characterised in detail. It is mentioned: " combining piroctone olamine and a derivative of a medium chain fatty acid, the combination showing enhanced in vitro fungal killing compared to a formulation containing piroctone olamine alone (data not shown). These data as well as more details on VB-001 should be given as it is difficult to review the data without this Information.

In conclusion there are a lot of variables in this study which may mask the real effect of VB-001. More Information would have been gained if VB-001 would have been compared against a Placebo (a Basic formulation without active ingredients) in a double blind study.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**Does the work include the necessary controls?**
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No

**Are the conclusions drawn adequately supported by the data shown?**
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Yes

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