ABSTRACT

Background: Hydrocolloid technology has been proven effective in treating dermal wounds. A previous study showed that a newly developed hydrocolloid patch (Compeed Cold Sore Patch; CSP) provided multiple wound-healing benefits across all stages of herpes simplex labialis (HSL) outbreaks.

Objective: To evaluate and compare the efficacy and safety of CSP and acyclovir cream 3% in the treatment of HSL.

Material and Methods: In a randomized clinical study comparing Compeed® Cold Sore Patch (CSP) to acyclovir cream 3% (Acyclovir Cream 5% [AC5%]), 728 subjects with a history of recurrent HSL were randomly assigned to use CSP (N=179) or Acyclovir Cream 5% (AC5%, n=172) at the onset of symptoms. No limits were placed on the frequency of patch application.

Results: CSP and acyclovir were highly effective (mean SGAT = 7.89 and 8.00, respectively), with no significant difference observed (P=0.37). Both treatments were well tolerated. CSP-treated subjects reported a high level of protection, less noticeable tenderness and swelling, and were randomized to use CSP (n = 179) or acyclovir (n = 172) at the onset of symptoms.

Conclusions: CSP was comparable with acyclovir cream 3% for the treatment of cold sores, resulting primarily from herpes simplex virus type 1 infection of the lips and perioral skin, in approximately 15%-40% of adults worldwide.

INTRODUCTION

Herpes simplex labialis (HSL) is characterized by recurrent cold sores resulting primarily from herpes simplex virus type 1 infection of the lips and perioral skin, occurring in approximately 15%-40% of adults worldwide.

Topical antiviral therapies, such as acyclovir or penciclovir, are the current standard of care for subjects with HSL. The overall benefit of these therapies is limited by several factors, including:

- need for frequent application
- lack of protection of the lesion
- aesthetic factors relating to the visibility/ appearance of the scab during the healing process

Many of the limitations of standard topical therapy may be addressed by a hydrocolloid patch, which provides continuous wound protection while maintaining a moist healing environment.

Compeed® Cold Sore Patch (CSP) is a semi-permeable, transparent, hydrocolloid bandage used for the treatment of cold sores. In a non-comparative study conducted in Denmark in 2004, CSP was effective in providing discrete wound-healing benefits to subjects with HSL lesions.

No study to date has evaluated the efficacy and safety of a hydrocolloid patch, such as CSP, in comparison with standard antiviral topical therapy in the treatment of HSL lesions.

RESULTS

Baseline Demographics of ITT Population

- Mean age was 42.7 ± 13.7 years
- 82% were female
- 92% were Caucasian.

Efficacy Analyses

SGAT ratings were highly favorable and similar in both treatment groups (Figure 2).

- mean ratings of 7.89 and 8.00 on 0-10 scale in the treatment groups (Figure 2)
- no statistically significant difference in SGAT between CSP and acyclovir at the end of therapy (P=0.65)
- no statistically significant difference in SGAT between CSP and acyclovir groups, respectively, with about half of each group having ratings of 9 or 10 and 80% of group having ratings of at least 7
- subjects with lesions healed who therefore had a lesion of known duration, mean healing times were comparable between the CSP and acyclovir groups (0.70 and 4.69 days, respectively).

- Results of subject-assessed mean peak severity and mean healing times for individual signs and symptoms are shown in Table 1.

- CSP-treated subjects reported a high level of protection/hygiene with mean ratings of 4.06 and 4.09, respectively, at the onset of symptoms.

- CSP-treated subjects showed that the therapy treatment made their cold sore less noticeable and helped to hide sores and blisters while they were healing (mean rating of 3.25 in 4-10 scale).

- A majority of CSP-treated subjects (95%) felt that the study treatment helped relieve the social embarrassment and anxiety of having a cold sore.

CONCLUSIONS

- CSP was comparable with acyclovir cream 5% for the treatment of cold sores, resulting primarily from herpes simplex virus type 1 infection of the lips and perioral skin, in approximately 15%-40% of adults worldwide.

- Both treatments were well tolerated and no serious AEs were reported.

- CSP-treated subjects (18.10%) reported a high level of protection/hygiene in comparison with acyclovir-treated subjects reported AEs.

- Subjects and clinicians reported adverse events (AEs) for the duration of the study. Treatment-emergent AEs were defined as those that started or worsened after study therapy initiation.

- Outcome measures were primary patient-reported variable was subject’s global assessment of therapy (ITT population).

- Statistical Analyses

- Sample size of 300 subjects (150 per treatment group) was estimated to achieve a statistical power of 0.8 to detect a 0.5-point mean difference between groups with 80% power (alpha = 0.05).

- Efficacy and safety analyses were based on the intent-to-treat (ITT) population, defined as all randomized subjects.

- Data were compared between the 2 treatment groups using analysis of variance (ANOVA) for quantitative variables and chi-square tests for categorical variables.

- The study was conducted to achieve a minimum clinically significant effect size.

- Subject Disposition (Figure 1)

- CSP and acyclovir were highly effective (mean SGAT = 7.89 and 8.00, respectively), with no statistically significant difference observed (P=0.37).

- Both treatments were well tolerated. CSP-treated subjects reported a high level of protection/hygiene, with mean ratings of 4.06 and 4.09, respectively, at the onset of symptoms.

- CSP-treated subjects showed that the therapy treatment made their cold sore less noticeable and helped to hide sores and blisters while they were healing (mean rating of 3.25 in 4-10 scale).

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