



# Evaluation of the antiseptic efficacy and local tolerability of Lavasept® 0.02% and 0.04% at different application times on the resident skin flora compared to a reference product

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## Background:

Lavasept® 0.02% and 0.04% (containing 0.02% and 0.04% polihexanide respectively as active substance) is a solution designed for the antiseptic treatment of wounds. Wound antiseptics are aimed to prevent and treat wound infections. As multiresistant bacteria are evolving, the development of antiseptic products is of great importance. Several active substances (e.g. povidone iodine, octenidine and chlorhexidine) are used as antiseptic agents, but they are not all suited for wound treatment because of poor tolerability or possible absorption of the substance. Therefore, polihexanide, the pharmaceutical active ingredient of Lavasept®, might display a favorable alternative in wound management. The primary objective of this study was to compare the antiseptic efficacy of the test products (Lavasept® 0.02% and Lavasept® 0.04%) to the comparator (0.05% chlorhexidine) after an exposure time of 30 minutes. The secondary objectives were to compare the antiseptic efficacy of the test products to the comparator after exposure times of 5 and 10 minutes and to evaluate the local tolerability of the test products.

## Methods:

This randomized, double-blind, comparator controlled, cross-over, three-armed single center study evaluated the antiseptic efficacy and tolerability of the wound antiseptic Lavasept®/polihexanide in two different ready-to-use cutaneous solutions containing 0.02% and 0.04% polihexanide respectively, in subjects with healthy skin. As no validated model is available to prove the efficacy of a wound antiseptic, the validated methodology of the German skin disinfection test model, designed for the testing of preparations based on alcohols, and published by the German Society for Hygiene and Microbiology (DGHM) was adjusted with regard to the requirements to test the efficacy of a wound antiseptic. Referring to the evaluation methods for chemical disinfectants and antiseptics DIN EN 12791 published by the European Committee for Standardization, the reduction of bacterial colonization was evaluated and the reduction factors were compared between the test products and the reference product, using the one-sided Wilcoxon matched-pairs signed-ranks test for significance testing. The tolerability of the study treatments were assessed by means of investigators rating of local skin tolerability (erythema and dryness) as well as subjects rating of local reactions (burning and pruritus).

## Results:

Twenty-one male and female subjects who met the in- and none of the exclusion criteria were randomized to receive all three treatments (Lavasept® 0.02% and Lavasept® 0.04% as test products and 0.05% chlorhexidine as comparator) on two study days (day 1 and day 8), applying each one of the test products in parallel with the comparator on one day. Both Lavasept® concentrations exhibited equal antiseptic efficacy in comparison to chlorhexidine 0.05% after 30 minutes application time, as no significant differences ( $p > 0.01$ ) were seen between both test products and the comparator. After shorter application times of 5 and 10 minutes, only the

higher Lavasept® concentration was as effective as chlorhexidine 0.05% ( $p > 0.01$ ), whereas Lavasept® 0.02% must be regarded as less effective than the comparator following shorter application times ( $p < 0.01$ ). Moreover an additional analysis, comparing both test products after 30 min of application indicates a more pronounced effect of Lavasept® 0.04% compared to Lavasept® 0.02% after 30 minutes application time ( $p = 0.0012$ ). The analyses of the tolerability as well as of the adverse events indicated good tolerability and a good safety profile of both test products, without any significant differences between the test products in either concentration and the comparator.

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