Monograph
**Allergy Nasaleze**

- *Nasaleze* is a Class 1 medical device in Europe
- Natural protection of allergy symptoms from hay fever, dust mites and animal dander
- Drug free, fast-acting and non-drowsy
- 30-day supply (200 doses)
- Safe for pregnant and breast feeding women
- Safe for children (under supervision)
- Refreshing mint flavour

**Ingredients**

Contains inert natural cellulose powder of vegetable origin and peppermint powder.

**What is Nasaleze**

Nasaleze, an inert proprietary grade of micronized cellulose powder, is composed of fine particles of inert cellulose that are applied to the inside of the nose via a unique delivery system. Nasaleze is clinically proven to deliver fast, effective protection against hay fever caused by airborne allergens such as dust mites and pet allergies.

A novel patented method ensures delivery of an effective dose via the nasal cavity.

Nasaleze is a unique, natural product that works with your body's own defence mechanism to strengthen your resistance to airborne allergens, it reduces the need to take rescue medication for symptoms caused by hay fever, pollen, dust mite or animal dander. Acting as a barrier to airborne allergens, Nasaleze stops the cause of allergies rather than just treating the symptoms.

Nasaleze meets both the highest purity and safety standards, it can be used successfully to relieve the most chronic symptoms reported by allergy sufferers. Studies have demonstrated that Nasaleze substantially improves the rate of Nasal Mucous Clearance and PNIFR (Peak Nasal Inspiratory Flow Rate) and significantly reduces the need for rescue medication.

**Who is it for?**

Many sufferers are looking for something new. Even ‘non-drowsy’ antihistamines can have a hangover effect and long term use of steroids is not desirable. Some sufferers will already be taking medication for other reasons and will not want to combine drugs. Others may be pregnant or breast feeding and parents of school age children will want genuinely non-sedating treatment.

**Indications**

When administered Nasaleze protects from and strengthens resistance to airborne allergens such as pollen, dust mites and animal dander. Nasaleze is a clinically-proven, unique, natural product that works with the body's own nasal defence mechanism.

**Mechanism of action**

Nasaleze gets to work when the cellulose powder meets the moisture always found present in the nasal tract to form a protective gel-like barrier. This barrier prevents contact between aggravating airborne allergens and the mucosa. Thereby preventing mast cell degranulation and the release of histamine. Thus avoiding the allergic reaction and classic symptoms of seasonal allergic rhinitis (SAR). Relief from symptoms can occur in minutes for many patients or within less than 3 hours for others. Over 20 positive clinical trials with statistically significant results have been conducted on Nasaleze. and the product is proven to effectively relieve symptoms such as sneezing, runny/itch nose and eyes as well as nasal inflammation. Severe allergy sufferers can combine Nasaleze with their regular drug treatment for added relief. Although our studies have proven that many sufferers can reduce their allergy drug intake by preventing their symptoms with Nasaleze alone.

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Contraindications
There are no contraindications making Nasaleze suitable for a broad range of patients.

Drug interactions
Nasaleze does not contain any antihistamines, steroids, drugs or medicines. Nasaleze is suitable for the elderly, adults, pregnant and breast feeding women, and children (with supervision).

Precautions
The amount, grade, and route of administration used in Nasaleze does not present any serious toxicological risks. Once opened, use within six months. Do not use if tamper evident seal is broken.

Side effects
Side effects are virtually unknown. Because it is steroid and antihistamine free, Nasaleze is often preferred to drugs by sufferers. Studies carried out in volunteers reveal no serious adverse effects when taking Nasaleze.

Getting the best out of Nasaleze
For maximum efficacy it is necessary to maintain a constant layer of gel across the lining of the nose. After blowing the nose therefore, it is necessary to re-administer Nasaleze to renew the barrier.

The usual dose is one puff of powder up each nostril three times a day, administering more frequently or taking two puffs per nostril may accelerate symptom relief, use as often as required.

Nasaleze should be taken as soon as symptoms appear.

Nasaleze can also be taken as a preventative measure before entering an environment where airborne allergens are likely to be present. Nasaleze helps to provide protection before symptoms occur in situations like going into the garden, dusting or if the pollen count is high.
Proven success in clinical trials

Reduces the need for rescue medication vs placebo

- Double blind placebo controlled study
- 97 adult volunteers with symptoms for at least 2 years
- Stratified random sample by gender and age range
- Pre-trial assessment showed no significant differences in severity of symptoms or medication taken in previous years
- Placebo was lactose powder
- Trial over 4 weeks of grass pollen season 2004
- Daily pollen counts from the national count station at National Pollen and Aerobiology Research Unit
- Allowed to take any medications as this was used as an outcome measure
- Likert scores of 7 symptoms

Results
- Significantly fewer amounts of rescue medication taken in the Nasaleze group
- Significant differences in numbers taking Nasaleze only or placebo only
- No adverse reactions reported

Significant reduction in grass pollen symptoms

Åberg, Ospanova, Niktin, Emberlin, Dahl. INT Arch Allergy Immunol 2014;163:313 -318
- 108 patients (18-40 years old)
- Placebo – 43
- Active – 54
- Seasonal allergic rhinitis nasal symptoms
- 1 puff, three times daily
- SMS reminders daily
- Daily severity reports update

Results
- Highly significant reduction in all symptoms
- Only 1 patient in each group received emergency antihistamine

Reduces symptoms of house dust mite allergy

- Double blind placebo controlled cross over trial
- People act as own controls, at least a week between challenges
- 15 volunteers with persistent rhinitis and with allergy to house dust mites diagnosed by skin allergy test
- Challenge by standardised dust mix delivered to nostrils by a micro spoon
- Equivalent to 5ug of Der p1 and 5ug of Der f1 per g of inert carrier fine particle dust
- Measurements at baseline and at regular intervals in clinic for 6.5hrs then twice to 24hrs

Results
- Significant improvement in symptom score for Nasaleze group
- Two and a half times more Nasaleze patients achieved complete control vs placebo
**Significantly reduces hay fever symptoms in small children**

Aberg N, Benson M. Presented at EAACI June 2010 and accepted for publication in Int Arch Allergy & Immunol.

- 53 patients (8-18 years old)
- Active 25
- Placebo 28
- 6% responses missing (of possible 13,356)
- 8 patients – irritation in nose/throat
  - 1 withdrew, 1 took nasal steroid for 1 day
  - Both in the placebo group

**Results**

- Significant symptom reduction
  - Less sneezing and runny nose
  - Improved lower airways and blocked nose relief

<table>
<thead>
<tr>
<th>Question</th>
<th>Treatment</th>
<th>Mean symptom rating</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Sneezing</td>
<td>Placebo</td>
<td>2.31</td>
<td>.060</td>
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<tr>
<td></td>
<td>Active</td>
<td>1.91</td>
<td></td>
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<tr>
<td>Running nose</td>
<td>Placebo</td>
<td>2.56</td>
<td>0.017</td>
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<tr>
<td></td>
<td>Active</td>
<td>2.03</td>
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<tr>
<td>Blocked nose</td>
<td>Placebo</td>
<td>.42</td>
<td>0.24</td>
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<tr>
<td></td>
<td>Active</td>
<td>2.13</td>
<td></td>
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<tr>
<td>Eye symptoms</td>
<td>Placebo</td>
<td>2.26</td>
<td>0.53</td>
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<tr>
<td></td>
<td>Active</td>
<td>2.11</td>
<td></td>
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<tr>
<td>Lower airways</td>
<td>Placebo</td>
<td>.63</td>
<td>0.48</td>
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<tr>
<td></td>
<td>Active</td>
<td>1.47</td>
<td></td>
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<tr>
<td>Sum of all symptoms</td>
<td>Placebo</td>
<td>11.170</td>
<td>0.97</td>
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<tr>
<td></td>
<td>Active</td>
<td>9.66</td>
<td></td>
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<tr>
<td>Sum of nasal symptoms</td>
<td>Placebo</td>
<td>7.29</td>
<td>0.033</td>
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<tr>
<td></td>
<td>Active</td>
<td>6.07</td>
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</table>

**Helps to increase the quality of life of hay fever sufferers**

Penechko, Sizyakina. Russian Allergy Journal, May 2011

- 30 participants
- Group one received standard.
- Group two received Nasaleze three times a day in addition to the basic therapy.
- 4 weeks with the patients visiting the clinic once a week.
- Used 7 point scale
  - 0 – No adverse effects
  - 6 – Severe adverse effects, both before and after treatment

**Results**

- Group one saw significant improvement in symptoms such as runny and stuffy nose.
- Group two saw statistically significant reduction in symptoms: runny nose, sneezing, itchy nose and stuffy nose.
- Significant improvement in quality of life for the second group.

**Helps prevents the symptoms of hay fever**

Diethart, Emberlin, Lewis. Presented as a Poster at EAACI XXVII Congress, Barcelona, Spain 7-11 June 2008

- In Vitro
- Der p1 used as dust mite allergen
- Amount of diffusion measured by ELISA
- Comparison with base-line amount

**Results**

- Nasaleze delays the diffusion of Der p1
- Re-application is needed to maintain optimum efficacy
<table>
<thead>
<tr>
<th>Study</th>
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<th>Measurements and Results</th>
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<tr>
<td>Use of Cellulose Powder for the Treatment of Seasonal Allergic Rhinitis</td>
<td>Ji Y. J., Steadman. Participants were instructed to have one puff in each nostril of Nasaleze. Drop treatment was allowed if a hayfever attack occurred. Participants kept a diary documenting the effectiveness of the powder (a score of 5 represents no symptoms and complete control) and average time to relieve symptoms.</td>
<td>102 participants</td>
<td>Overall average daily score was reported as 3.65 (on the 5-point scale) for men and women indicating a minimum 75% success rate, in chronic hay fever sufferers. Only 32% of respondents recorded a daily average score under 2. Showing a higher score than all pharmaceutical alternatives that were comparatively referred to. Relief was obtained within 0-1.5 hours.</td>
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<tr>
<td>Clinical study of Nasaleze for relief of allergic symptoms including sneezing, itchy nose, itchy and watery eyes Presented at the Pan-Hellenic Conference of ENT Specialists on 19th March 2004 in Thessaloniki, Greece. Open Clinical Trial</td>
<td>Wahlin, K. The product was used once a day, usually in the morning or shortly before the known time of day when symptoms usually appear. One application per nostril. Evaluation at time 0, 3 weeks and 6 weeks. Trial took place from December 2003 till March 2004 so that participants were premenal or chronic allergy sufferers rather than seasonal sufferers.</td>
<td>40 participants</td>
<td>All participants were using a pharmaceutical treatment (Desonide 35% cortisone und 42.5%, antihistamines 2.5%, corticosteroid antihistamine combination 20%) at the beginning of the study. Participants were asked to discontinue use of this medication during the study. After 3 weeks of use 85% of participants realized improvement in their allergy symptoms. After 6 weeks of use 90% of participants realized improvement in their symptoms. No reported side effects.</td>
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<td>24 female and 16 male Mean age: 44</td>
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<tr>
<td>Measure of improvement in nasal mucociliary clearance and PNIFR (peak nasal inspiratory flow rate) in children with allergic rhinitis Presented at World Allergy Congress in Munich, Germany June 2005 Published in Nea Pediatrica Chronica, June 2005, Vol 5 no 2. Open Clinical Trial</td>
<td>Aivazis, Bourli, Manatou et al. Conducted at the University of Thessaloniki, Greece. The mucociliary clearance was determined with use of a non-invasive dye (Ideal Orange 3% + CaHPO42H2O 97%) in vivo. The participant's mucociliary clearance was measured prior to using Nasaleze and then 2 days after finishing the week treatment.</td>
<td>100 participants</td>
<td>There was significant improvement in nasal mucociliary clearance (reduced from 39 minutes to 18.15 minutes) and PNIFR values. The mean clearance time was reduced from 55.23 minutes to 21.2 minutes. Out of the 51 children who started the trial with abnormally prolonged clearance all but 5 children had improved nasal mucous clearance times. No adverse effects were reported.</td>
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<td>15 – 8.2</td>
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<td>A double blind placebo controlled trial of inert cellulose powder for the relief of symptoms of hay fever in adults Current Medical Research and Opinion 2006;22(2):79-85 Poster presented at World Allergy Congress, Munich 2005</td>
<td>Embrelle, Lewis. A double blind, placebo controlled trial in 2004. Participants could take any other medication along with Nasaleze or the placebo.</td>
<td>97 participants</td>
<td>The amount of rescue medication used by the placebo group (overall and in individual categories e antihistamines, nasal sprays and eye drops) was significantly greater than that used by the active (Nasaleze) group. No significant difference found in the symptom scores for the two groups. Nasaleze significantly reduced the need for rescue medication. No adverse effects were reported.</td>
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<td>40 male and 57 female Age range: 18+</td>
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<td>Double blind placebo controlled cross over trial of inert cellulose powder, by nasal provocation with grass pollen to assess efficacy of the product in controlling symptoms of hay fever Poster presented at EAACI, Vienna June 2006</td>
<td>Embrelle, Lewis. A trial of Nasaleze by nasal provocation with grass pollen (350 grains per cubic metre). At baseline and at regular intervals after challenge scores were taken for 6 symptom categories, moose were taken of nasal peak inspiratory and expiratory flow and ECP was tested for in nasal secretions.</td>
<td>11 participants</td>
<td>Nasaleze had significant effects in reducing symptoms of sneezing and itchy eyes (p&lt;0.01) due to grass pollen allergy. It can also have significant effects in reducing nasal inflammations, as measured as nasal PE, PIF and as ECP in secretions (p&lt;0.05). Results indicate that use of Nasaleze can help to alleviate symptoms of hay fever.</td>
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<td>Age range: 18+</td>
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<td>Double blind placebo controlled trial of cellulose powder as a remedy for persistent allergic rhinitis, by nasal provocation with Der p 1 and Der f 1 Presented as a Poster EAACI, Gothenburg June 2007 Current Medical Research and Opinion; Vol 23; No 10; 2007, 2422-2431</td>
<td>Embrelle, Lewis. A trial of Nasaleze by nasal provocation tests with Der p 1 and Der f 1. Base line measurements were taken before the challenge of 0.01μg dose containing 5μg of Der p 1 and 5μg of Der f 1 per g. Measurements taken at 15 minute intervals for the first hour, then at 30 minutes until 6 hours, then at 6 hours and at 24 hours.</td>
<td>15 participants</td>
<td>There was a significant difference in the results for sneezing, itchy nose, runny nose and ECP in nasal secretions. The peak nasal respiratory and inspiratory flow were also significantly different but there was considerable variation. There was no significant difference between the other symptoms and there were no adverse reactions. The Nasaleze can have significant effects in reducing some symptoms of persistent rhinitis due to house dust mite allergy.</td>
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<td>Age range: 18+</td>
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<td>Nasaleze cellulose powder delays dust mite allergen (Der p 1) diffusion in vitro Presented as a Poster at EAACI XXVII Congress, Barcelona, Spain 7-11 June 2008</td>
<td>Diethart and Embrelle of University of Warwick and Eswin of Wessex Stoney International Hospital. The amount of Der p 1 (house dust mite allergens) that diffused through the cellulose and agar gel was compared to the baseline allergen content at 15, 30, 45, 60, 180 and 300 minutes after the application of the allergen solution. In vitro</td>
<td></td>
<td>There was a significant reduction in the amount of Der p 1 that diffused through the Nasaleze compared to the control at all points of time. Only 0.76% of the allergen passed through the cellulose layer after 15 minutes. After 360 minutes only 14% of the baseline Der p 1 had crossed the cellulose gel while 100% had passed through the agar layer.</td>
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<td>A meta-analysis of the Efficacy and Safety of Nasaleze in the Prevention and Management of Allergic Rhinitis Published in The Open Allergy Journal 2008, 1, 1-4</td>
<td>A meta-analysis paper by Professor Patrick JD Bousc, Division of Medical Microbiology, Dept of Pathology, University of Stellenbosch, South Africa. Published in The Open Allergy Journal, 2008, 1, 1-4.</td>
<td>N/A</td>
<td>The meta-analysis review the clinical data conducted on Nasaleze between 2004 and 2008. Presented under 3 categories: Study designs and patient population studied, Study outcome measures, safety and product acceptability and Possibilities of product development.</td>
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<td><strong>Efficacy and safety of medical device: Nasaleze in prevention and treatment of persistent allergic rhinitis in adults and children</strong>&lt;br&gt;Presented at Moscow XVI Congress for Man and Drugs April 06-10, 2009</td>
<td>Participants were administered Nasaleze 3 times per day over the course of 4 weeks. 48 total participants: 25 adults and 23 children Age range: 2-62</td>
<td>The severity of AR symptoms and the tolerability of the product were assessed during each visit to the investigator. The results showed that Nasaleze reduces the severity of AR symptoms already in the first week of treatment and overall there was significant improvement in symptom reduction by week 4. Aavoided improvement in the quality of life of the full patients was measured. Furthermore, using Nasaleze is an effective and safe method of prevention and treatment of allergic rhinitis both in adults and children.</td>
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<td><strong>A nasally applied cellulose powder in seasonal allergic rhinitis (SAR) in children and adolescents; reduction of symptoms and relation to pollen load</strong>&lt;br&gt;Presented as a Poster in EAACI London 2010</td>
<td>There was a significant reduction in total symptom scores for the nose (p&lt;0.013) and specifically a running nose (p&lt;0.0017). There was a trend for all symptoms scores to be lower for the active group. During dry or moderate pollen season there is a significant reduction in total nasal symptoms and running nose along with sneezing severity.</td>
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<tr>
<td>Intra-nasal Inert Cellulose Powder in Prevention and Management of Seasonal Allergic Rhinitis (SAR) in children</td>
<td>Gezer, Sersöz, Kodak, Kocak. The study took place at the Clinic of Child Diseases at the JAM Sechenov Moscow Medical Academy in 2009. An open comparative randomized study. Participants divided into 4 groups depending on their current treatment. Each group received a different medication. Group 1: Nasaleze twice a day; Group 2: Montelukast 5 mg once a day; Group 3: 2 doses of 50mg Sodium Cromoglicate; Group 4: Budesonide 50mcg 3-4 times a day.</td>
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<td><strong>Presented as a Poster at EAACI London 2010.</strong>&lt;br&gt;<strong>Open non-comparative study to evaluate the effectiveness of Nasaleze preparation for patients with allergic rhinitis</strong>&lt;br&gt;Published in Russian allergy Journal in No. 2 (March – April 2011)</td>
<td>50 participants Age range: 8 – 18</td>
<td>26 patients demonstrated positive results from the first application of Nasaleze. After 6 weeks treatment, Group 1 demonstrated a significant decrease (alive&lt;0.001) of all SAR symptoms: rhinorrhea, sneezing, nasal blockage, nasal itching, eye itching, nasal pruritus, and nasal blockage. Children using Nasaleze decreased frequency of use of antihistamines, decongestants and topical steroids. Nasaleze has minimal side effects and is appropriate for children.</td>
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<td><strong>Nasal mucociliary clearance and mucociliation of hydroxypropylmethylcellulose of powder used for alleviation of allergic rhinitis</strong>&lt;br&gt;Presented as a Poster at EAACI, London 2010</td>
<td>12 participants Female and 3 male Mean age: 32.8&lt;br&gt;Mean age: 37.0</td>
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<td><strong>Published in Natural Science Vol.2, No.2, 79-84 (2010)</strong>&lt;br&gt;<strong>Efficacy of cellulose powder as part of a complex therapy if patients with intermittent allergic rhinitis</strong>&lt;br&gt;Russian Allergy Journal, May 2011</td>
<td>10 participants Age range: 18 – 33</td>
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<td><strong>Study of the effects of nasal cellulose powder on the nasal mucosa</strong>&lt;br&gt;Published Paediatric Allergy and Immunology 22 (2011) 594-599 (2011)</td>
<td>30 participants in general good health&lt;br&gt;30 participants in perennial or seasonal AR</td>
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<tr>
<td><strong>A Nasally Applied Cellulose Powder in Seasonal Allergic Rhinitis in Adults with Grass Pollen Allergy: A Double-blind, Randomized, Placebo-Controlled, Parallel-Group study</strong>&lt;br&gt;INT Arch Allergy Immunol 2014;163:313 - 318</td>
<td>108 participants Age range: 18 – 40</td>
<td>Significant reductions were found in severity scores for sneezing, runny nose, stuffy nose and symptoms from eyes and lower airways, both separately and together (alive&lt;0.001) reflective of an effect and opens on treatment at follow-up visits (both&lt;0.01) confirmed a high efficacy. There was a significant difference between the global opinions of the two groups. 87.1% of the active participants found the product had a good effect. The product provided significant protection against all seasonal allergic rhinitis symptoms. There were no severe adverse events.</td>
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<td><strong>Micronized cellulose powder enhances efficacy of and locally applied in patients with allergic rhinitis</strong>&lt;br&gt;Poster presented at EAACI, Copenhagen 2014</td>
<td>There was a significant reduction in total symptom scores for the nose (p&lt;0.013) and specifically a running nose (p&lt;0.0017). There was a trend for all symptoms scores to be lower for the active group. During dry or moderate pollen season there is a significant reduction in total nasal symptoms and running nose along with sneezing severity.</td>
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<td><strong>Nasaleze.com</strong></td>
<td>Valerieva, Staevska, Kralimarkova, Hristova, Petkova, Belcheva, Åberg, Ospanova, Nikitin, Emberlin and Dahl. The study was performed in different medical centers. 12 healthy volunteers were tested at the end of the grass pollen season in 2008. The mucociliary clearance time was tested in the absence and then presence of HPMC using a modified Andersen saccharine test.</td>
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<td>30 participants 18 female and 12 male Mean age: 28.5</td>
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<td><strong>Efficacy and safety of medical device: Nasaleze in prevention and treatment of persistent allergic rhinitis in adults and children</strong>&lt;br&gt;Presented at Moscow XVI Congress for Man and Drugs April 06-10, 2009</td>
<td>53 participants Age range: 8 – 18</td>
<td>There was a significant reduction in total symptom scores for the nose (p&lt;0.013) and specifically a running nose (p&lt;0.0017). There was a trend for all symptoms scores to be lower for the active group. During dry or moderate pollen season there is a significant reduction in total nasal symptoms and running nose along with sneezing severity.</td>
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Nasaleze endorsed by hay fever sufferers.

Results from 190 questionnaires returned by readers or family members of readers of Woman magazine who are hay fever sufferers and tried Nasaleze.

“It worked better than any other product I have bought for my hay fever”

“A good product which works quickly with no side effects”

“Works instantly, wasn’t hard to use”

“I’m breastfeeding my baby, which rules out a lot of hay fever medications so it was great to find something effective that is safe for me to take”

“I would highly recommend. Great relief all day long from symptoms”

1) Gently blow your nose, then breathe out.
2) Place finger over the nostril to close it.
3) Place Nasaleze bottle in other nostril.
4) Quickly and firmly push the sides of the bottle together to deliver one ‘puff’ of Nasaleze powder while inhaling gently. Wait two seconds, gently exhale the powder to penetrate into the nasal passages. (Repeat steps 2-4 on other nostril.)

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