



WITH MINT

# ALLERGY Nasaleze

natural allergy prevention

# Monograph



[www.nasaleze.com](http://www.nasaleze.com) · [info@nasaleze.com](mailto:info@nasaleze.com)

## Nasaleze<sup>®</sup>

- Nasaleze is a Class 1 medical device in Europe
- Natural prevention 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 hayfever caused by airborne allergens such as pollen, also protects against dust and pet allergies.

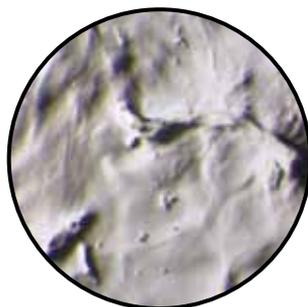
A novel patented method ensures delivery of an effective dose via the nasal cavity.

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 the symptoms of hay fever, pollen, dust mites and animal dander. Acting as a barrier to airborne allergens, Nasaleze stops the cause of allergies that are inhaled through your nose 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.



BEFORE - Nasaleze powder dry  
(taken from 100 x magnification)



AFTER - Nasaleze powder after  
exposure to damp surface (taken  
from 100 x magnification)

## 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

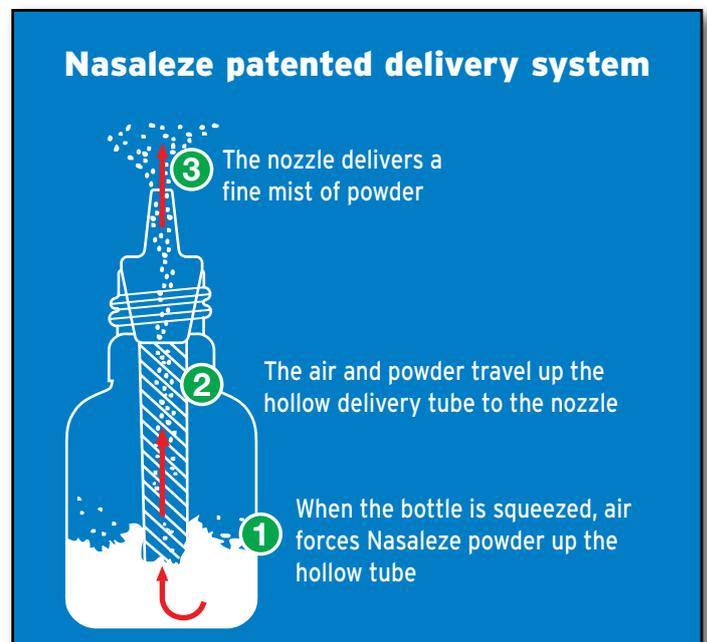
When administered Nasaleze protects from and strengthens resistance to airborne allergens such as pollen, dust mites and animal dander. Nasaleze is a clinically-proven, unique, natural product that works with the body's own nasal defence mechanism.

## Mechanism of action

Nasaleze is a chemically inert material, the mechanism of action of Nasaleze is estimated to be the cellulose powder reacting with moisture within the airway to produce a protective barrier over the nasal mucosa, preventing airborne allergens from binding with receptor sites and avoiding mast cell degranulation. Nasaleze forms a colourless, mucus-like fine gel lining in the nasal tract that acts as a filter for allergens, pollutants, dust and animal dander. Relief from symptoms may occur within minutes (at least 77% of users - Josling Study) but usually within three hours of use.

## Contraindications

There are no known contraindications.



## 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 medications containing drugs/chemicals by sufferers. Studies carried out in volunteers reveal no serious adverse effects when taking Nasaleze.

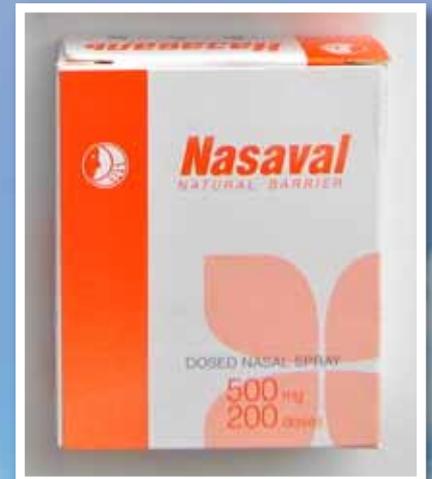
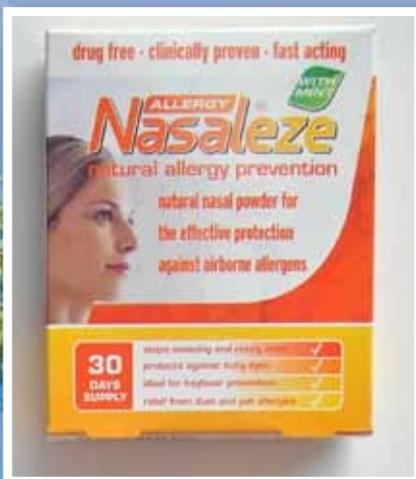
## Getting the best out of Nasaleze

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 may accelerate symptom relief, use as often as required.

Nasaleze should be taken as soon as symptoms appear.

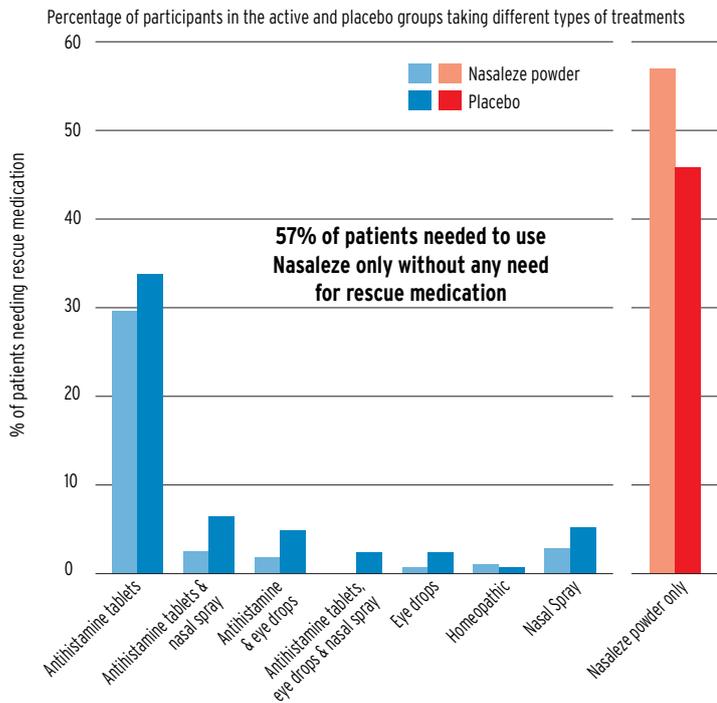
Nasaleze can also be taken as a preventative measure before entering an environment where airborne allergens are likely to be present. Nasaleze helps to provide protection before symptoms occur in situations like going into the garden, dusting or if the pollen count is high.



A selection of Nasaleze packaging from some of our worldwide distributors



# Proven success in clinical trials



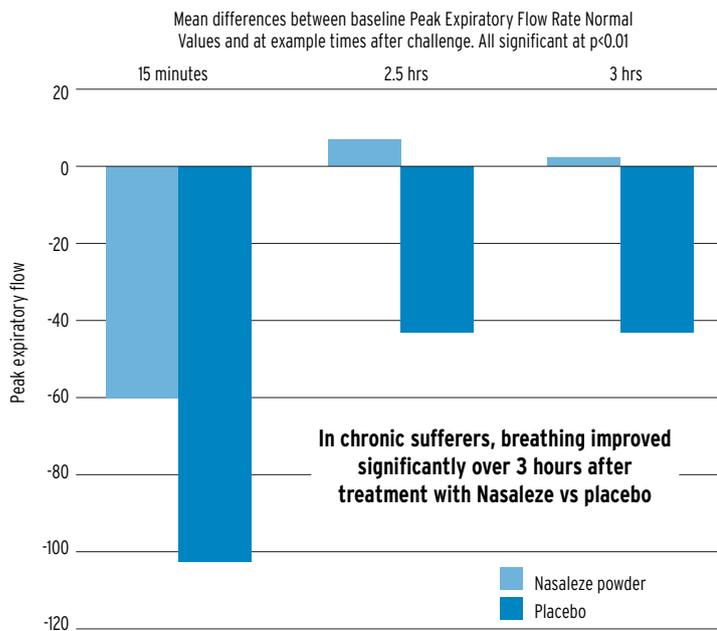
## Reduces the need for rescue medication vs placebo

Emberlin J, Lewis R. Curr Med Res Opin 2006;22(2):275-285.

- 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



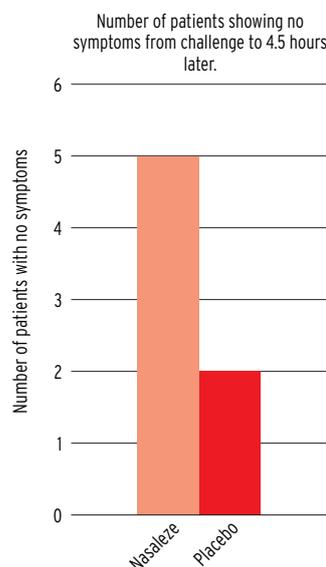
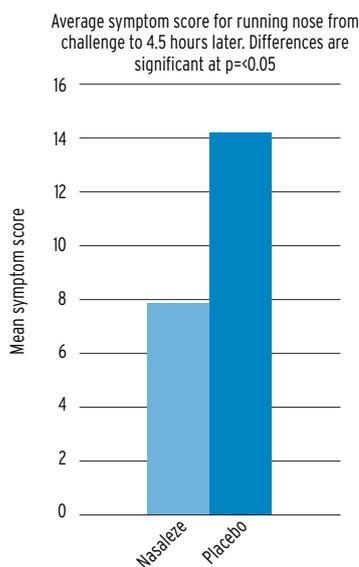
## Helps alleviate symptoms of hayfever

Emberlin J, Lewis R. Presented at EAACI, Vienna, Austria, June 2006; p370: ISBN 3-9810999-0-7.

- Double blind placebo controlled cross over trial with 11 adults with a history of hayfever
- Diagnosed allergic to grass but not trees by skin prick test
- Grass pollen challenge of 350 grains per cubic metre mixed grasses (ALK-Abello) by micro spoon
- Severity scores for 6 symptom categories
- Eosinophil Cationic Proteins (ECPs), Peak Expiratory Flow Rate Normal Values (PEFn), Peak Inspiratory Flow Rate Normal Values (PIFn)

### Results

- No adverse reactions reported
- Significant improvement in PEFn over 3 hours



## Reduces symptoms of house dust mite allergy

Emberlin J, Lewis R. Curr Med Res Opin 2007;23(10): 22423-2431.

- 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

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

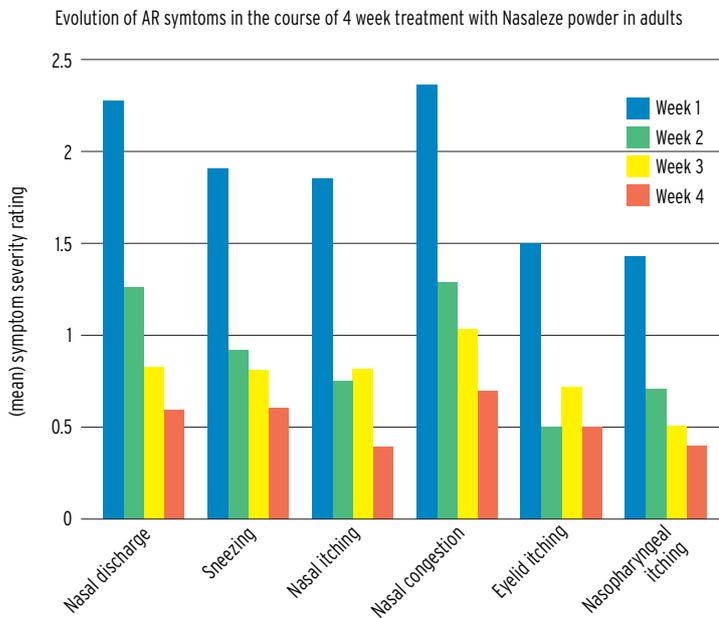
## Significantly reduces hayfever symptoms in children and teenagers

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 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



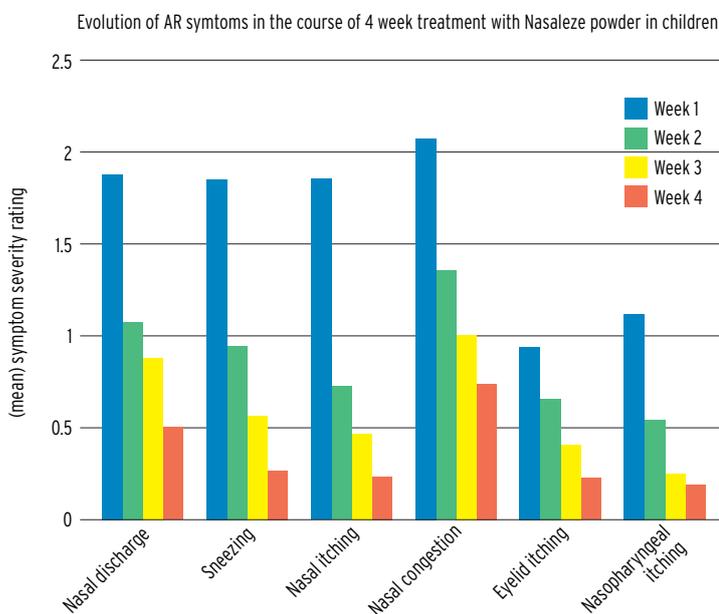
## Improves quality of life (QOL) for adults and children suffering from Allergic Rhinitis (AR)

Zakharzhevskaya TV, Sidorenko IV, Treskunov VK, Karaulov AV. Sechenov Medical Academy, Moscow. Presented at Moscow XVI Congress for Men and drug April 06-10, 2009.

- Open, non competitive clinical study
- 25 adults and 23 children
- Persistent allergic rhinitis
- Patients examined weekly over 4 weeks
- Children accompanied by parents
- 1 puff per nostril 3 x day or more if required
- QOL questionnaire week 1 and 4
- Patients maintained diary

### Results

- Nasaleze powder reduces the severity of AR symptoms even in the first week of treatment
- Effective and safe in preventing and treating allergic rhinitis in adults and children
- No adverse reactions reported
- Twofold improvement in the quality of life



Proven success in clinical trials

# Details of clinical trials on Nasaleze

Study	Description	Population	Measurements and results
<b>Prevention and treatment of Seasonal Allergic Rhinitis</b>	Josling P, Steadman S. Use of cellulose powder for the treatment of seasonal allergic rhinitis Adv Ther. 2003 Jul-Aug;20(4):213-9. Open Clinical Trial.	102 participants (66 female and 36 male)	Utilized a questionnaire format with 5 point rating scale (score of 5 represents no symptoms and complete control.) Overall average daily score was reported as 3.85 for men and women combined 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 total control of symptoms score of 88%. Cellulose powder earned on average a higher score than all pharmaceutical alternatives. Relief was obtained within 0.1-3 hours. Rarely, an uncomfortable sensation in the back of the throat was the only side effect reported (10%).
<b>Clinical study of Nasaleze for relief of allergy symptoms including sneezing, runny nose, itchy and watery eyes</b>	Vlahtis K. Clinical Study Results Summary. Presented at the Pan-Hellenic Conference of ENT Specialists on 19th March 2004 in Thessaloniki, Greece. Open Clinical Trial.	40 participants	All participants were using a pharmaceutical treatment (decongestant 35%, corticosteroids 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.
<b>Measure of improvement in nasal mucociliary clearance and PNIFR (peak inspiratory flow rate) in children with allergic rhinitis.</b>	Aivazis V, Bourli E, Maratou E et al. Study of Mucociliary Clearance and Peak Nasal Inspiratory Flow Rate in Children Before and After Therapy with Natural Cellulose Powder. University of Thessaloniki, Greece. Presented at World Allergy Congress in Munich, Germany June 2005, also published in Nea Paediatrica Chronica, June 2005, Vol 5 no 2. Open Clinical Trial.	100 children with allergic rhinitis (age 1.5-18, mean 8.2 years)	Significant improvement in Nasal Mucous Clearance (reduced from 39 minutes to 18.15 minutes) and PNIFR value (increased up to 25.7%) was reported. The improvement in the Nasal Mucous Clearance and PNIFR values were due to the regeneration and normalization of the ciliary's epithelium. Cellulose allows the filtration of the inhaled air and protects the nasal mucosa from irritants such as allergens, pollutants, and viruses. Mucociliary Clearance and PNIFR improve since allergic inflammation and edema are avoided.
<b>Effect of Nasaleze on symptoms of hayfever in adults and the difference in amount of and type of rescue medication required for adult hayfever sufferers to control their symptoms during grass pollen season.</b>	Emberlin JC, Lewis RA. A double blind placebo controlled trial of inert cellulose powder for the relief of symptoms of Hay fever in adults. Current Medical Research Opinion 2006;22(2)275-85.	97 hay fever sufferers (aged 18 years and older)	The amount of rescue medication used by the placebo group (over all and in individual categories e.g. antihistamines, nasal sprays and eye drops) was significantly greater than that used by the active (Nasaleze) group. Few differences in the symptom scores during the trial for the two groups were reported. Nasaleze significantly reduced the need for rescue medication. No adverse effects were reported.
<b>Efficacy of Nasaleze for use in hayfever via pollen provocation tests</b>	Emberlin JC, Lewis RA. A 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 the symptoms of hay fever. Presented as a Poster at EAACI, Vienna June 2006.	11 volunteers	Significant differences ( $p < 0.05$ and $p < 0.01$ ) occurred in data at various times from challenge in peak nasal expiratory flow between placebo and active treatments, and also in nasal PIF, in sneezing and in itching eyes. The results for other lung function tests and symptoms were slightly under the level for significance. The results for the nasal secretions were significantly different at $p < 0.05$ . No adverse reactions occurred. Conclusion - results of trial show that inert cellulose powder can have significant effects in reducing symptoms of sneezing and itchy eyes due to grass pollen allergy. It can also have significant effects in reducing nasal inflammation, as measured as nasal PEF, PIF and as ECP in secretions. Results indicate that use of inert cellulose powder can help to alleviate symptoms of hay fever.
<b>Double blind placebo controlled dust mite challenge study</b>	Emberlin JC, Lewis RA. Double blind placebo controlled cross-over trial of Nasaleze by nasal provocation tests with Der p1 and Der f1. Presented as a Poster EAACI, Gothenburg June 2007. Current Medical Research Opinion; Vol 23; No 10; 2007, 2423-2431.	15 volunteer adults (aged 18 years and older)	The results show significant differences ( $p < 0.05$ ) for sneezing, itchy nose, runny nose and ECPs in nasal secretions. The results were also significant at this level for peak nasal expiratory and inspiratory flow but there was considerable variation. The results for other symptoms were not significantly different between the cellulose powder and the placebo. There were no adverse reactions. Conclusion - the inert cellulose powder can have significant effects in reducing some symptoms of persistent rhinitis due to house dust mite allergy.
<b>Efficacy and safety of Nasaleze in prevention and treatment of persistent allergic rhinitis in adults and children.</b>	This paper describes the findings of an open non-comparative clinical study of efficacy and safety of an ultra-disperse cellulose preparation in prevention and treatment of persistent allergic rhinitis (AR). The volunteers were administered Nasaleze 3 times per day over the course of 4 weeks. Study was presented Moscow XVI Congress for Man and Drug April 06-10, 2009.	25 adults and 23 children, 48 total.	The volunteers visited the investigator weekly, i.e. 4 times during the study period. The severity of AR symptoms and the tolerability of the product were assessed during each visit. 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 as the study progressed over the 4 weeks. A twofold improvement in the quality of life of the AR patients was recorded. Therefore proving Nasaleze is an effective and safe method of prevention and treatment of allergic rhinitis both in adults and children.

Study	Description	Population	Measurements and results
<b>A meta-analysis of the Efficacy and Safety of Nasaleze in the Prevention and Management of Allergic Rhinitis</b>	A meta-analysis paper by Professor Patrick JD Bouic, 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 reviews the clinical data conducted on Nasaleze between 2004 and 2008.
<b>Nasaleze cellulose powder delays house dust mite allergen (Der p1) diffusion in vitro</b>	Purpose of the study was to investigate this theory about the mechanism of action of the gel in relation to house dust mite allergen (Der p1). Presented as a Poster at EAACI XXVII Congress, Barcelona, Spain 7-11 June 2008. Bernadette Diethart and Professor Jean Emberlin of University of Worcester, UK; Richard Lewis, Worcestershire Royal Hospital, UK. Published in Natural Science Vol.2, No.2, 79-84 (2010).	In vitro	The diffusion of the allergen through Nasaleze showed a significant reduction in all points of time. After 15 minutes only 0.76% of baseline amount had diffused through. After 360 minutes only 14% had diffused through. With the control 100% had diffused through.
<b>Clinical study in children suffering from allergic rhinitis.</b>	Åberg N and Benson M. A nasally applied cellulose powder reduces symptoms of seasonal allergic rhinitis (SAR). A double blind, placebo controlled trial in children and adolescents. Conducted at The Queen Silvia Children's Hospital, Gothenburg, Sweden. Presented EAACI London 2010. Pediatric Allergy and Immunology 22 (2011) 594-599 (2011).	53 children with allergic rhinitis aged 8-18 years	A very good compliance was obtained. Intention to treat analysis showed a significant reduction of total symptom scores from the nose (P 7,29, A 6,07, p=0,033) and specifically for running nose (P 2,56, A 2,03, p=0,017). All symptoms from the nose, eyes and lower airways were lower in the active group but reached significance only as above. The cellulose powder reduces symptoms of SAR in children and adolescents.
<b>Intranasal Inert Cellulose Powder in Prevention and Management of Seasonal Allergic Rhinitis (SAR) in Children.</b>	Geppe N.A., Snegotskaya M.N.; Kolosova N.G.; Konopelko, O.U. Conducted at the Clinic of Child Diseases at The I.M. Sechenov Moscow Medical Academy. An open comparative randomized study in order to evaluate the efficacy and safety of intranasal inert cellulose powder in preventing seasonal allergic rhinitis (SAR) in children. The study was conducted between April and June 2009 and presented as a Poster in EAACI London 2010.	50 children aged 4-14 with seasonal allergic rhinitis were selected	26 patients (86.4%) demonstrated positive results from the very first application of cellulose powder therapy. After six weeks treatment, Group 1 demonstrated a steady decrease of all SAR symptoms: rhinorrhea - from 1.8 to 0.6 (p<0.001); sneezing - from 1.5 to 0.5 (p<0.001); nasal blockage - from 1.8 to 0.5 (p<0.001); nasal itching - from 1.2 to 0.4 (p<0.001); eye itching - from 0.8 to 0.4 (p<0.001); nasopharyngeal itching - from 0.8 to 0.2 (p<0.001). Conclusion: Children that received inert cellulose powder throughout the study period demonstrated a significant decrease of SAR symptoms. Inert cellulose powder may be used as part of standard SAR therapy.
<b>Open non-comparative study to evaluate the effectiveness of nasaleze for patients with allergic rhinitis.</b>	Conducted at the Russian Federal Medical Biological Agency by Chief clinical physician, professor, Doctor of medical sciences NI Iliina. An open study to determine the effectiveness of Nasaleze at treating allergic rhinitis by nasal provocation test with significantly causative aeroallergens. To be published in Russian Allergy Journal in No. 2 (March-April 2011)	Study included 30 patients (40% men, 60% women) suffering from allergic rhinitis, meeting criteria for inclusion/exclusion. Mean age of the patients was 28.5.	A total of 30 patients (100%) completed the study in accordance with the protocol. Of the 30 patients who completed the study, the therapy using Nasaleze was found to be effective in 28 (99.6%) of the patients, which showed a statistically valid decrease in nasal reactivity to a significantly causative allergen. The best results were obtained in patients with isolated dust sensitivity and a mild period of rhinitis.
<b>Nasal mucociliary clearance and mucoadhesion of hydroxypropylmethylcellulose powder used for alleviation of allergic rhinitis</b>	A study to prove whether the attachment of HPMC to nasal mucus (mucoadhesion) slows down nasal clearance, thus enabling a longer period of cellulose residence in the nose acting as a protective barrier against airborne allergens. Bernadette Diethart of School of Human and Health Sciences, Swansea University, Jean Emberlin of National Pollen and Aerobiology Research Unit, University of Worcester and Richard Lewis, Worcestershire Royal Hospital. Poster presented at EAACI XXVIII, London 2010. Published Pediatric Allergy and Immunology 22 (2011) 594-599 (2011)	Twelve volunteers were tested after the end of the grass pollen season 2008.	The mean mucociliary clearance time at baseline was 11.14 minutes. This base-line MCT 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 50.37 minutes and thus a further increase >120 % (>420 % longer MCT compared to baseline). This elongation of MCT was statistically significant when compared to baseline and 10 mg HPMC (p < 0.0005).
<b>Efficacy of cellulose powder as part of a complex therapy for patients with seasonal allergic rhinitis</b>	E.M.Penechko, L.P.Sizyakina. The patients were divided into 2 groups. Group one received standard therapy (second generation cetirizine antihistamine, sorbents and topical glucocorticosteroids. Group two received cellulose powder three times a day in addition to the basic therapy. The quality of life and symptom control of both groups was analysed and compared. The observation period was 4 weeks with the patients visiting the clinic once a week.	30 subjects aged between 18 and 33	A comparative analysis of the effectiveness of including the cellulose powder in the complex treatment of intermittent allergic rhinitis has shown that it leads to a faster alleviation of the symptoms of allergic rhinitis and improves the quality of life of patients. The information presented in this study allows the conclusion to be drawn that including the cellulose powder as part of the complex treatment for intermittent allergic rhinitis is beneficial.

# Nasaleze endorsed by hayfever sufferers

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

"It worked better than any other products I've bought for my hayfever"

"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 hayfever 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"

83%

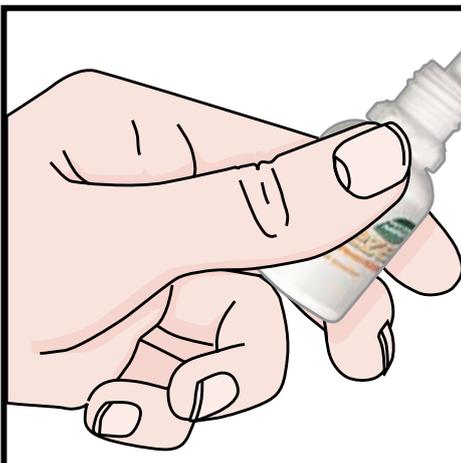
Liked that Nasaleze was drug free and would recommend it to other people

86%

Found it easy to use

74%

Found it rapidly relieved hayfever 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.

Directions: Before every application, always shake the bottle.

1. Gently blow your nose.
2. Breathe out.
3. Place a finger over one nostril to close it.
4. Place Nasaleze bottle nozzle in the other nostril.
5. Quickly and firmly push the sides of the bottle together to deliver one 'puff' of Nasaleze powder while inhaling gently.
6. Wait two seconds and then gently inhale to enable the Nasaleze powder to penetrate into the nasal passages. Repeat steps 2-6 on the 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 the barrier between the aggravating allergens and sensitive membrane within the nasal tract. This stops the body's natural defence system from releasing histamine, thereby avoiding the typical suffering of symptoms such as runny nose and itchy eyes. Nasaleze can be taken as a preventative measure whenever pollen counts are high or before entering an environment containing airborne allergens e.g. going out to the garden, doing the dusting.

January 2012

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