

# Hamamelis in children with skin disorders and skin injuries: results of an observational study

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**Abstract** Published clinical experience with hamamelis ointment in children is limited. This observational study included children (age 27 days to 11 years) with minor skin injuries, diaper dermatitis, or localized inflammation of skin. The children received either hamamelis ointment or dexpanthenol ointment in groups at a 3-to-1 ratio. Baseline and post-treatment assessments compared the total scores of predefined signs and symptoms for each condition. Physicians and parents were asked for a global assessment of efficacy and tolerability of the respective treatments at the end of therapy. A total of 309 children were treated (hamamelis n=231; dexpanthenol n=78). The treatment groups were comparable regarding demographic data and baseline total scores of signs and symptoms. In all three diagnosis groups, the efficacy of hamamelis and dexpanthenol was shown by a statistically significant and clinically relevant decrease of total scores from baseline to endpoint ( $p < 0.0001$  for each group, Wilcoxon signed-rank test). Overall, the results for the hamamelis and the dexpanthenol groups were similar. Descriptive advantages for the hamamelis group were observed for a number of param-

eters and diagnosis groups. Both treatments were well tolerated. Ratings of the tolerability of hamamelis were “excellent” or “good” in 99.1% (physicians) and 98.2% (parents) of cases, respectively. The corresponding ratings for dexpanthenol were 97.4 and 92.3%. In conclusion, hamamelis ointment is an effective and safe treatment for certain skin disorders in children up to the age of 11 years. The observed effects are similar to dexpanthenol.

**Keywords** Dermatitis · Hamamelis ointment · Dexpanthenol ointment · Skin injuries · Diaper dermatitis · Skin inflammation

## Introduction

Hamamelis ointment [1] contains a distillate of leaves and bark of *Hamamelis virginiana*, also known as witch hazel. It has been commercially available in Germany since 1878 [15] and in many other countries as a healing ointment. Preclinical and clinical investigations have demonstrated the anti-mutagenic [8], anti-viral [13], anti-inflammatory [11, 17–19, 21, 28, 31–33], and anti-oxidative [26, 27] properties of *Hamamelis virginiana* extracts.

Areas of medicinal use of hamamelis ointment are minor skin injuries, local inflammation of skin and mucous membranes, as well as hemorrhoids. Hamamelis was found to be effective and safe in a number of clinical studies including conditions like toxic-degenerative and endogenous eczema/atopic dermatitis [14, 22, 28, 33], dry aging skin [35], and hemorrhoids [16, 25, 32]. In case of hypersensitivity to Hamatum® ointment or to one of its constituents, allergic reactions may occur in very rare cases.

Depending on the causes of local skin inflammation in children, a number of potent chemical entities may be

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considered as treatment options, e.g., topically administered steroids, antifungals, tacrolimus, or topical and systemic antibiotics. However, all are associated with potential and distinct side-effects, which include but are not limited to skin atrophy and local infections (steroids) [5, 9, 38], hypersensitivity skin reactions or systemic contact allergies (antifungals, antibiotics) [3, 10, 23], pruritus, skin burning, erythema, and hyperesthesia (all with tacrolimus) [29]. For this reason, some physicians prefer herbal medicines like hamamelis, which are less likely to produce severe side-effects than other treatment options and provide similar efficacy.

Because published experience with hamamelis in children is rather limited, the aim of this observational study was to collect data on safety, tolerability, and clinical effects of the use of hamamelis ointment in babies, infants, and children, under practice conditions. Additionally, a second group of babies, infants and children was treated with dexpanthenol ointment, a well-documented therapy option that is quite comparable to hamamelis ointment with respect to their vehicle composition. Data on safety, tolerability, and clinical effects was also collected for this second group. The most prominent effects of dexpanthenol include stimulation of epithelization, granulation, and mitigation of itching. It has been effectively and safely used in the treatment of wounds and in skin care for decades [12] and has shown its efficacy in the treatment of diaper dermatitis [20, 30].

## Materials and methods

**Study population** Observational data of patients aged between 27 days and 11 years with minor skin injuries, diaper dermatitis, or localized inflammation of skin or mucous membranes and without a concomitant therapy with internal or external corticoids, antibiotics, antifungal agents, or antiseptics was collected. Furthermore, patients with known or putative hypersensitivity to Hamamelis virginiana or to one of the components of hamamelis ointment or dexpanthenol ointment were not included. No further selection criteria have been set.

**Study objective** The aim of this observational study was to collect data on safety, tolerability, and clinical effects of the use of hamamelis ointment (Hametum® Wund- und Heilsalbe, Spitzner Arzneimittel, Ettlingen, Germany) for the treatment of skin injuries, diaper dermatitis, and skin/mucous membrane inflammation in children.

**Study design** This was a prospective, open-label, multicenter, observational study performed by general practi-

tioners, dermatologists, and pediatricians in Germany. Children with the above-mentioned conditions received either hamamelis ointment or dexpanthenol ointment in two groups at a 3-to-1 ratio. In order to avoid patient selection bias, physicians were asked to treat all their respective cases either with hamamelis or with dexpanthenol. The preparations were used according to the instruction leaflet (external thin application several times a day) or according to the advice of the physician. The duration of treatment in each patient was at the discretion of the attending physician. Ideally the patient should be examined at baseline and after 7 to 10 days.

Signs and symptoms assessed were loss of skin elasticity, erythema, weeping, scab formation, and others (e.g., local edema) for minor skin injuries; pruritus/restlessness, erythema, dryness, scaling, weeping, erosions/fissures, and others (e.g., papulae) for local inflammations of skin; and signs and symptoms of diaper dermatitis at up to 11 skin regions (e.g., torso, abdomen, genitals, thighs). The physicians used standard methods to assess the specific signs and symptoms, e.g., visual evaluation. Further interceding examinations were not performed.

For minor skin injuries and inflammation of skin and mucous membranes, scores for each of the signs and symptoms were assessed using a five-point scale (0=none, 1=mild, 2=moderate, 3=severe, 4=very severe), which were then added to total scores. A score of 0 represented the best clinical condition, scores of 20 (minor skin injuries) and 28 (inflammation of skin and mucous membranes) represented the worst clinical condition.

The five-point scale to assess diaper dermatitis included 0=none, 1=mild (mild erythema with minimal maceration or wound friction and/or chafing), 2=moderate (moderate erythema with or without satellite papules, with maceration and chafing), 3=severe (severe erythema with papulopustules and maceration), 4=very severe (extreme erythema with erosions or ulcerations). These scores were assessed at 11 skin regions (upper part of the body, abdomen, genitals, right inner thigh, left inner thigh, right outer thigh, left outer thigh, back, perianal regions, right buttock, left buttock). Therefore, a score of 44 represents the worst clinical condition, and a score of 0, the best [7].

In each of the three diagnosis groups, a global assessment of the clinical impression was given by the physician (0=none, 1=mild, 2=moderate, 3=severe, 4=very severe).

Baseline and post-treatment assessments compared the total scores. In addition, physicians and parents were asked for a global assessment of efficacy and tolerability of the respective treatments at the end of therapy. Subgroup analyses were performed by age groups (27 days to 11 months, 1 to 5 years, and 6 to 11 years).

**Statistical analysis** Total score changes from baseline to endpoint were tested using the Wilcoxon signed-rank test for each treatment group. All statistical tests and confidence intervals are two-sided and are to be interpreted descriptively.

## Results

This observational study was performed by 40 general practitioners, dermatologists, and pediatricians in Germany between August and November 2004 and included 309 children. A total of 72 children had minor skin injuries (e.g., excoriations, rhagades, scratch wounds), 142 had local inflammation of skin (e.g., perianal eczema, vulvitis, perioral dermatitis), and 97 had diaper dermatitis. Two children were included who had both diaper dermatitis and local inflammation of skin and were included in both diagnosis groups. A total of 231 children received hamamelis and 78 dexpanthenol for their respective conditions. One additional child was enrolled in the hamamelis group but did not receive treatment.

The overall median treatment duration was 8 days in each treatment group (hamamelis group: range of 1 to 18 days; dexpanthenol group: range 3 to 36 days). Median treatment duration in the three age groups and the three diagnosis groups was also 8 days.

## Demographics

Table 1 shows demographic characteristics of the study population by treatment groups.

Slightly more boys than girls received hamamelis; the opposite was the case in the dexpanthenol treatment group. In the total population, the mean age was 3.9 years, mean height 96.7 cm, and mean weight 16.9 kg. The number of children in the three age groups were evenly distributed

**Table 1** Demographics

Demographic variable	Hamamelis n=231	Dexpanthenol n=78
Sex (M/F)	118/105 <sup>a</sup>	35/40 <sup>b</sup>
Age (years; mean±SD)	3.8±3.5	4.1±3.8
Age group		
6–11 years	74 (32.0%)	25 (32.1%)
1–5 years	84 (36.4%)	28 (35.9%)
27 days–11 months	73 (31.6%)	25 (32.1%)
Weight (kg; mean±SD)	16.6±10.0	17.9±12.7
Height (cm; mean±SD)	96.3±28.3	97.8±29.9

<sup>a</sup> Missing information for eight children

<sup>b</sup> Missing information for three children

among the two treatments. Most of the patients were treated according to the instruction leaflet (full analysis set 98.4%; hamamelis: 98.3%, dexpanthenol 98.7%).

## Clinical effects

**Treatment effects (total scores)** The decreases in total scores for the three diagnoses groups between start and end of treatment with hamamelis and dexpanthenol were statistically significant ( $p < 0.0001$ ) (Table 2).

In patients treated with hamamelis, mean total scores decreased by  $5.1 \pm 3.9$  points in patients with minor skin injuries,  $5.2 \pm 4.0$  points in patients with local inflammation, and by  $6.0 \pm 5.4$  points in patients with diaper dermatitis. Overall, the results for the hamamelis and dexpanthenol groups were similar. The same holds true when data were analyzed by the three defined age groups (data not shown here). Only four patients (hamamelis: 2, dexpanthenol: 2) showed an increase in total score (data not shown).

**Assessment of individual signs and symptoms by severity** The assessment of signs and symptoms by severity for each diagnosis group at baseline and changes from baseline confirms the favourable treatment effect of hamamelis (data not shown here).

**Overall assessment of treatment effects by severity** Treatment with hamamelis led to statistically significant mean

**Table 2** Treatment effects (total scores) comparing baseline and endpoint

Diagnosis	Hamamelis	Dexpanthenol
Minor skin injuries	n=48	n=24
Baseline (mean±SD, median)	8.1±3.0 (7.5)	8.5±2.6 (8.0)
[95% confidence interval]	[7.2; 8.9]	[7.4; 9.6]
Change from baseline (mean±SD, median)	-5.1±3.9 (-4.0)****	-4.2±2.8 (-4.0)****
[95% confidence interval]	[-6.2; -4.0]	[-5.4; -3.0]
Local inflammation of skin or mucous membranes	n=109	n=33
Baseline (mean±SD, median)	7.7±3.5 (7.0)	7.4±3.7 (7.0)
[95% confidence interval]	[7.0; 8.4]	[6.1; 8.7]
Change from baseline (mean±SD, median)	-5.2±4.0 (-5.0)****	-4.7±3.2 (-4.0)****
[95% confidence interval]	[-5.9; -4.4]	[-5.8; -3.5]
Diaper dermatitis	n=75	n=22
Baseline (mean±SD, median)	7.8±5.1 (6.0)	8.9±5.9 (8.5)
[95% confidence interval]	[6.6; 9.0]	[6.2; 11.5]
Change from baseline (mean±SD, median)	-6.0±5.4 (-4.0)****	-6.6±4.1 (-7.5)****
[95% confidence interval]	[-7.3; -4.8]	[-8.5; -4.8]

\*\*\*\*  $p < 0.0001$

decreases ( $p < 0.001$ ) in severity score of  $1.6 \pm 0.9$  points (skin injuries),  $1.2 \pm 0.9$  points (local inflammation) and  $1.6 \pm 0.9$  points (diaper dermatitis). The results for the dexpanthenol group were similar for all of the three diagnosis groups (see Table 3). Stratification by age groups showed similar results (data not shown here).

*Overall efficacy assessment by physicians and parents*  
Percentages of “excellent” and “good” treatment effects were highest in the group of patients with minor skin injuries. In all three diagnosis groups, hamamelis was mostly assessed as “excellent” by both physicians and parents, whereas assessment for dexpanthenol was in the majority of cases “good” (data not shown here).

## Safety

12 out of 309 children experienced adverse events, 1 out of 78 in the dexpanthenol treatment (conjunctivitis) and 11 out of 231 in the hamamelis treatment group (concussion, head lice, cough/allergic reaction, fungal infection/deterioration, otitis, erythema increased, rhinopharyngitis, burning sensation, superinfection, diaper candidiasis, and obstructive bronchitis). Only two adverse events were considered as potentially drug related, i.e., erythema and burning sensation observed with hamamelis treatment. Both adverse events had resolved or improved at study end.

## Overall tolerability assessment

At endpoint, physicians and parents assessed overall tolerability of the respective treatments the patients had

**Table 3** Overall assessment of treatment effects by severity (scores: 0=none, 1=mild, 2=moderate, 3=severe, 4=very severe)

Diagnosis	Hamamelis	Dexpanthenol
Minor skin injuries	n=48	n=24
Baseline (mean±SD, median)	2.1±0.7 (2.0)	2.1±0.8 (2.0)
Change from baseline (mean±SD, median)	-1.6±0.9 (-2.0)**	-1.4±0.7 (-1.0)**
Local inflammation of skin or mucous membranes	n=109	n=33
Baseline (mean±SD, median)	2.0±0.7 (2.0)	2.2±0.6 (2.0)
Change from baseline (mean±SD, median)	-1.2±0.9 (-1.0)**	-1.4±0.9 (-2.0)**
Diaper dermatitis	n=75	n=22
Baseline (mean±SD, median)	2.1±0.7 (2.0)	2.0±0.7 (2.0)
Change from baseline (mean±SD, median)	-1.6±0.9 (-2.0)**	-1.4±0.7 (-1.5)**

\*\*  $p < 0.001$

received. Percentages of “excellent” or “good” ratings of the tolerability of hamamelis by physicians and parents were 99.1 and 98.2%, respectively. The corresponding ratings for dexpanthenol were 97.4 and 92.3%. Both treatments were safe and well tolerated (Table 4).

In children aged 27 days to 11 months with diaper dermatitis, both physicians and parents judged the tolerability of hamamelis as being “excellent” in 77.8% as compared to 30.8% with dexpanthenol. A similar observation was made with regard to tolerability in children aged 1 to 5 years with local inflammation of skin or mucous membranes. Parents’ assessment showed “excellent” tolerability with hamamelis in 71.1% compared to 28.6% with dexpanthenol treatment. In other diagnoses and age groups, there were similar results for both treatments. Slight advantages of the treatment with hamamelis over dexpanthenol with respect to the overall tolerability in infants with diaper dermatitis and 1- to 5-year-old children with local inflammation of skin and mucous membranes were seen (data not shown here).

## Discussion

In this observational study in 309 children with minor skin injuries, skin inflammation, and diaper dermatitis, the treatment with hamamelis ointment was similar to that with dexpanthenol ointment, the latter considered often as standard treatment for these conditions. Both treatments led to clinically relevant and statistically significant improvements of all three conditions as assessed by predefined overall severity scores as well as individual signs and symptoms scores when applied for a median treatment duration of 8 days.

Although both treatments were safe, the tolerability of hamamelis ointment appeared to be even better than that of dexpanthenol in certain age groups and conditions, i.e., in

**Table 4** Overall tolerability assessment of treatments by physicians and parents

Assessment	Hamamelis (n=231)	Dexpanthenol (n=78)
Physicians		
Excellent	167 (73.9%)	44 (56.4%)
Good	57 (25.2%)	32 (41.0%)
Moderate	1 (0.4%)	2 (2.6%)
Poor	1 (0.4%)	0 (0.0%)
Missing assessment	5	0
Parents		
Excellent	171 (76.0%)	38 (48.7%)
Good	50 (22.2%)	34 (43.6%)
Moderate	2 (0.9%)	6 (7.7%)
Poor	2 (0.9%)	0 (0.0%)
Missing assessment	6	0

infants with diaper dermatitis aged between 27 days to 11 months as well as in children aged between 1 to 5 years with local inflammation of skin.

It is of interest that to our knowledge no publications exist about controlled studies on the effects of any medications for the general terms “minor skin injuries” and “skin and mucous membrane inflammation”, whereas some references are available on clinical studies with regard to diaper dermatitis. Given the high prevalence of these conditions, this comes as a surprise. On the other hand, the scientific interest in these diseases may be low due to a lack of awareness of the issue or a perceived low medical need to treat these conditions. The effects of dexpanthenol ointment for prevention and treatment of diaper dermatitis in premature and newborn infants have been shown in two studies [20, 30] whereas no published data are available for hamamelis ointment in this indication. As demonstrated by these study results, hamamelis shows similar results in treating infants and children with minor skin injuries, diaper dermatitis, and other inflammatory conditions of skin.

A series of physical, chemical, enzymatic, and microbial changes related to diaper’s holding of urine and feces to the skin are responsible for diaper dermatitis [4, 37]. Zinc oxide and other skin protectants as well as mild to mid-potency corticosteroids, topical antifungals, and combination steroid/antifungal drugs also approved for other uses are frequently prescribed to treat diaper dermatitis [1]. However, safety is a concern with corticosteroids and antifungals in young children [7]. With topically applied steroids caution is required as babies percutaneously absorb proportionately greater quantities of topical medication than adults [36]. They should, therefore, be reserved for limited use where the condition is of a more severe degree. Antifungal therapy should not be used routinely, only when *Candida* infection is established or suspected [2]. Similarly, antibacterial agents should not be used, as it is known that bacterial infection does not have a role in diaper dermatitis and the normal microflora should be preserved [24].

In addition, the practice of applying “barrier preparations” in the diaper area has been established for many years with the goal to reduce friction, wetting, and contact with urine and feces [2]. Barrier preparations work either by providing a lipid film over the surface of the skin or by providing lipids that can penetrate into the stratum corneum, simulating the effects or normal intercellular lipids [6]. However, healthcare professionals have indicated unease over the widespread use of such skincare products, because they often contain potentially allergenic preservatives [34].

It is in this particular context the study results offer an alternative therapeutic option with hamamelis as a herbal medicine in the treatment of this condition.

In conclusion, the clinical effects of hamamelis ointment in the treatment of certain skin disorders in young patients up to the age of 11 years were similar to that observed with dexpanthenol, a very commonly used non-prescription drug for the described conditions. Physician’s and parents’ efficacy assessments revealed similar or better ratings of treatment with hamamelis ointment than with dexpanthenol. Both treatments were well tolerated. There appeared to be slight advantages of hamamelis ointment over dexpanthenol ointment with respect to the overall tolerability in infants with diaper dermatitis and 1- to 5-year-old children with local inflammation of skin.

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