Research Article

BIOMEDICAL Journal of Scientific & Technical Research

ISSN: 2574 -1241

DOI: 10.26717/BJSTR.2025.63.009841

Effectiveness and Safety of Zenasinil® Nasal Drops in Patients with Upper Airways Inflammation

Oreana Franca Falvo[1], Umberto Di Maio[2], Antonino Bagnulo[3], Maria Potenza[3] and Andrea Cerciello[3]*

[1]*Private practitioner, Via Gugliemo Marconi, 196 – 00146 Roma (RM)*

[2]*Shedir Pharma Group SpA, Via Bagnulo, 95 – 80063 Piano di Sorrento (NA) – Italy*

[3]*Neilos Srl, Via Bagnulo, 95 – 80063 Piano di Sorrento (NA) – Italy*

***Corresponding author:** Andrea Cerciello, Neilos Srl, Via Bagnulo, 95 – 80063 Piano di Sorrento (NA) – Italy

ARTICLE INFO

Received: August 08, 2025

Published: August 28, 2025

Citation: Oreana Franca Falvo, Umberto Di Maio, Antonino Bagnulo, Maria Potenza and Andrea Cerciello. Effectiveness and Safety of Zenasinil® Nasal Drops in Patients with Upper Airways Inflammation. Biomed J Sci & Tech Res 63(1)-2025. BJSTR. MS.ID.009841.

ABSTRACT

Upper airways inflammation is a common disorder of respiratory tract related to the development of irritation and swelling of nose, sinuses and pharynx. Examples of these conditions are rhinitis, rhinosinusitis, pharyngitis. Zenasinil® drops is a medical device formulated with the patented technology ARGINECID® which aids in decreasing mucus secretion, restoring physiological nasal airflow as well as prevents the upper respiratory tract inflammation. The aim of this retrospective clinical survey was to evaluate the effectiveness, tolerability, and usability of Zenasinil® drops based on its consolidated intended use in association with conventional anti-inflammatory treatments. Results after 2 months of treatment showed a pronounced reduction in symptoms including dense secretions, poor sleep, criyng more than usual, looking for a parent frequently in 94 patients affected by upper respiratory tract inflammation. More complex and controlled clinical trials are necessary to confirm the interesting results obtained with the present retrospective clinical survey.

Keywords: Nasal Congestion; Insomnia in Children; Nasal Drops; Upper Airways Inflammation

Introduction

Upper airways inflammation is a common disorder of respiratory tract related to the development of irritation and swelling of nose, sinuses and pharynx. This condition is frequently caused by viral or bacterial infections, presence of allergens or by environmental irritants [1]. Clinical manifestations usually include sore throat, nasal congestion, cough and sometimes fever. Generally, these symptoms are mild and self-limiting, while in some cases they can lead to severe complications especially in patients with immune system or long-term lung diseases. Inflammation of nasal mucosa is called rhinitis and is considered as a chronic disorder both in children and adults. There are two different kind of rhinitis: not-allergic and allergic ones. Rhinitis is often characterized by nasal congestion, sneezing and runny nose [2]. Allergic rhinitis is considered the most common form of inflammation of nasal mucosa with prevalence of 27,3% in children and 29,8% in adults. This kind of rhinitis is associated to IgE-mediated immune response by environmental allergens [2]. In order to reduce symptoms of rhinitis is often suggesting to use nasal saline irrigation, anticholinergic nasal sprays, decongestants and oral antihistamines. These pharmacological treatments can drastically decrease the nasal congestion, irritation of nasal mucosa and the excessive runny nose. Rhinosinusitis, also known as sinusitis, is an inflammatory condition of the sinuses and nasal cavities which can be recognized as an acute or chronic disorder.

Acute rhinosinusitis lasts less than 4 weeks and affects about 2% of population [3] while the chronic rhinosinusitis occurs globally in 10-15% [4] of people, lasting more than 12 weeks. The common symptoms of rhinosinusitis are nasal obstruction, facial discomfort, lost sense of smell and production in some cases of nasal polyps. As mentioned above for rhinitis, also in this case the use of nasal irrigation, decongestants and nasal corticosteroids can help to reduce the pain, leading to decongestion of nasal cavities [5]. Inflammation of

pharynx is called pharyngitis and can be provoked by viral or bacterial infections. Typically, pharyngitis shows as main symptoms the sore throat and difficulty swallowing. Sometimes, other symptoms like headache, cough or nasal congestion can be associated with this pathology [6]. As concerning to the epidemiology of pharyngitis, it is noteworthy that its prevalence among the global population is about 15-30% in children and 5-10% in adults [6]. In most cases, the viral pharyngitis is self-limiting and the symptoms disappear within few days. Instead, for the treatment of bacterial pharyngitis is requested the use of antimicrobials and antipyretics in order to eliminate the infection and prevent complications such as fever [6]. The management of upper airways inflammation is still today a challenge for the researchers because does not exist a multi-target therapy useful for decreasing of all associated symptoms.

Nevertheless, there is an increasing interest in different therapeutic areas in developing novel non-pharmacological approaches especially with food supplements or medical devices characterized by high therapeutic efficacy and minimal side effects, able to act on different symptoms [7]. Zenasinil® drops is a medical device formulated with the patented technology ARGINECID® which aids in decreasing of mucus secretion, restoring physiological nasal airflow as well as prevents the upper respiratory tract inflammation. The aim of this retrospective clinical survey was to evaluate the effectiveness, tolerability, and usability of Zenasinil® drops based on its consolidated intended use in association with conventional anti-inflammatory treatments.

Materials and Methods

Settings

The clinical survey has been conducted by an Italian paediatrician and is based on its clinical experience in patients taking Zenasinil® drops. The retrospective observational survey was conducted in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. Data were retrospectively collected in the period December 2022 – November 2023 by the paediatrician located in Lazio a region in the centre of Italy. Ethical approval was not necessary according to National Code on Clinical Trials declaration because this data derives form a real life retrospective study [8].

The aim of the present study was to evaluate the effect of Zenasinil® drops administration in patient with inflammatory upper respiratory tract conditions at T0 and after two months, performing therapeutic cycle of administration according to Zenasinil® drops instruction for use. The medical device was associated with the conventional anti-inflammatory drugs prescribed.

Study Population, Treatment and Evaluated Parameters

A specialist in paediatrics conducted a clinical evaluation beginning in December 2022, enrolling paediatric patients with defined upper respiratory tract inflammation that was considered as inclusion criteria. A total of 94 paediatric patients met these criteria and were enrolled in the study, with a mean age of of 6,9 months. At the first medical examinations, the doctor reported for each paediatric patient its age, illness, any comorbidities, use of medications and the presence or not of yellow or greenish dense secretions. Then, the patients clinical condition was assessed through a questionnaire compiled with the help of a parent. The questionnaire used for children assessment was CANADIAN ACUTE RESPIRATORY INFECTION AND FLU SCALE (CARIFS) consists of 18 items covering three domains: symptoms, functions children and parental impact [9]. The most important item in the field of medical device application were consider to be: does not sleep well, cries more than usual, seeks a parent and has a fever. These one were rated on a scale from 0 (no symptoms) to 3 (severe symptoms).

Then, each participant was advice to apply Zenasinil® drops according to the method of use and posology indicated on the package leaflet (3 drops for each nostril 3 times a day) and to re-show for a follow-up visit after 2 months.

At the second visit, the paediatric patients were again assessed by the doctor monitoring the presence of yellow or greenish dense secretions and through the same questionnaire mentioned above with the help of a parent, ranking the symptoms on a scale from 0 to 3 where a high score indicates a greater symptom severity. Some of participants also received concomitant pharmacological treatment, including anti-inflammatory agents, antihistamines, these co-treatments were administered based on individual clinical needs and physician discretion.

Results and Discussion

As reflected in questionnaires, children enrolled showed at first visit (T0) with yellow or greenish dense secretions caused by inflammation of the upper respiratory tract. During the follow-up visit (T2), the doctor recorded the total absence of dense secretions in all of the patients enrolled except one who was affected by dense secretions both during the first (T0) and the follow-up visit (T2). In particular, 93 of 94 children had no yellow or greenish secretion after Zenasinil® drops treatment in association with conventional anti-inflammatory drugs, respecting the mode of use reported on the leaflet of the medical device. Other relevant monitored symptoms from CARIFS questionnaire were: does not sleep well (insomnia), cries more than usual and seeks a parent. Each symptom was analysed according to the number of manifestations recorded in the enrolled patients and the severity degree. In the next figures are reported the number of patients recorded with the questionnaire symptoms considered and its relative severity scale. It is clear that after 2 months following treatment with medical device Zenasinil® drops in association with conventional anti-inflammatory drugs, the number of patients with a complete resolution for every symptom was very high. Particularly, in Figure 1, is reported the parameter insomnia: at the first visit almost all patients showed mild symptom of insomnia, while after 2 months

of treatment about 90% of the total of patients had a resolution with better quality of sleep and only 10% maintained mild symptoms of insomnia.

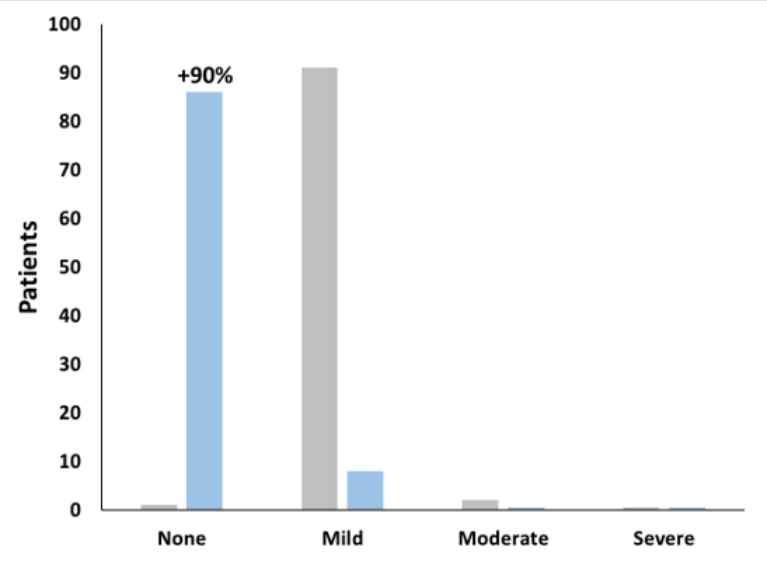

Figure 1: Distribution of symptoms rank for sleep quality (insomnia): severe, moderate, mild and no symptoms at T0 (grey) and T2 (blue) after Zenasinil® drops administration.

Probably, the treatment with Zenasinil® drops, thanks to its patented technology, is able to improve nasal congestion and so the breathing capability enhancing the sleep quality. Other 2 symptoms very important in managing upper respiratory inflammation, indicating are a not well- being in children, are cry more than usual and looking for a parent more frequently. As reported in Figure 2, at the enrolment visit 78 patients presented moderate, 13 patients mild and 3 patients severe score of crying more than usual. After two months of association of Zenasinil® drops with conventional anti-inflammatory therapies, about 95% of the total of patients resolved this problem and only 5% of the total of patients maintained mild symptomatology. Finally, maybe as most important parameter, the score related to seek a parent more than usual is reported in Figure 3. In fact, most patients with upper respiratory flogosis recruited in the present retrospective survey experienced at T0 severe increase in the seeking of a parent compared to usual. After the treatment with conventional drugs for rhinitis or other inflammatory conditions related to upper airways in association with Zenasinil® drops, this score was sensibly reduced with a resolution for about 84% of children and only 16% of the examined population maintained the symptoms with the following score: 9 patients mild, 3 patients moderate and 3 patients severe.

No side effects were reported from parents of each children demonstrating the high safety of treatment with Zenasinil® drops in association with conventional treatments for inflammation conditions of upper airways. The observed effect in this retrospective clinical survey are related to the components of the patented technology named ARGINECID®; in fact, high molecular weight hyaluronic acid, due to its highly polymeric and hygroscopic nature, attracts water within the nasal cavities, thereby improving mucus viscosity and facilitating its elimination [10-12]. At the same time, bioactive metabolites from Iceland moss (Cetraria islandica), bind to mucus mucins, promoting their removal along with external irritants such as dust particles and allergens [13]. Finally, the optimized Zenasinil® drops formulation, in association with conventional pharmacological drugs, thanks to the synergistic effect of all its ingredients, actively contribute in reducing the typical children symptomatology in upper respiratory tract inflammations.

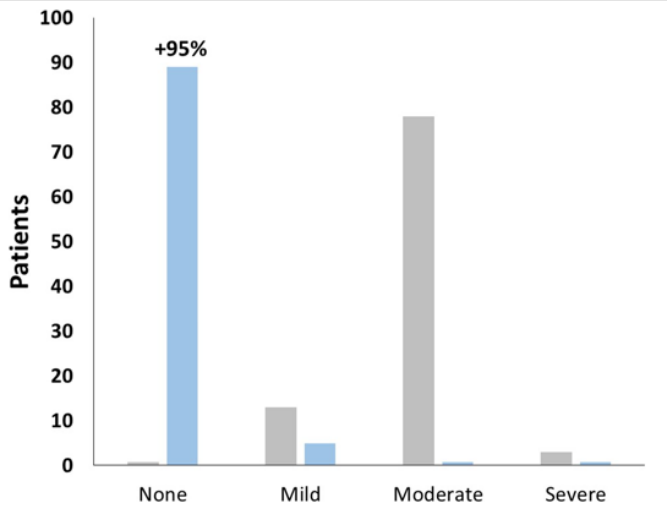

Figure 2: Distribution of symptoms rank for the parameter cry more than usual: severe, moderate, mild and no symptoms at T0 (grey) and T2 (blue) after Zenasinil® drops administration.

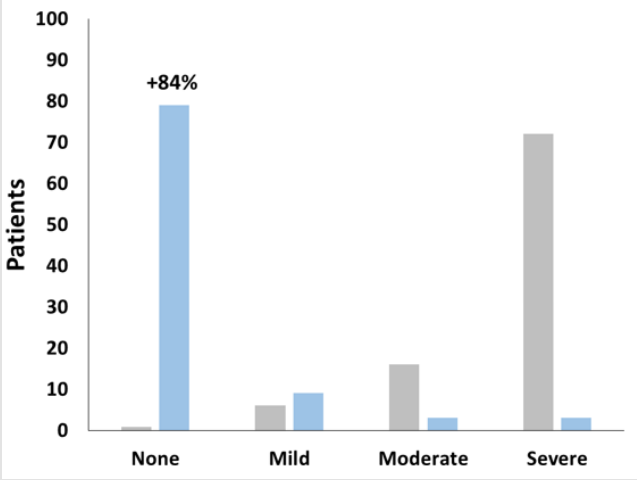

Figure 3: Distribution of symptoms rank for the parameter looking for a parent more frequently: severe, moderate, mild and no symptoms at T0 (grey) and T2 (blue) after Zenasinil® drops administration.

Conclusion

The retrospective survey conducted with the aim to analyse post-marketing clinical experience concerning the use of Zenasinil® drops in the paediatric population has shown a pronounced reduction in symptoms including dense secretions, poor sleep, cries more than usual, seeks a parent in 94 patients affected by upper respiratory tract inflammation. As a result, it was observed an increasing in the number of children without any of the above mentioned symptoms after the treatment with Zenasinil® drops in association with conventional prescribed anti-inflammatory drugs. The obtained data demonstrated the efficacy, safety and usability of Zenasinil® drops medical device in paediatric population with upper respiratory tract diseases and related symptoms. More complex, controlled and randomized clinical trials with a wide range of population evaluated are necessary to confirm the interesting results reported in this retrospective survey and to recommend Zenasinil® drops as an adjuvant treatment in upper respiratory tract disorders.

Conflicts of Interest

We declare that Umberto Di Maio is a Shedir Pharma Group S.p.A. member, Antonino Bagnulo, Maria Potenza and Andrea Cerciello are Neilos S.rl. members.

Funding

This research was funded by a grant from Neilos S.r.l.

Authors' Contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

References

1. Varricchio Attilio, Ignazio La Mantia, Francesco Paolo Brunese, Giorgio Ciprandi (2020) "Inflammation, infection, and allergy of upper airways: new insights from national and real-world studies." Italian journal of pediatrics 46(1): 18.
2. Eifan Aarif O, Stephen R Durham (2016) "Pathogenesis of rhinitis." Clinical & Experimental Allergy 46(9): 1139-1151.
3. Bittner Claudia B, Michael Plach, Hubert Steindl, Dimitri Abramov Sommariva, Christoph Abels, et al. (2022) "Prevalence of antibiotic prescription in patients with acute rhinosinusitis treated by general practitioners and otolaryngologists in Germany—a retrospective cohort study." Antibiotics 11(11): 1576.
4. DeConde Adam S, Zachary M Soler (2016) "Chronic rhinosinusitis: epidemiology and burden of disease." American journal of rhinology & allergy 30(2): 134-139.
5. Suh Jeffrey D, David W Kennedy (2011) "Treatment options for chronic rhinosinusitis." Proceedings of the American Thoracic Society 8(1): 132-140.
6. Bisno Alan L, Michael A Gerber, Jack M Gwaltney Jr, Edward L Kaplan, Richard H Schwartz (2002) "Practice guidelines for the diagnosis and management of group A streptococcal pharyngitis." Clinical infectious diseases 35(2): 113-125.
7. Camerlingo A, U Di Maio, A Cerciello (2023) "Pain relief effect of Crackdol® fast foam in osteoarticular disorders." J Clin Stud Med Case Rep 10(5): 193.
8. Kıraç FS (2013) Is ethics approval necessary for all trials? A clear but not certain process. Mol Imaging Radionucl Ther 22: 73-75.
9. Jacobs B, Young N L, Dick P T, Ipp M M, Dutkowski R, et al. (2000) Canadian Acute Respiratory Illness and Flu Scale (CARIFS): development of a valid measure for childhood respiratory infections. Journal of clinical epidemiology 53(8): 793-799.
10. Necas J, Bartosikova L, Brauner P, Kolar J (2008) Hyaluronic acid (hyaluronan): a review. Vet Med-Czech 53(8): 397-411.
11. Snetkov P, Zakharova K, Morozkina S, Olekhnovich R, Uspenskaya M (2020) Hyaluronic Acid: The Influence of Molecular Weight on Structural, Physical, Physico-Chemical, and Degradable Properties of Biopolymer. Polymers (Basel) 12(8): 1800.
12. Di Cicco M, Alicandro G, Claut L, Cariani L, Luca N, et al. (2014) Efficacy and tolerability of a new nasal spray formulation containing hyaluronate and tobramycin in cystic fibrosis patients with bacterial rhinosinusitis. J Cyst Fibros 13(4): 455-460.
13. Assessment report on *Cetraria islandica* (L.) Acharius s.l., thallus.

ISSN: 2574-1241

DOI: 10.26717/BJSTR.2025.63.009841

Andrea Cerciello. Biomed J Sci & Tech Res