ENCAPSULATED BENZYL PEROXIDE (E-BPO): A NOVEL FORMULATION OF BPO FOR LONG-TERM MANAGEMENT OF ROSEacea

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INTRODUCTION

Key Points

1. The safety of BPO in rosacea has been limited due to its lack of efficacy and risk of skin irritation
2. A new formulation incorporating microencapsulation technology is tolerable over long-term use
3. BPO has a complex history in rosacea
4. Limited data is available in previous studies, especially with microencapsulation technology
5. While proven effective, unencapsulated BPO causes skin irritation, including dryness, scaling, and burning/stinging
6. Demonstrated to be effective in killing Demodex folliculorum

Drug Microencapsulation Background

Benefits of Microencapsulation

• Creates a silicone dioxide (silica) microcapsule shell between the BPO and the skin
• Helps control the release rate of the drug to improve tolerability
• Can preserve the advantages of BPO while minimizing limitations

Figure 1. Encapsulation

Silica is added in ~5-10 repetitive cycles to build up a silica shell around the BPO

REFERENCES


METHODS

Sample Design

INTRODUCTION

• 12-week phase 3 trials of microencapsulated benzoyl peroxide cream, 5% (E-BPO), previously reported,
• The safety and tolerability of E-BPO (Table 1)
• This 52-week study observed efficacy, rapid onset of action after 2 weeks, and good safety and tolerability at week 12

• A new formulation incorporating microencapsulation technology is tolerable over long-term use

Safety endpoints:

• Effect of therapy on local and systemic adverse events
• Investigator cutaneous safety assessment (erythema and scaling) and local tolerability assessment (itching and burning/stinging) at baseline and all postbaseline study visits

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E-BPO is a potent oxidizing agent

Figure 2. Study Design

Vehicle

Table 1. Baseline Demographic and Clinical Characteristics

<table>
<thead>
<tr>
<th>Study 1 and 2</th>
<th>SGT 54-07</th>
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<tbody>
<tr>
<td>547 enrolled in SGT 54-07</td>
<td>184 previously treated with E-BPO in Study 1 and 2</td>
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Table 2. Patient Adverse Event Summary

<table>
<thead>
<tr>
<th>Event</th>
<th>All Patients (n=535)</th>
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<tbody>
<tr>
<td>Any TEAE</td>
<td>185 (34.6%)</td>
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<tr>
<td>Any serious TEAE</td>
<td>10 (1.9%)</td>
</tr>
<tr>
<td>Discontinued E-BPO because of a TEAE</td>
<td>5 (0.9%)</td>
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<td>(Note: Treatment-emergent adverse events are those events with an onset after the first application of E-BPO Cream 5%). Related defined as “definitely,” “probably,” or “possible.” Not related defined as “unlikely” or “not related.”)</td>
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RESULTS

E-BPO was well-tolerated over the course of 52 weeks, with mild, moderate, and severe local and systemic adverse events, the percentage of subjects with no adverse events during the course of the study was 80.8% to 86.5% during the first 3 weeks of the study and 80.8% to 90.4% after 4 weeks. Reporting of cutaneous safety and local tolerability evaluations included 2 subjects with dryness, 1 subject with itching, and 1 subject with burning/stinging at week 40. There was no severe cutaneous safety evaluation at week 52.

Figure 3. Erythema at Postbaseline Visits, Safety Population

Figure 4. Kaplan–Meier Analysis of Time to First Retreatment

SUMMARY

The cutaneous safety and local tolerability assessments demonstrated that E-BPO, when applied once daily for up to 52 weeks, was generally safe and well-tolerated.

The evaluations of IGA score and facial erythema showed improved clinical outcomes after 4 weeks and for up to 52 weeks of treatment with E-BPO.