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.

nasaleze.com
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.

nasaleze.com
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 5µg of Der p1 and 5µg 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 EACCI 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 withdraw, 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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<tr>
<td>Sneezing</td>
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<td>.060</td>
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<td>Active</td>
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<td></td>
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<td></td>
<td>Active</td>
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<td>Lower airways</td>
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<td>Active</td>
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<td></td>
<td>Active</td>
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</tbody>
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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
Use of Cellulose Powder for the Treatment of Seasonal Allergic Rhinitis


Joring, Steadman. Participants were instructed to have one puff in each nostril of Nasaleze. Dry treatment was allowed if a full 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.

102 participants
66 female and 36 male
Mean age: 44
Overall average daily score was reported as 3.05 (on the 5-point scale) for men and women indicating a minimum 77% success rate, in chronic hay fever sufferers. Only 12% of volunteers recorded a daily average score under 2.9 revealing a higher score than all pharmaceutical alternatives that were comparatively referred to. Relief was obtained within 0-1.3 hours.

Clinical study of Nasaleze for relief of allergy symptoms including sneezing, runny nose, itchy and watery eyes

Presented at the Pan-Hellenic Conference of ENT Specialists on 19th March 2004 in Thessaloniki, Greece. Open Clinical Trial

Wahli, 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, 6 weeks and 6 weeks. This took place from December 2003 till March 2004 so that participants were perennial or chronic allergy sufferers rather than seasonal sufferers.

40 participants
24 female and 16 male
All participants were using a pharmaceutical treatment (Decongestant 33%, antihistamines 20%, oral antihistamines 20%, nasal corticosteroids 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 adverse effects were reported.

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, June 2005, Vol 5 no 2. Open Clinical Trial

Avanz, Borel, Maratou et al. Conducted at the University of Thessaloniki, Greece. The mucociliary clearance was determined with use of a non-invasive dye (Eicol Orange 3% + CaH2PO42H2O 97%) in vivo. The participants' mucociliary clearance was measured prior to using Nasaleze and then 2 days after finishing the 6-week treatment.

100 participants
Mean age: 8.2
Age range: 1.5 – 8.2
There was significant improvement in nasal mucociliary clearance (reduced from 90 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 mucosa clearance times. No adverse effects were reported.

A double blind placebo controlled trial of inert cellulose powder for the relief of symptoms of hay fever in children

Current Medical Research and Opinion 2006;22(2):275-85
Poster presented at World Allergy Congress, Munich 2005

Emberlin, Lewis. A double blind, placebo controlled trial in 2004. Participants could take any other medication along with Nasaleze or the placebo.

97 participants
40 male and 57 female
Age range: 18+
The amount of rescue medication used by the placebo group (overall and in individual categories e.g. 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.

Double blind placebo controlled trial with nasal provocation test to demonstrate effect of Nasaleze in children with perennial rhinitis

Presented at EAACI, Vienna June 2006

Emberlin, 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, measures were taken of nasal peak inspiratory and expiratory flow and ECP was tested for in nasal secretions.

11 participants
Age range: 18+
There was significant improvement in symptoms of nasal itching, sneezing, blocked nose and rhinorrhea. There was no difference in symptom scores for the two groups. Nasaleze had a significant effect in reducing symptoms of sneezing and itchy nose (p<0.01) due to grass pollen allergy. It can also have significant effects in reducing nasal inflammation, as measured at nasal PIF, PIF and as ECP in secretions (p<0.05). Results indicate that use of Nasaleze can help to alleviate symptoms of hay fever.

Double blind placebo controlled trial of cellulose powder as a remedy for persistent allergic rhinitis, by nasal provocation with Der p1 and Der f1

Presented as a Poster EAACI, Gothenburg June 2007

Emberlin, Lewis. A trial of Nasaleze by nasal provocation tests with Der p1 and Der f1. Base line measurements were taken before the challenge of 0.31 g/kg dose containing 5pg of Der p1 and 5pg of Der f1 per 5g. Measurements taken at 15 minute intervals for the first hour, then at 30 minutes until 4 hours, then at 6 hours and at 24 hours.

15 participants
Age range: 18+
There was a significant difference in the results for sneezing, itchy nose, runny nose and IOP in nasal secretions. The peak nasal inspiratory and flow rates 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.

Nasaleze cellulose powder delays house dust mite allergens (Der p1) diffusion in vitro

Presented as a Poster at EAACI XXVII Congress, Barcelona, Spain 7-11 June 2006

Dietrich and Emberlin of University of Worcester and Lewis of Worcestershire Royal Hospital. The amount of Der p1 (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
There was a significant reduction in the amount of Der p1 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 30 minutes only 14% of the base line Der p1 had crossed the cellulose gel while 100% had passed through the agar layer.

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

A meta-analysis paper by Professor Patrick JD Rook, Division of Medical Microbiology, Dept of Pathology, University of Stellenbosch, South Africa. Published in The Open Allergy Journal, 2008, 1, 1-4.

N/A
This 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.

nasaleze.com
A nasally applied cellulose powder in seasonal allergic rhinitis (SAR) in children and adolescents; reduction of symptoms and relation to pollen load

Zakharievskaya, Sidinru, Tsenkanov and Kasalov at the Sechenov Medical Academy, Moscow. The paper describes the findings of an open non-comparative clinical study of efficacy and safety of Nasaleze in prevention and treatment of persistent allergic rhinitis (PAR). Participants were administered Nasaleze 3 times per day over the course of 4 weeks.

Presented at Moscow XVI Congress for Man and Drugs April 06-10, 2009

Intranasal Inert Cellulose Powder in Prevention and Management of Seasonal Allergic Rhinitis (SAR) in children

Gorup, Sorokotina, Kolovova, Konopelko. The study took place at the Clinic of Child Diseases at the L.M.Scheschnov 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 (5mg) 4 times a day.

Presented as a Poster in EAACI London 2010.

Intranasal Inert Cellulose Powder in Prevention and Management of Seasonal Allergic Rhinitis (SAR) in children

Preseved in Russian Allergy Journal, May 2011

Nasal mucociliary clearance and mucociliation of hydroxypropylmethylcellulose of powder used for alleviation of allergic rhinitis

Birthfeld of School of Lumin and Health Sciences, Swamin University, Emberton of National Pollen and Aerobiology Research Unit, University of Worcester and R. Lewis, Worcester Royal Hospital. 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.

Presented as a Poster in EAACI London 2010

Efficacy of cellulose powder as part of a complex therapy if patients with intermittent allergic rhinitis

Russian Allergy Journal, May 2011

Study of the effects of inert cellulose powder on the nasal mucosa

Antonyeva and Zakhabovskikh. The study took place at the Russian Medical Academy of Postgraduate Education. Two types of participants (healthy and diagnosed with allergic rhinitis) took part in the study. The participants’ quality of life was assessed using a questionnaire before treatment with inert cellulose powder (Nasaleze and Nasaleze GB) and after treatment.


A Nasally Applied Cellulose Powder in Seasonal Allergic Rhinitis in Adults with Grass Pollen Allergy: A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group study

INR Arch-Allergy Immunol 2014;163:313 - 318

Nasaleze.com

Published Paediatric Allergy and Immunology 22 (2011) 594-599

Presented EACCI London 2010

Published in Russian allergy Journal in No. 2 (March – April 2010)

Nasal mucociliary clearance and mucociliation of hydroxypropylmethylcellulose of powder used for alleviation of allergic rhinitis

Intranasal Inert Cellulose Powder in Prevention and Management of Seasonal Allergic Rhinitis (SAR) in children

Presented as a Poster in EAACI London 2010.

Efficacy and safety of medical device Nasaleze in prevention and treatment of persistent allergic rhinitis in adults and children

Zakharievskaya, Sidinru, Tsenkanov and Kasalov at the Sechenov Medical Academy, Moscow. The paper describes the findings of an open non-comparative clinical study of efficacy and safety of Nasaleze in prevention and treatment of persistent allergic rhinitis (PAR). Participants were administered Nasaleze 3 times per day over the course of 4 weeks.

Presented at Moscow XVI Congress for Man and Drugs April 06-10, 2009

A nasally applied cellulose powder in seasonal allergic rhinitis (SAR) in children and adolescents; reduction of symptoms and relation to pollen load

There was a significant reduction in total symptom scores for the nose (p<0.033) and specifically a running nose (p<0.017). There was a tendency for all symptoms scores to be lower for the active group. During low or moderate pollen count there was a significant reduction in total nasal symptoms and running nose along with sneezing severity.

Presented EACCI London 2010

26 patients demonstrated positive results from the very first application of Nasaleze. After 6 weeks treatment, Group 1 demonstrated a significant decrease (all p<0.001) of all SAR symptoms: rhinorrhea, sneezing, nasal blockage, nasal itching, eye itching, nasal pyrophagia and itching.

Children may nasalise decreased frequency of use of antimicrobials, decongestants and topical steroids. Nasaleze has minimal side effects and is appropriate for children.

When the HPMC was applied to the nostril it significantly increased the mucociliary clearance time. The mean mucociliary clearance time at baseline was 11.14 minutes this significantly increased to 35.45 minutes when 10 mg of HPMC were applied to the nostril prior to the test (p<0.0005). Application of 20 mg resulted in a mean MCT of 58.37 this increase in MCT was statistically significant when compared to baseline and 10 mg of HPMC (p<0.0000). The HPMC reduced the mesh spacing of the mucus to form a barrier slowing down MCT.

When the HPMC was applied to the nostril it significantly increased the mucociliary clearance time. The mean mucociliary clearance time at baseline was 11.14 minutes this significantly increased to 35.45 minutes when 10 mg of HPMC were applied to the nostril prior to the test (p<0.0005). Application of 20 mg resulted in a mean MCT of 58.37 this increase in MCT was statistically significant when compared to baseline and 10 mg of HPMC (p<0.0000). The HPMC reduced the mesh spacing of the mucus to form a barrier slowing down MCT.

13 participants
Female and 3 male
Mean age: 37.0

There was no statistically significant effect for either group and there was no drug related allergic reactions. The mucociliary transport was unaffected in both groups.

30 participants in general good health.
30 participants with perennial or seasonal AR

Group one only saw significant improvement in symptoms such as runny and stuffy nose. Participants in group two condition improved by the end of the first week and at the end of the fourth week there was statistically significant improvements in symptoms: runny nose, sneezing, itchy nose and stuffy nose. Analysis of the questionnaire showed significant improvement in quality of life for the second group. Comparative analysis demonstrated that Nasaleze leads to faster alleviation of symptoms and improves quality of life.

Study of the effects of inert cellulose powder on the nasal mucosa

Perechina, Szirmai. Participants were divided into 2 groups. Group one received standard therapy (second generation cetirizine antihistamine, sodium and topical glucocorticosteroids). Group two received Nasaleze three times a day in addition to the basic therapy. The observation period was 4 weeks with the patients visiting the clinic once a week.

108 participants
Age range: 18 – 40

Baseline PNIF was measured on day 15. The study shows that Nasaleze enhances the decongestant effect of nasal oxymetazoline in patients with allergic rhinitis. One week of such regular treatment augments the nasal patency and this effect carries over after another week after its discontinuation.
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”

DIRECTIONS FOR USE

When first using Nasaleze, it is advised to test the pressure required to administer an ideal dose.

This should be done by squeezing the bottle away from yourself.

Before every application, always shake the bottle.

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 inhale the powder to penetrate into the nasal passages. (Repeat steps 2-4 on other nostril.

Nasaleze can be used as often as required, but is recommended three times a day (minimum). The key to getting the best out of Nasaleze is to make sure you maintain a constant layer of powder across the lining of your nose.

Doing this creates a barrier between the aggravating allergens and sensitive membrane within the nasal tract. This stops the body’s natural defence system from realising histamine, thereby avoiding the typical suffering of symptoms such as runny nose and itchy eyes.

Nasaleze can be taken as a preventative measure when ever pollen counts are high or before entering an environment containing airborne allergens e.g. going out to the garden, doing the dusting.

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