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The Role of Multi-Herbal Menthol Lozenges in the Treatment of Acute Sore Throat, Cough and Associated Symptoms

Kapil Mehta*, Manesh Jagtap, Ameya Satam

J. B. Chemicals & Pharmaceuticals Limited, Mumbai, India
Email: *kapil.mehta@jbpharma.com

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Abstract

Background: Acute sore throat and cough are common complaints in primary care settings. Pharyngeal inflammation often leads to interconnected symptoms including throat pain, hoarseness and cough, which reduce quality of life. Topical therapies offer localised symptomatic relief through direct mucosal application. This study evaluated the efficacy of a multi-herbal menthol lozenge for treating acute sore throat, cough and associated symptoms. **Methods:** This prospective, open-label, single-arm study was conducted in Maharashtra, India (August-October 2010). Two hundred patients aged ≥ 6 years with recent onset sore throat were enrolled in two independent cohorts (N = 100 each) at separate investigation sites. Cohort A included patients with normal and severe disease course, while Cohort B only enrolled patients with normal disease. Patients received one 2.7 g lozenge every 2 hours or as needed (maximum 8 - 10 lozenges daily) for 3 days or up to 3 weeks in severe cases. Primary outcomes included changes from baseline in throat pain, inflammation, exudates, cough, and hoarseness assessed using visual analogue scales (VAS) and four-point rating scales. Secondary outcomes included adverse events and global impression scores. **Results:** All 200 patients completed the study (89% normal disease course in Cohort A, 100% in Cohort B). A statistically significant improvement in throat pain was observed from minute 15 onwards in both cohorts, with mean VAS scores decreasing from 2.85 to 0.03 (Cohort A) and 1.52 to 0.00 (Cohort B) by Day 3. Similar patterns were observed for inflammation (98.8% - 99.2% reduction), cough (91.8% - 97.1% reduction), and hoarseness (90.0% - 100% reduction). Complete symptom resolution was achieved in 92.1% - 97.1% of Cohort A patients and 84% - 100% of Cohort B patients by Day 3. Patients with severe disease (11% of Cohort A) showed progressive improvement, achieving complete recovery by Day 21.

Global impression scores rated efficacy and safety as "excellent" or "good" in approximately 98% of cases. Only two patients experienced mild adverse events deemed unrelated to treatment. **Conclusion:** The multi-herbal menthol lozenge used in this study demonstrated rapid onset of action with significant symptomatic relief and an excellent safety profile, supporting its use for self-management of acute sore throat, cough and associated symptoms.

Keywords

Pharyngitis, Cough, Lozenges, Menthol

1. Introduction

Acute sore throat is one of the most common complaints associated with upper respiratory tract infections (URTIs) and a frequent reason for seeking medical care in primary care [1] [2]. On average, adults experience 13.5 - 14.4 episodes of sore throat per 100 patient-years, while rates in children can reach 82.2 - 82.5 episodes per 100 patient-years [3]. Although acute sore throat is generally a self-limiting condition, its associated physical symptoms can impose a substantial psychosocial burden and reduce the quality of life [4] [5].

Sore throat often involves more than localized discomfort. Pharyngeal inflammation can lead to throat pain, hoarseness, and cough. [6] A study reported that sore throat is typically the most bothersome symptom at the initial start of a cold, followed by nasal congestion and later, cough. While cough is less prominent during the early stages, it is frequently present throughout the course of illness and becomes increasingly disruptive in the later stages. The impact of cough on sleep and daily functioning contributes significantly to overall symptom burden, patient discomfort and reduced quality of life [7] [8]. Notably, 54% - 60% of patients who sought medical care report experiencing moderate-to-severe sore throat and other associated symptoms, frequently accompanied by sleep disturbances and impaired daily functioning [9].

Sore throat aetiology is predominantly infectious, with most cases being of viral origin and group A streptococci (GAS) accounting for most bacterial infections [10]. Antibiotic therapy is generally not recommended for uncomplicated sore throat and should be reserved for confirmed GAS pharyngitis [1] [3]. Of note, no or delayed antibiotic prescription is recommended in patients with a low-to-moderate clinical probability of GAS pharyngitis [1]. Therefore, the availability of topical throat preparations (e.g., topical lozenges, gargles and sprays) containing analgesics and/or nonsteroidal anti-inflammatory drugs plays an increasingly important role in the self-management of sore throat, cough and other symptoms.

Topical therapies deliver the active ingredients directly to the oropharyngeal mucosa, offering rapid symptomatic relief from acute sore throat [11]. These formulations differ substantially in delivery efficiency and onset of action. Sprays rely

on coarse droplets to target affected areas but lose potency through swallowing [11]. Gargles are limited by the gag reflex, depositing active ingredients only in the anterior oral cavity in the anterior oral cavity [11]. In contrast, lozenges dissolve slowly, ensuring sustained drug delivery to all affected areas of the throat [11].

Scintigraphy analyses revealed significantly greater initial drug deposition in oropharyngeal mucosa from solid dosage forms (*i.e.*, lozenge and tablet) compared to liquid formulations (*i.e.*, throat sprays or gargles) [12]. While both solid forms exhibited similar clearance rates, lozenges maintained significantly higher mucosal drug retention than tablets in the first 20 minutes [12]. These findings indicate that lozenge formulation provides fast, effective and sustained delivery of active ingredients, offering distinct therapeutic advantages to those who experience pharyngeal inflammation.

This study investigated the efficacy of a multi-herbal menthol lozenge containing menthol and herbal extracts with analgesic, antiviral, antioxidant, antitussive and immune-boosting properties that could potentially help provide effective relief from acute sore throat and cough due to various aetiologies. Menthol and ginger (*Zingiberaceae*) are used in traditional medicine for pain relief, while liquorice (*Glycyrrhiza glabra*) acts as an antitussive agent. In addition, amla (*Emblica officinalis*) is a rich source of vitamin C with antioxidant activities, helping to support the immune system. Two independent patient cohorts (N = 100 each) were prospectively enrolled under the same study protocol to enhance analytical robustness. Results from each study group were analysed separately to evaluate consistency in efficacy and safety trends, providing complementary verification of treatment effects while maintaining analytical independence.

2. Methods

2.1. Study Design

This prospective, open-label, single-arm, two-cohort study was conducted between 4 Aug 2010 and 7 Oct 2010 in two investigational sites located in Maharashtra, India. An independent ethics committee reviewed and approved the study protocol prior to the study initiation (Protocol ID: IS/06/DML/07/10). The study was conducted in full accordance with Good Clinical Practice and the Declaration of Helsinki. All patients or their parents/caregivers provided written, informed consent prior to study enrolment.

2.2. Subjects

Patients aged ≥ 6 years with recent onset of sore throat < 4 days who are in good general health and agree to attend regular follow-up visits were enrolled in the study. Patients were ineligible to participate in the study if they had a history of nasal reconstruction surgery; needed antibiotic treatment for respiratory infection; a history of severe or malignant hypertension; hyperpyrexia (*i.e.*, temperature of >40.8˚C); life-threatening illness and were hospitalised; elevated intraocular

pressure; hyperthyroidism; a severe form of diabetes mellitus; severe liver (*i.e.*, serum transaminases > 3 × upper limit of normal levels) or renal (*i.e.*, serum creatinine ≥ 250 μmol/L) impairment; previously participated in the same study, or participated in another study parallel to or within 30 days before study entry; and history or suspected of not being able to comply with the study protocol or unable to attend regular follow-up visits.

To enhance the robustness of our findings, we structured the study into two distinct cohorts: Cohort A, which included patients with a subset of severe cases of sore throat and cough, and Cohort B, consisting of patients with only normal, less severe cases. Patients with severe disease were defined as those suffering from severe throat pain, severe Inflammation, cough or hoarseness of voice at baseline (Refer to the "Assessment" section). This differentiation was made to evaluate the therapy's effectiveness across a spectrum of symptom severity. By including severe cases in Cohort A, we aimed to assess the treatment's potential in a population that may benefit from more intensive intervention, while Cohort B allowed us to examine the effects in a typical, less severe patient population. This dual-cohort design facilitates a comprehensive understanding of the therapy's efficacy and safety, ensuring that results can be generalized to both severe and normal cases of sore throat and cough.

2.3. Intervention

All eligible patients were prescribed one 2.7 g multi-herbal menthol lozenge (containing 15 mg of liquorice, 10 mg of ginger, 10 mg of amla and 7 mg of menthol) every 2 hours or as needed, with a maximum of 8 - 10 lozenges per day, for 3 days or up to 2 - 3 weeks in patients with severe disease. Patients were only allowed to use other nonpharmacological methods to provide pain relief, such as steam inhalation. No anti-inflammatory medications were allowed during the study period.

On Day 1, patients were asked to suck one lozenge (Minute 0), and symptomatic improvement was assessed at Minutes 5, 10, 15 and 20 after dosing. Subsequently, patients were prescribed the lozenges, which were to be taken at home for the next 2 days. Study assessments were conducted on Days 2 (normal disease) and 3 (normal and severe disease) during the study period. Additional assessments were performed on Days 7, 14 and 21 for patients with severe disease.

2.4. Assessment

Throat pain was assessed using a Visual Analogue Scale from 0 to 10 with pain severity graded as: 0 (no pain), 1 (1 to 3 = mild pain), 2 (4 to 6 = moderate pain) and 3 (7 to 10 = severe pain) at every study visit. Inflammation, cough and hoarseness of voice were rated using the four-point scale (0 = no pain to 3 = severe) at every visit. The presence or absence of exudates was also recorded at every visit. At the study endpoint, the global impression of the treatment's efficacy and safety (1 = poor to 4 = excellent) was completed by both patients (or parents) and inves-

tigators.

2.5. Outcome Measures

The primary outcome measures were changes from baseline in throat pain, inflammation, exudates, cough and hoarseness of voice. Secondary outcome measures were the incidence of adverse events (AEs) as well as global impression of treatment's efficacy and safety by patients and investigators at the study endpoint.

2.6. Statistical Analysis

The obtained data were coded, analysed and tabulated. Categorical variables were expressed in counts and percentages. Meanwhile, continuous variables were expressed as mean and standard deviation (SD). Student's T-test was used to compute the association between quantitative variables with normal distribution, while Mann-Whitney U test was used for non-normally distributed variables. Wilcoxson signed rank test for repeated measures was used to establish differences in throat pain, cough, hoarseness and inflammation. A p-value less than 0.05 was considered statistically significant.

3. Results

3.1. Baseline Characteristics

A total of 100 patients were enrolled in each of two study cohorts (Cohort A & Cohort B) and completed the study (60% female in Cohort A and 44% female in Cohort B). Baseline patient demographics and clinical characteristics are shown in Table 1. In Cohort A, 89 patients (89%) had a normal disease course, while all patients (100%) in Cohort B had a normal disease course.

Table 1. Baseline patient demographics and clinical characteristics.

Characteristic	Cohort A		Cohort B
	Normal disease course (n = 89)	Severe disease course (n = 11)	Normal disease course (n = 100)
Gender, n (%)			
Female	52 (58.4)	8 (72.3)	44 (44.0)
Male	37 (41.6)	3 (27.3)	56 (56.0)
Age (mean), years	12.05	11.45	32.04
Aetiology, n (%)			
Pharyngitis	37 (41.6)	4 (36.4)	57 (57.0)
Pharyngolaryngitis	19 (21.3)	1 (9.0)	0
Tonsilitis	19 (21.3)	4 (36.4)	0
Tonsillopharyngitis	12 (13.5)	2 (18.2)	0
Laryngitis	2 (2.3)	0	17 (17.0)

Continued

Bronchitis	0	0	24 (24.0)
Others	0	0	2 (2.0)
Parameter scores			
Throat pain (mean)	2.85	3.00	1.52
Inflammation (mean)	2.60	3.00	1.22
Cough (mean)	2.73	3.00	1.95
Hoarseness of voice (mean)	0.80	NA	0.27
Presence of exudates, n (%)	69 (77.5)	11 (100)	47 (47.0)

Abbreviation: NA, not available.

A total of 11 patients (11%) in Cohort A had severe disease requiring extended treatment for up to 3 weeks. These severe cases had high mean scores of throat pain, inflammation and cough at baseline, with pharyngeal exudates observed in all affected patients.

3.2. Efficacy Endpoints

The mean symptom scores showed consistent improvement over time after treatment with the lozenges among patients with a normal disease course in both study cohorts (Figure 1). Most patients in both cohorts achieved complete resolution of all symptoms by Day 3, with 92.1% - 97.1% of patients in Cohort A and 84% - 100% in Cohort B demonstrating complete symptom resolution. All remaining patients reported only mild residual symptoms.

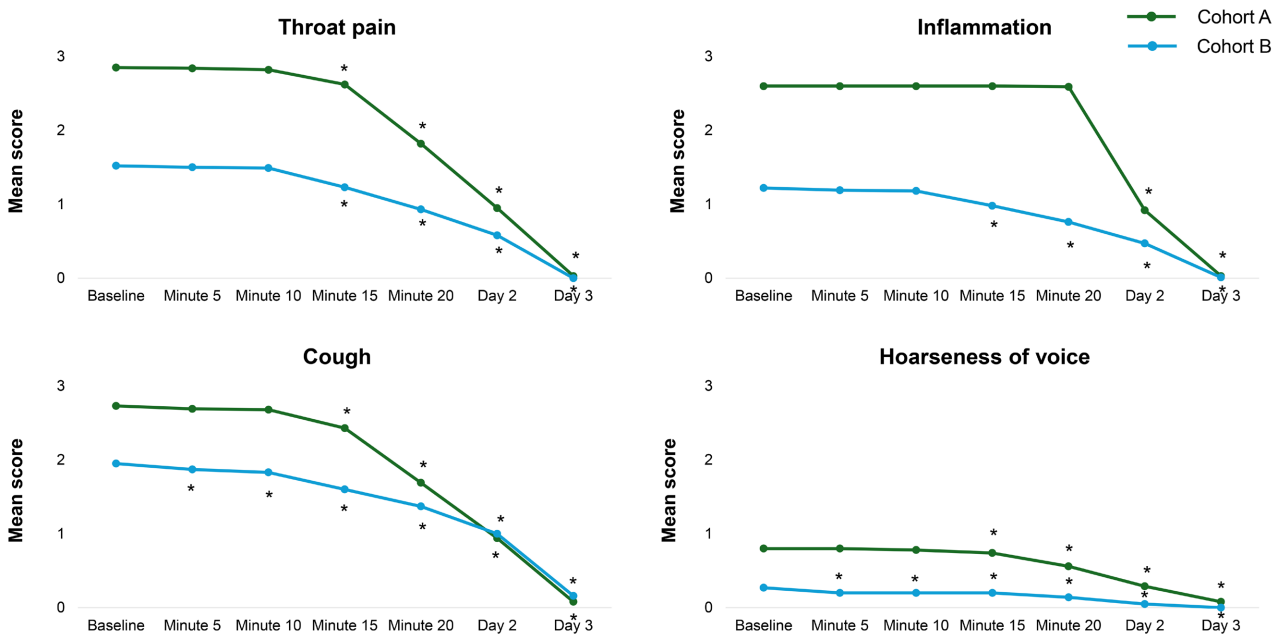


Figure 1. Changes in mean symptom scores from baseline among patients with normal disease course in Cohorts A and B.

Both cohorts exhibited marked reductions in mean throat pain scores from baseline to Day 3, decreasing from 2.85 to 0.03 for Cohort A and from 1.52 to 0.00 for Cohort B. Statistically significant improvement was observed from Minute 15 onwards for Cohorts A and B, with corresponding reductions of 8.1% and 19.1% that ultimately reached 98.9% and 100% by Day 3, respectively. Mean inflammation scores also demonstrated progressive improvement, decreasing from 2.60 at baseline to 0.03 on Day 3 for Cohort A and from 1.22 at baseline to 0.01 on Day 3 for Cohort B. Significant improvement first occurred at Day 2 for Cohort A and at Minute 15 for Cohort B, with reductions of 64.6% and 19.7%, respectively. By Day 3, mean inflammation scores have reduced by 98.8% for Cohort A and 99.2% for Cohort B.

Mean cough scores also showed sustained improvement, declining from 2.73 to 0.08 for Cohort A and 1.95 to 0.16 for Cohort B. The mean scores decreased significantly from Minute 15 onwards for both cohorts, with reductions of 11.0% and 17.9% that subsequently reached 97.1% and 91.8% by Day 3 for Cohorts A and B, respectively. Mean scores of voice hoarseness declined from 0.80 at baseline to 0.08 on Day 3 for Cohort A, and from 0.27 at baseline to 0.00 on Day 3 for Cohort B. Statistically significant improvement first occurred at Minute 15 for Cohort A and Minute 5 for Cohort B, with reductions of 7.5% and 25.9%, respectively. By Day 3, mean scores of voice hoarseness have reduced by 90.0% for Cohort A and 100.0% for Cohort B.

Similarly, mean scores of all symptoms showed consistent improvement from Day 3 onwards among patients with severe disease course in Cohort A (**Figure 2**). All patients recovered from their disease pathology by Day 21, with no patients reporting any pain for all relevant symptoms. Mean scores of throat pain reduced from 3.00 at baseline to 0.00 on Day 21. Statistically significant improvements were observed from Day 3 onwards, with reductions of 33.3% on Day 3, 63.6% on Day 7 and 100% on Days 14 and 21. Mean inflammation scores declined from 3.00 at baseline to 0.00 on Day 21. The mean scores decreased significantly from Day 3 onwards, with reductions of 27.3% on Day 3, 60.6% on Day 7, 93.9% on Day 14 and 100% on Day 21. Mean cough scores also reduced from 3.00 at baseline to 0.00 on Day 21. Statistically significant improvements were observed from Day 3 onwards, with per cent reductions of 27.3% on Day 3, 57.6% on Day 7, 87.9% on Day 14 and 100% on Day 21.

3.3. Global Impression

The global impression of the investigators and patients favoured using the multi-herbal menthol lozenges to treat acute sore throat. Among patients with normal disease course, investigators rated the medication's efficacy and safety as "excellent" or "good" in nearly 98% of the cases in both cohorts. Similarly, patients or their parents rated the medication's efficacy and safety as "excellent" or "good" in about 98% of the cases in both cohorts (**Figures 3(a)-(c)**). Among patients with severe disease, both investigators and patients/parents/caregivers rated the medication's efficacy and safety as "excellent" or "good" in all cases.

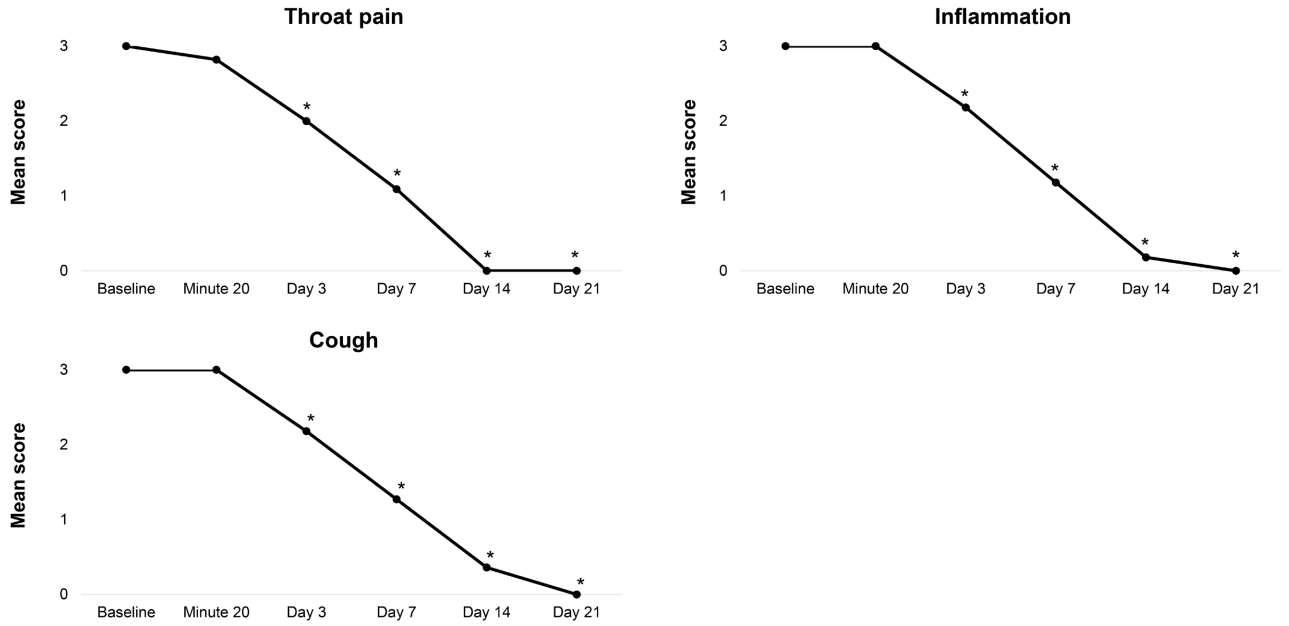
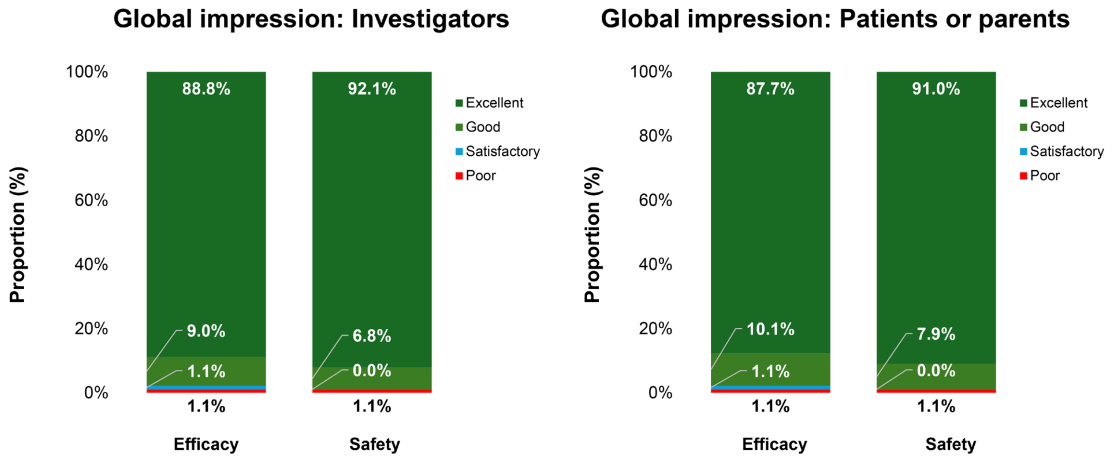
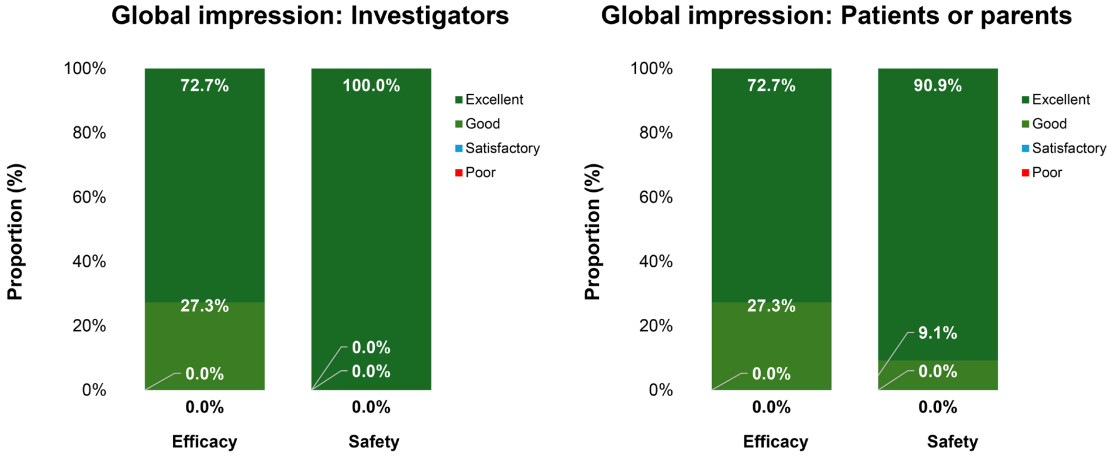


Figure 2. Changes in mean symptom scores from baseline among patients with severe disease course in Cohort A.



(a)



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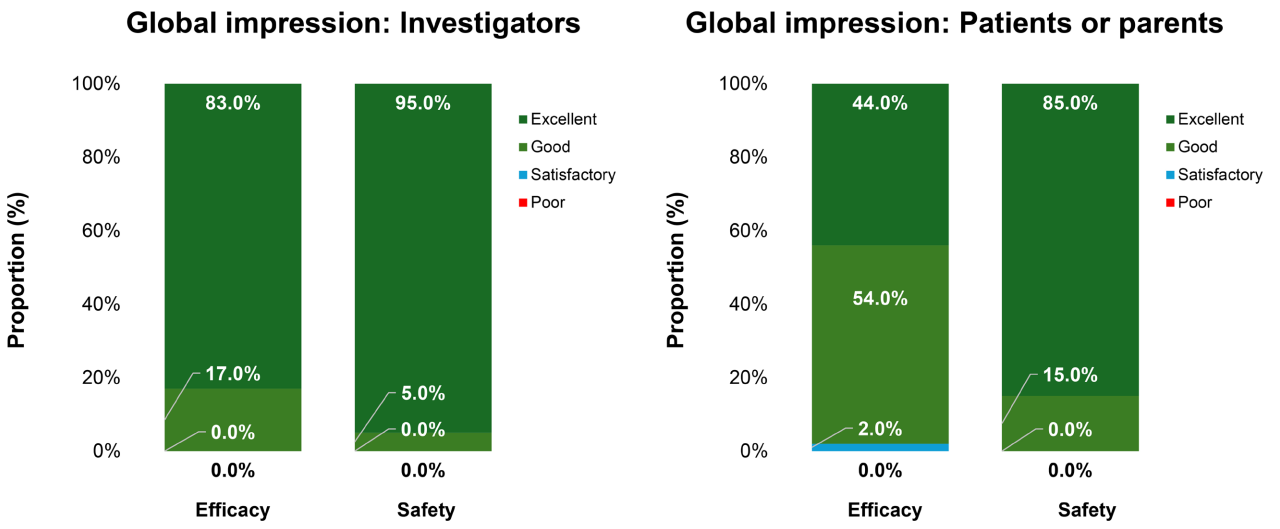

(c)

Figure 3. (a) Global impression of treatment's efficacy and safety by investigators and patients/parents in normal disease course in Cohort A; (b) Global impression of treatment's efficacy and safety by investigators and patients/parents in severe disease course in Cohort A; (c) Global impression of treatment's efficacy and safety by investigators and patients/parents in normal disease course in Cohort B.

3.4. Safety Endpoints

Overall, two patients (2.2%) from Cohort A developed AEs of mild intensity during the study period. One patient complained of nausea, and the other had throat irritation—both events were deemed unrelated to the study medication. No patients in Cohort B or those with severe disease developed any AEs during the study period.

4. Discussion

This study assessed the efficacy of a multi-herbal menthol lozenge for treating acute sore throat, cough and associated symptoms due to various aetiologies. The lozenges (when administered every 2 hours) demonstrated significant clinical relevance as a local analgesic and antitussive agent, with rapid onset of action that provided effective symptomatic relief and minimal AEs. Patients treated with the lozenges reported significant improvement in throat pain as early as 15 minutes post-administration.

The lozenges also achieved clinical and statistically significant reductions from baseline in inflammation, cough, hoarseness of voice and presence of exudates from 5 to 15 minutes post-administration (**Figure 4** & **Figure 5**). The high global impression scores associated with treatment efficacy and safety that were reported by patients or their parents/caregivers confirmed the overall beneficial effect of the lozenges. Our study also supported the therapeutic efficacy and safety of the lozenges for as-needed use (up to 8 - 10 lozenges per day) throughout the 3-day treatment period. Notably, mild AEs were reported in only two patients, which ultimately were deemed unrelated to the study medication.

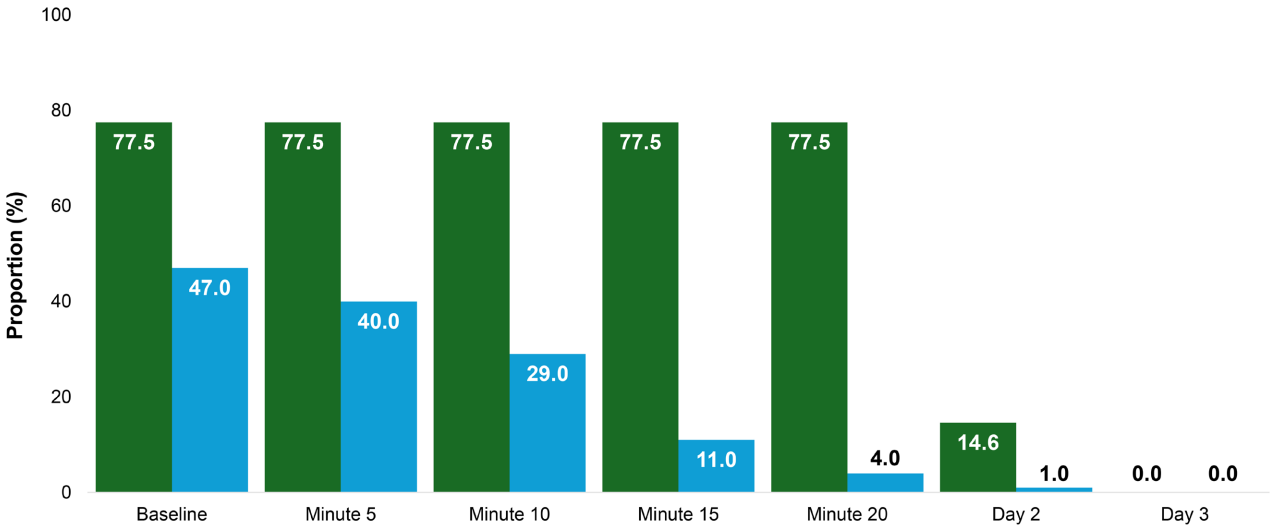

Figure 4. Proportion of patients with normal disease course having exudates in Cohorts A (green bars) and B (blue bars).

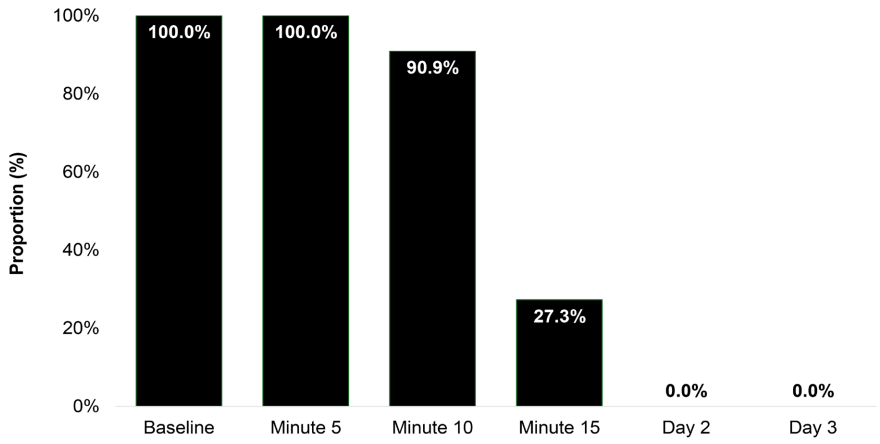

Figure 5. Proportion of patients with severe disease having exudates in Cohort A.

Topical therapies serve as a key component in the self-management of acute sore throat and cough, offering localised symptomatic relief through direct mucosal application. This targeted approach facilitates rapid analgesic and antitussive effects while minimising systemic exposure and associated risks. The lozenges contain menthol and herbal extracts with various medicinal properties, including liquorice (*Glycyrrhiza glabra*), ginger (*Zingiberaceae*) and amla (*Emblica officinalis*).

As a topical agent, menthol activates the transient receptor potential melastatin-8 (TRPM8) receptor, which may inhibit respiratory reflexes to mediate pain, reduce irritation and alleviate coughing [13] [14]. Activation of the TRPM8 channels produces a cooling sensation, which serves as a counter-irritant that reduces pain from inflammation and respiratory irritation response. [14] Menthol's broad antitussive effects are mediated through a reflex mechanism involving TRPM8-dependent activation of the afferent neurons and modulation of sensory irritant receptors in the airway [13] [15].

Meanwhile, liquorice-derived bioactive compounds exhibit anti-inflammatory, antioxidant, antiviral and analgesic properties [16]. Its primary role in cough relief is often as part of compound formulations, where it serves as a sweet, palatable demulcent [17]. Traditionally, liquorice has been used to ease sore throats, relieve persistent cough and as an expectorant [18] [19]. Its demulcent properties help form a protective film over mucous membranes, thus providing symptomatic relief as an antitussive. A randomised controlled trial (RCT) demonstrated that administering liquorice gargles 5 minutes before induction of anaesthesia significantly reduced the incidence and severity of postoperative sore throat and cough after tracheal intubation [20].

Ginger is known as a natural remedy used for common ailments like sore throats, coughs, fevers and digestive issues owing to its rich composition of bioactive compounds [21]. These bioactives contribute to ginger's potent antioxidant and anti-inflammatory properties. Its expectorant action also helps loosen and expel phlegm, making it an effective option for cough relief [22]. A systematic review has highlighted the antioxidant benefits of dried ginger, supporting its use as a home remedy for the prevention and treatment of colds, sore throats and coughs [22]. Beyond respiratory symptoms, several RCTs have investigated the therapeutic potential of ginger across a range of inflammatory and painful conditions, such as primary dysmenorrhea and muscle pain, knee osteoarthritis and rheumatoid arthritis [23].

Separately, amla has a long history of use in traditional medicine for several therapeutic actions, including the reduction of sore throat and dryness of the mouth [24]. Clinical studies have shown its effectiveness in reducing sore throat and hoarseness following general anaesthesia with endotracheal intubation, as well as in alleviating cough during endobronchial ultrasound bronchoscopy [24] [25]. In addition to its antitussive effects, a separate preclinical study also showed that continuous treatment with amla extract significantly alleviated postoperative and neuropathic pain in murine models [26].

Taken together, there is enough evidence to support the role of a lozenge formulation containing these herbal ingredients in the management of inflammatory conditions, such as acute sore throat and its associated symptoms, as demonstrated through the findings from this study. While this study's single-arm, open-label design presents inherent limitations in the interpretation of results where we acknowledge the potential for a significant placebo effect—common in trials for cough and sore throat remedies—it is important to note that patients reported significant relief from throat pain and cough within just 15 minutes of administration. This rapid onset of symptom relief suggests that the observed effects are most likely attributable to the effectiveness of the therapy itself, rather than solely to placebo responses. Nonetheless, future studies are warranted to further validate these findings.

5. Conclusion

This study shows that a multi-herbal menthol lozenge (administered every 2 hours

for up to 8 - 10 lozenges per day over 3 days) is effective in managing acute sore throat, cough and associated symptoms, demonstrating rapid symptomatic relief and good safety profile. This effective symptomatic relief is especially important in the clinical context of managing upper respiratory tract infections, where viral etiologies are common. By alleviating symptoms, such a lozenge could play a crucial role in supporting rational antibiotic stewardship, potentially reducing inappropriate use of antibiotics for viral infections. This approach not only enhances patient comfort but also contributes to broader public health efforts aimed at combating antibiotic resistance.

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Disclosure

All authors are employees of J. B. CHEMICALS & PHARMACEUTICALS LIMITED, the manufacturer of the product discussed in this manuscript.

Author Contributions

All authors contributed equally to the conceptualisation, investigation, analysis and review of this study.

Informed Consent

All patients or their parents/caregivers provided written, informed consent prior to study enrolment.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics Approval

This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki). Approval was granted by an independent ethics committee (Protocol ID: IS/06/DML/07/10).

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's website (Figures S1-S3).

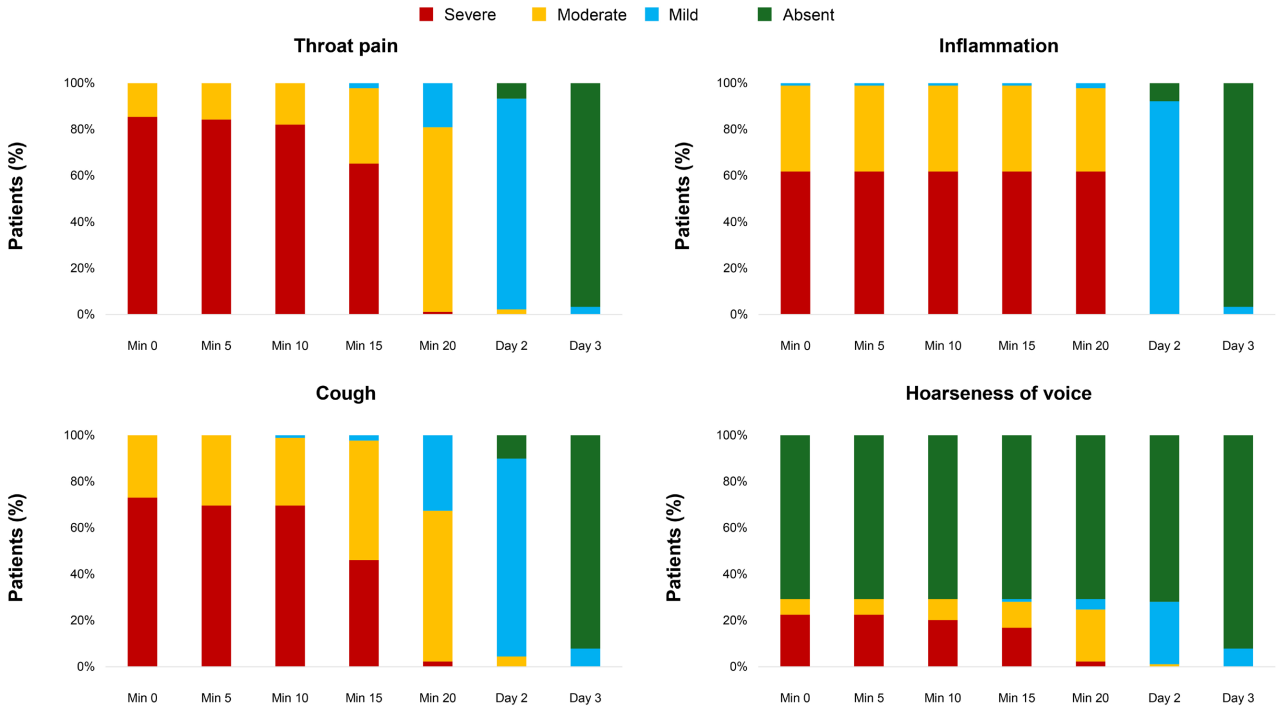

Figure S1. Changes in disease severity among patients with normal disease course over time in Cohort A.

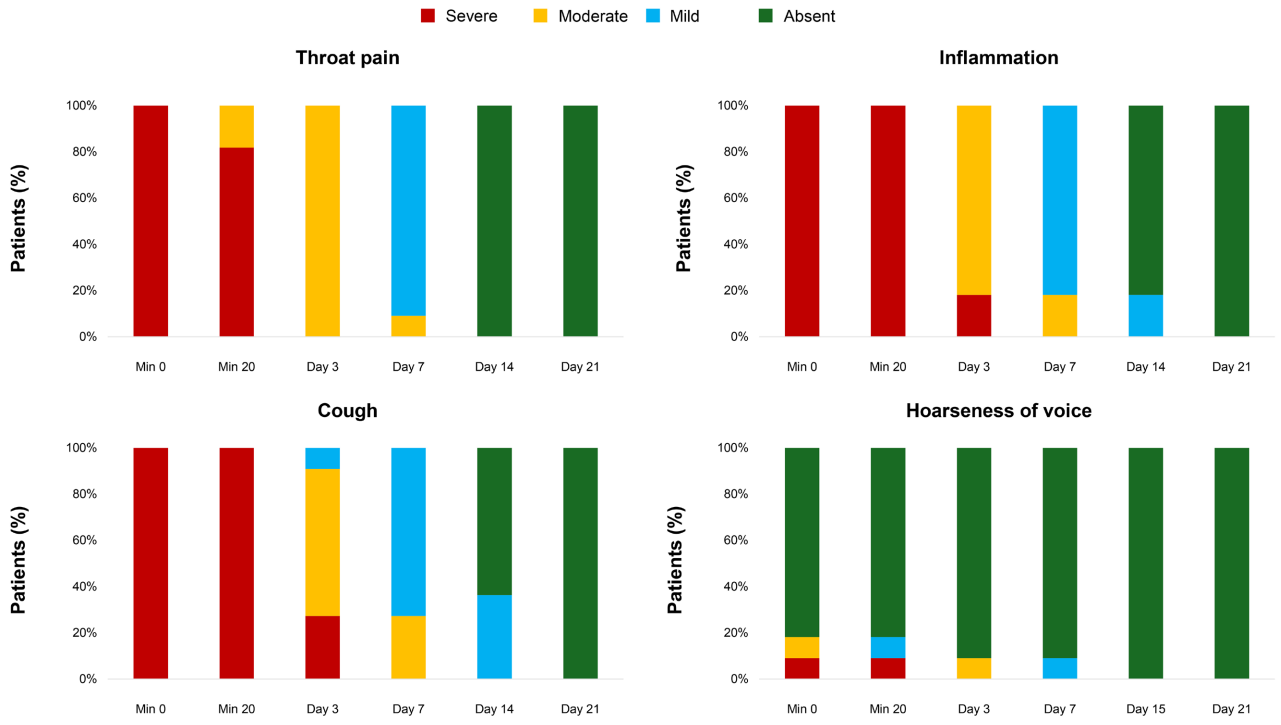

Figure S2. Changes in disease severity among patients with severe disease course over time in Cohort A.

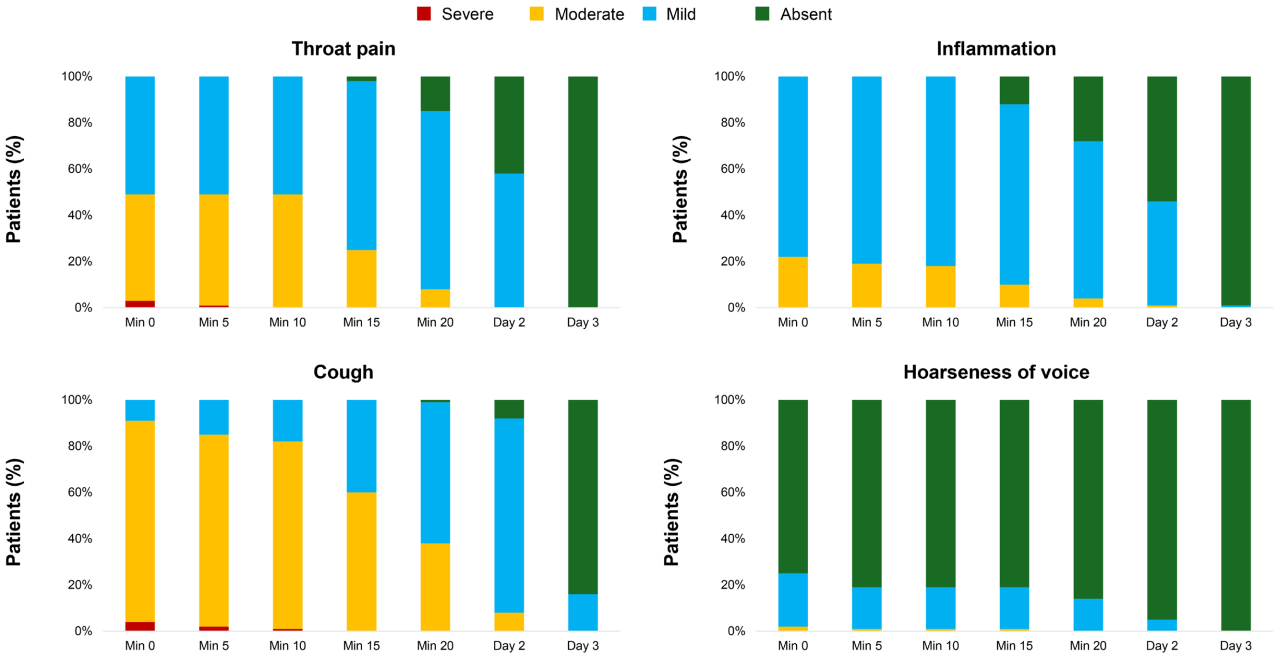

Figure S3. Changes in disease severity among patients with normal disease course over time in Cohort B.