COLD Nasaleze®

natural prevention for the common cold

Clinical Trial Data 2003-2012

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COLD AND FLU BLOCKER
COLD
Nasaleze
a natural common cold prevention
forms a natural barrier to help
block colds before they start
30
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Nasaleze® Cold

- Natural protection from airborne germs and viruses
- Fast acting
- Great tasting
- 30 day supply
- Carry with you and take before entering a crowded environment

Nasaleze Cold is a natural nasal powder spray containing a blend of cellulose, peppermint and odour controlled wild garlic that delivers fast, continuous protection from airborne germs that are inhaled via the nose.

What is Nasaleze Cold? - Nasaleze Cold is a natural nasal powder spray containing a blend of cellulose, peppermint and odour controlled garlic that delivers fast protection from airborne germs that are inhaled via the nose. By trapping, absorbing and neutralising air borne germs, Nasaleze Cold stops the causes of infection rather than just treating the symptoms. In addition, the peppermint gives the sensation of your airways opening up, allowing you to breathe easier.

Why garlic? - the garlic used in Nasaleze Cold is odour controlled European wild garlic. This wild garlic extract contains copious amounts of ajoene. This component has been shown to posses excellent antiviral capabilities (Weber et al Planta Med 58 1992 417-423) outperforming all other garlic thiosulphinates in terms of anti-viral activity. As our European wild garlic is odour controlled there is little taste to it.

Why peppermint? - of all species of mint, peppermint contains the most menthol, a phytochemical that has antibacterial and antiviral effects.

The menthol in peppermint has long been used as a cough suppressant and decongestant. Even in the United States, where herbal medicine is not widely used, menthol is a common ingredient in cough drops, nasal spray, and mentholatum chest rubs. The FDA actually approved the marketing of peppermint as a cold remedy, as did a panel of experts in Germany that evaluates the safety and efficacy of herbs. *

* www.vitaminstuff.com/herbs-peppermint.html

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Where Nasaleze Cold works

Catch colds before they catch you, used as a handy daily nasal spray, Nasaleze Cold helps the body to create a barrier against germs, which effectively makes you less likely to 'catch a cold'.

Airborne germs are the most common way to catch colds and viruses, particularly in crowded places such as buses, trains, planes or the underground. Using Nasaleze Cold before exposure to a crowded area will make it much more difficult to pick up colds and germs.

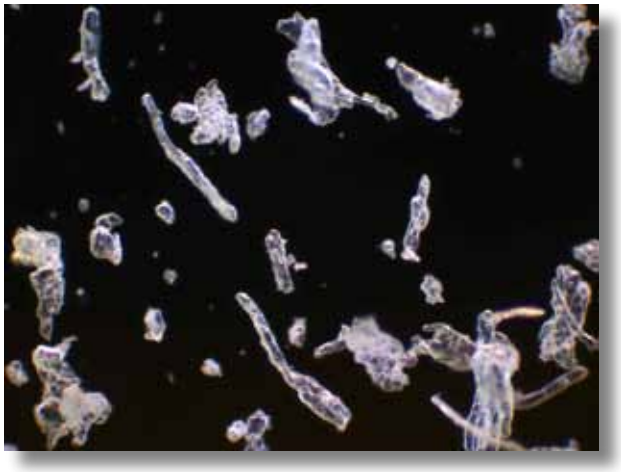
"Nasaleze Cold works by strengthening the nasal barrier against external germs and irritants", says Dr Ron Cutler, principal lecturer in microbiology at the University of East London (UEL) in the UK. "It actually helps the nose to filter out germs and dust so prevents the viruses and airborne infections from invading the body. You could say it's an addition to the body's armoury to help protect against colds and flu – before they start."

Simple and Safe

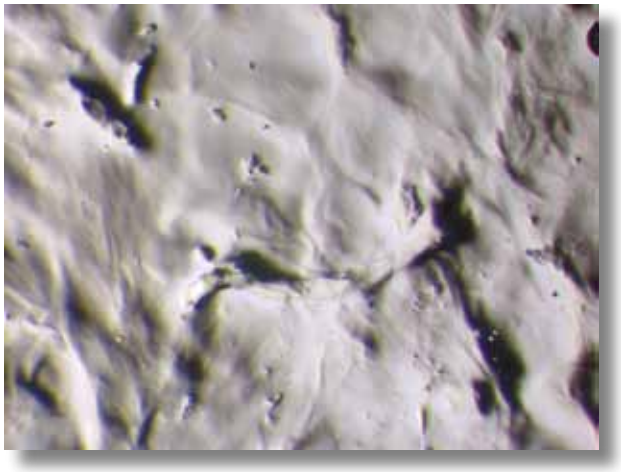
Nasaleze Cold couldn't be simpler to use. One squeeze from the easy to use dispenser bottle into each nostril will rapidly distribute fine powder throughout the upper nasal passages and sinuses and remain effective for several hours. For increased protection administer Nasaleze Cold up to three or four times per day.

Nasaleze Cold contains no drugs or medicines, has no known side effects and is non drowsy. Registered as a Class One Medical Device with the MHRA (Medicines Healthcare Regulatory Agency) which means it is 100% safe for all the family, including children over seven years and pregnant women.

Anyone who wishes to avoid catching a cold should take Nasaleze Cold but those who are more frequently exposed to airborne germs should definitely take it.



BEFORE
Nasaleze powder dry (taken from 100 x magnification)



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

For example: frequent flyers, office workers, school teachers, athletes, flight attendants, hospital workers, people working in closed ventilation systems and commuters.

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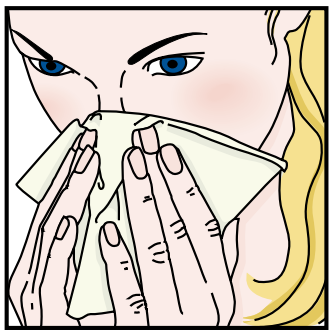
Nasaleze patented delivery system

3 The nozzle delivers a fine mist of powder

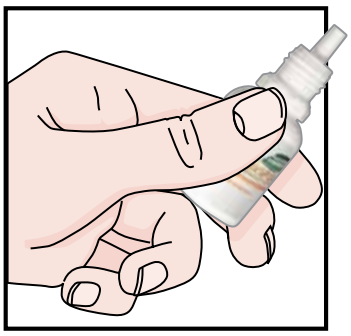
2 The air and powder travel up the hollow delivery tube to the nozzle

1 When the bottle is squeezed, air forces Nasaleze powder up the hollow tube

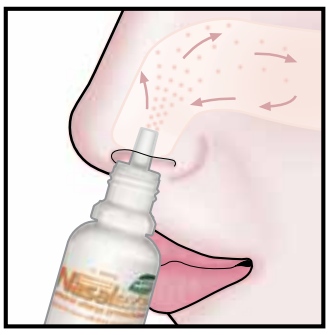


Gently blow nose

Test the pressure needed to administer an ideal dose, which is a two inch plume of powder



Gently inhale the Nasaleze powder into the nasal passages



Preventing air-borne infections with an intra nasal cellulose powder formulation. (Nasaleze Cold®)

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ABSTRACT

Fifty two volunteers were recruited to take part in a dual centred, randomized, blinded study to determine whether the level of airborne infections could be significantly reduced in patients receiving either plain Nasaleze cellulose extract or a combination of Nasaleze cellulose with PGE added (powdered garlic extract).

Volunteers were randomized to receive a plain cellulose extract delivered intra nasally or the same cellulose formulation with added PGE (powdered garlic extract). One puff into each nostril was recommended and if the volunteer caught an infection whilst travelling then at least 3 puffs per nostril were recommended until the symptoms reduced. The study took place over an 8 week period across Finland and England between November and March 2006/07. Volunteers were instructed to use a five-point scale to assess their health and record any common cold infections and symptoms in a daily diary. The active-treatment group (Nasaleze with PGE) had significantly fewer colds than the control group (20 vs 57, P<.001). The active treatment group also experienced far fewer days where a viral infection was obviously present (126 days in the active group vs 240 days in the control group p <0.05). Consequently, volunteers in the active group were less likely to pick up an airborne infection with the addition of PGE to this novel cellulose extract. Volunteers in the control were much more likely to get more than one cold over the treatment period or to suffer much longer periods of infection. This unique Nasaleze Cold formulation can significantly reduce the number of airborne infections that volunteers are exposed to whilst travelling throughout their respective countries.

Keywords: Nasaleze cellulose extract, Powdered garlic extract

INTRODUCTION

The common cold is the world's most widespread viral infection, with most people suffering approximately two to five colds per year. More than 200 different viruses are known to cause the symptoms of the common cold. Some, such as the rhinoviruses, seldom produce serious illnesses. Others, such as parainfluenza and respiratory syncytial virus, produce mild infections in adults but can precipitate severe lower respiratory infections in young children.

Rhinoviruses (from the Greek rhin, meaning "nose") cause an estimated 30 to 35 percent of all adult colds, and are most active in early fall, spring, and summer. More than 110 distinct rhinovirus types have been identified. These agents grow best at temperatures of about 91 degrees Fahrenheit, the temperature inside the human nose.

Scientists think coronaviruses cause a large percentage of all adult colds. They bring on colds primarily in the winter and early spring. Of the more than 30 kinds, three or four infect humans. The importance of coronaviruses as a cause of colds is hard to assess because, unlike rhinoviruses, they are difficult to grow in the laboratory.

Approximately 10 to 15 percent of adult colds are caused by viruses also responsible for other, more severe illnesses: adenoviruses, coxsackie viruses, echoviruses, orthomyxoviruses (including influenza A and B viruses, which cause flu), paramyxoviruses (including several parainfluenza viruses), respiratory syncytial virus, and enteroviruses.

The causes of 30 to 50 percent of adult colds, presumed to be viral, remain unidentified. The same viruses that produce colds in adults appear to cause colds in children. The relative importance of various viruses in pediatric colds, however, is unclear because it's difficult to isolate the precise cause of symptoms in studies of children with colds.

This is primarily an airborne infection, whose primary entry point in a human being is the nasal cavity. Touching your skin or environmental surfaces, such as telephones and stair rails, that have cold germs on them and then touching your eyes or nose or inhaling drops of mucus full of cold germs from the air are the most common methods of transmission.

Unfortunately airborne infections are commonplace all year round nowadays and although the chance of picking up an infection in the summer months is only 1 in 4 compared to winter there are some special factors that may increase the risk. Long haul jet flights appear to pose a special risk as there are no other periods when we are likely to be squeezed as tightly together with 400 potential sources of common cold infection. The chances are that any number of passengers will have the temerity to spread an airborne infection in the confined space of a jetliner making this an ideal environment for transmission of airborne disease. Experiments on exposing uninfected volunteers to others with common cold infections have shown that the chances of catching a cold are directly related to the number of hours of exposure to infection. Hence, you are much more likely to get a cold on a long haul

flight to the USA compared with a short hop to Europe. Our lifestyles often demand air conditioning which may contribute to infection. Although the lining of the nose is covered with a thin layer of mucus which protects against infection unfortunately air conditioners extract moisture from the air and therefore they may cause some drying of the protective mucous blanket in the nose and predispose to infection. This feature is one that our active test compound Nasaleze Cold® will significantly improve. The cold air may also help viruses to establish a hold in the nose as they reproduce better in a cold nose.

Travelling itself to different population areas, on public transport can significantly increase the risk of viral infection as we have probably already been exposed to all the current common cold viruses in our home environment but are likely to encounter quite new viruses, to which we have no immunity, as we circulate amongst our fellow human beings! We could ourselves be responsible for introducing new viruses into a foreign country if we arrive at a holiday or business destination with an active infection. With modern jet travel viruses are rapidly spread and this is why influenza spreads so rapidly around the world during an epidemic.

Sadly, since there are so many airborne infections available re-infection is prevalent.1 Published literature on the activity of garlic extracts (amongst others) against viral infections is sparse.2,3 but one report 4 describes that during an influenza epidemic, the former Soviet Union imported more than 500 tons of garlic cloves for acute treatment. Among the viruses thought to be sensitive to garlic extracts are the human cytomegalovirus, human rhinovirus type 2, herpes simplex types 1 and 2, and influenza B. Many consumers already take natural remedies including Echinacea, vitamin C, Zinc and garlic supplements as a preventive and report an absence of infection 5 colds or symptoms associated with viral replication.

Cellulose powder is used as a thickener in many liquid nasal sprays and is generally regarded as safe. The unique proprietary grade of micronized cellulose in this study (Nasaleze®) uses a patented device that ensures delivery into the nose of a suitable amount of material drawn from the container. Compared with liquid nasal sprays, which require preservatives, powdered cellulose inhibits bacterial and viral growth to a limited extent. While not a medicine, it is classified as a medical device that is safe to use throughout the year. This powdered cellulose product addresses the cause of allergic reactions, rather than the symptoms, because it works as a facial mask in preventing inhaled pollen, dirt, and allergens from reaching the lungs. This mechanism was also thought to help protect an individual from attack by airborne pathogens in particular viruses. In a healthy individual, the nose and nasal tract extract these materials from the inhaled air, including air that has been exposed to mucus membranes and therefore been stripped of allergens. Mucus has a low surface tension and can easily absorb allergens and infectious organisms from air as it passes down into the lungs.

Uniquely, the cellulose powder described herein turns into a gel on contact with the moisture always present in the nasal cavity. This gel is similar to normal mucus and helps to maintain delivery of a supply of clean air to the lungs.

This survey was designed to determine whether the addition of a simple garlic extract to Nasaleze® cellulose would enhance the capability of this formulation to trap airborne infections, disarm them and remove them safely into the stomach during normal mucociliary clearance. A randomized, blinded study design was incorporated in two countries, Finland and the United Kingdom to test whether the addition of PGE (powdered garlic extract) would increase the likelihood of preventing airborne infection amongst individuals travelling around locally and nationally during the cold winter period when airborne infections are at their peak.

METHODS

Following recruitment through advertisements in London and Helsinki daily newspapers, 52 participants were selected. A diary was designed in which each volunteer recorded general well-being for 8 weeks on a five-point scale as they travelled to and from work or on various other trips across the UK or Finland.

5 = well, no problems;

4 = quite well with occasional sneeze, not disruptive to normal routine;

3 = can feel a cold coming on, some minor symptoms;

2 = feeling low and beginning to exhibit symptoms;

1 = full cold symptoms [headache, sneezing, runny nose, tiredness].

If an infection occurred, volunteers noted the number and variety of symptoms, the day recovery began, and the day they felt completely better. The volunteers were separated into two groups of 26 participants each. A

simple random number generator assigned volunteers to the active or control group, and they were instructed to take one sniff up each nostril every day, according to the manufacturer's recommendation and if an infection was received then volunteers were instructed to take up to 3 sniffs per nostril every day that the infection was present to determine if the infectious period could be reduced in either group. Randomization codes were kept secure at the Herbal Research Centre and were not broken until all the diaries had been returned. Volunteers were contacted every 2 weeks to ensure that they were complying with the dosage regimen and that diary entries were made daily.

Diary Analysis

After diaries were returned, the number of infections experienced by volunteers was counted. An active infection was defined as a score of 3 or less that lasted for 4 days in succession. The duration of symptoms was the number of days with a recorded score of 3, 2 or 1, leading to an average recovery time that ended with a score of 4 or 5 taken across all recorded infections. The number of volunteers who did not experience a single airborne infection throughout the study period was recorded in each group.

Statistical Analysis

The average symptom length in days and the average number of days challenged by a cold were subjected to calculations of standard deviation, sample variance, and standard error of the difference of the means. Data were analysed by means of a Student's *t* test to gain a probability coefficient allowing for the calculated number of degrees of freedom.

RESULTS

No participants withdrew from the study and therefore an intention to treat analysis was performed on all completed diaries. At the end of the 56 - day study, 57 major infections were recorded in the control group, but the active group recorded a total of only 20 infections. This result is highly significant (P<.001) in favour of the addition of PGE to Nasaleze® as a preventative for airborne infections whilst travelling in daily lives.

The control group had 12 serious cases where an infection lasted for 7 days whereas the active group only had 6 such cases. Similarly the number of days reported with an active infection warranting a recorded score of 3 or less in the control group was 240 days whereas in the active group this was reduced to 126 days. This result is also highly significant at p<0.05.

During the study, the 11 volunteers taking the control experienced multiple infectious episodes but this was reduced to only 2 volunteers taking the active treatment suggesting that this was indeed a preventative option.

The details of our statistical analysis indicated that the sample variance and standard deviation was low and that although the two groups were composed of mostly female volunteers they were well matched statistically with a standard error for the difference of the means of just 0.76 for the number of active airborne infections suffered by each group so that the probability using a Students *t* test was p<0.01. Significance dropped to p<0.05 for both the number of volunteers with a serious infection lasting 7 days and the number of days reported with an active infection. However these figures clearly

	CONTROL GROUP (NASALEZE®)	**ACTIVE GROUP (NASALEZE COLD®)**
Number of active infections during the study period	57	20 p<0.01
Number of volunteers without any infection	6	10
Number of volunteers with a serious infection lasting over 7 days	12	6 p<0.05
Number of days reported with an active infection	240	126 p<0.05
Number of volunteers experiencing multiple infections during the study period	11	2

Table 1 Results of randomized blinded comparison between 2 types of Nasaleze® cellulose extract administered intra nasally.

show a difference between the groups with the Nasaleze Cold® product proving superior to the plain Nasaleze® extract.

Volunteers were also asked to record in their diaries any other concerns they had during the study, such as comments about the acceptability of taking the product, side effects, taste, or other reason that might warrant discontinuation of treatment. Generally both groups were extremely well tolerated although in the active group several volunteers (3 in total) recorded that they could easily taste the PGE although this did not stop them from continuing with the treatment.

DISCUSSION

In this pilot investigation, two inert cellulose powder formulations, both dosed intra nasally using a novel, patented delivery system were compared in a pilot randomized and blinded study to see which formulation could provide the best protection against airborne infections of indiscriminate identity. Volunteers were encouraged to go about their normal daily lives travelling around their local and national boundaries. Some volunteers even ventured out internationally so this was a genuinely fair assessment of the relative dangers of picking up an airborne infection throughout the winter period and how that might be prevented.

The results were clearly in favour of the Nasaleze Cold® formulation now containing cellulose, mint and PGE (powdered garlic extract). Results indicate that a significant reduction in the number of airborne infectious pathogens picked up by volunteers was seen in this group when compared to plain Nasaleze® powder.

Examination of the volunteer diaries clearly shows that the control group suffered much more that the active group in terms of the number and duration of infectious episodes. Thus we can conclude that the addition of a potentially antiviral compound, in this case, a powdered garlic extract, can significantly reduce the number of infectious challenges that people meet during their travelling lives. The results also suggest that infection and reinfection may be effectively prevented by its daily use throughout the year, with an enormous potential savings to national industry in terms of reduced sick days. This product clearly exhibits excellent antiviral activity and warrants further investigation to determine the nature and method of its viral destruction.

ACKNOWLEDGMENTS

We should like to thank all the volunteers in both the United Kingdom and Finland, Charlotte Duxbury for her excellent assistance, Nasaleze International Limited for supplying the test materials.

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EUROPEAN JOURNAL FOR NUTRACEUTICAL RESEARCH

Virucidal activity of Nasaleze and Nasaleze Cold in cell cultures infected with pathogenic avian flu virus (H5N1)

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Abstract

This *in vitro* study determined the viral efficacy of two cellulose formulations presented as Nasaleze and Nasaleze Cold against Influenza A/Duck/Novosibirsk/56/05 (Avian Flu H1N1) at concentrations that did not exhibit toxicity. Both test substances were used at sub-optimal dosing levels. The virucidal activity of both formulations was measured at 48, 72 and 112 hour periods after incubation. Results showed that both formulations were able to reduce the viral titre of Influenza A/Duck/Novosibirsk/56/05 (Avian Flu H1N1) significantly when compared to the control virus titre. The extract Nasaleze Cold showed greater activity and both formulations showed potential to be used as preventative agents. These data reinforce the established antiviral activity of these formulations acting as barrier prevention and disruption of viral replication.

Introduction

In recent years a number of countries in East and South-East Asia have seen an outbreak of avian flu A (H5N1). The infection mainly affects poultry (chickens and ducks) which are then wiped out in their hundreds of thousands. But there have also been cases where the virus has affected people. The total number of people killed by the infection has been low but the fatality rate has been astonishing: around 70% of those infected have died, even when given treatment. The highly pathogenic avian flu virus arrived in Russia in July 2005 and to date the H5N1 flu virus has been recorded in many parts of the Russian Federation: in Western Siberia, in the Urals and in the Astrakhan province.

As we know, flu is primarily an infection which affects birds, mainly waterfowl, and all of the strains of the human flu virus come from avian bird flu viruses. The genome of any human virus contains genes from avian viruses.

Avian flu is extremely dangerous for humans, but fortunately it cannot be transmitted between people and can only be caught from infected birds. Human flu is easily transferred between people but the strains we are familiar with have become manageable on account of their joint evolution. However, some animals, primarily pigs, are easily infected with this and other types of flu. When the avian flu epizootic combines with a human flu epidemic (and they normally occur during the same months), both viruses can be found in pigs. The simultaneous reproduction of the two viruses in pigs may lead to reassortment and to the emergence of a new "hybrid" virus, in which the "avian" proteins and antigens of the avian flu A virus will combine with the ability to be transferred from person to person. At this point, a disaster is almost inevitable: the new agent will be infectious like human flu and lethal like bird flu. There is therefore a real threat of a new pandemic strain appearing.

We therefore need to develop new treatments and preventive measures for flu. At the D.I. Ivanovsky Scientific Research Institute of Virology we carry out research into the avian flu virus, developing diagnosis methods and treatment and preventive measures for the infection. Practically all known strains of avian and human flu viruses are held at the State Virus Collection at the Institute. It is precisely these viruses which could serve as the building blocks for a future pandemic virus. In particular, during the first outbreak of the H5N1 flu virus, we isolated the first highly pathogenic strains of this virus from patients and poultry (ducks and chickens) that had died from the disease, which were then deposited at the State Virus Collection. We are currently researching the decoding of the epizootics amongst birds in different parts of the country including the Republic of Kalmykia and the Astrakhan Province. Moreover, the research at the Institute is aimed at improving diagnosis methods, preventive measures and the treatment of this infection.

The D.I. Ivanovsky Scientific Research Institute of Virology at the Russian Academy of Medical Sciences, is licensed to carry out pre-clinical trials of different products, received commercial samples of two products to be studied from Pharmaval Inc. Nasaleze (Nasaval in Russia) and Nasaleze Cold (Nasaval PLUS in Russia), manufactured by Nasaleze Ltd, in Ramsey, Isle of Man. The aim of the research was to study the activity of these unique cellulose powder extracts against infection with the pandemic flu A/H5N1 virus in cell cultures, which we isolated during the poultry epizootic in July 2005 in the Novosibirsk province.

Materials and Methods

The virus

Our observations were carried out on both test substances and we determined the anti-viral activity against strains of the flu A/Duck/Novosibirsk/56/05 virus which was isolated in summer 2005 from infected ducks in the Novosibirsk province and deposited at the State Virus Collection. The virus multiplies in Madin-Darby canine kidney (MDCK) cell cultures (embryonic canine kidney cell cultures), in SPEV cell lines (porcine embryo kidney) and in many other cell cultures.

Cell cultures

Porcine embryo kidney cell cultures (SPEV) were used as the substrate for studying antiviral activity. This virus multiplies and accumulates in a titer of up to 4.5 lg TCD50 in these cultures. SPEV cell cultures were cultivated in medium 199 with the addition of 10% foetal bovine serum and antibiotics. As the support medium for the cells which have been infected with the flu virus we used the same nutrition medium composition without adding the serum. The cells were cultivated in single-use 24-hole sterile plastic culture plates.

Test Samples

Nasaleze and Nasaleze Cold were used in the form of a ready-prepared nasal spray in 500mg bottles providing 200 doses, which we received from the Pharmaval Inc. During our trials we used one dose of each of the products which was the equivalent of one spray, equal to 2.5mg of the product.

Trial protocol
1st variant

On the second day after planting the SPEV cell cultures in 24-hole plastic plates, a cell monolayer had formed in the holes. The nutrient medium was removed from each of the holes, the holes were washed with 0.4 ml of the support medium, after which the holes were drained off, leaving around 0.1 ml of the medium in the hole. The spray containing each test substance was sprayed into each hole with a cell monolayer, with 1 spray of each of the products in 8 of the holes with the cell cultures. 10 minutes after the cells had been treated with the powder spray 20 µl of the flu A virus was added to 4 of the holes in a dose of 10.0 $TCID_{50}$, and 20 µl of the flu A virus was added to another 4 holes in a dose of 1.0 TCD_{50}. The 8 holes with a cell culture monolayer were infected with the flu virus in doses of 10.0 $TCID_{50}$ and 1.0 $TCID_{50}$ (4 holes for each dose), but were not treated with the products. The remaining 8 holes with a SPEV cell culture monolayer were not infected with the virus but were treated with the test substances in the same doses. After 30 minutes contact between the virus and the cells, 0.4 ml of the support medium (medium 199 with added antibiotics but without foetal bovine serum) was added to each of the holes and they were left in a germinator at 36.7° C. The percentage of healthy cells was determined towards the end of the experiment using methylene-blue.

2nd variant

On the second day after planting the SPEV cell cultures in 24-hole plastic plates, a cell monolayer had formed in the holes. The nutrient medium was removed from each of the holes, the holes were washed with 0.4 ml of the support medium, and the support medium was then drained off. Then 20 µl of the flu A virus was added to 8 holes in a dose of 10.0 $TCID_{50}$, and 20 µl of the flu A virus was added to another 8 holes in a dose of 1.0 $TCID_{50}$. After 30 minutes of contact for the virus to be adsorbed onto the cells, the powder spray containing Nasaleze and Nasaleze Cold was sprayed into each of the holes with the infected cell monolayer, with 1 spray of each of the products for the 4 holes with the cell cultures. The remaining 4 holes with the monolayer of infected SPEV cell cultures were not treated with the products. 0.4 ml of the support medium (medium 199 with added antibiotics but without foetal bovine serum) was then added to each of the holes and they were left in a germinator at 36.7° C. The infected cultures were observed over 4-5 days, and cytopathic changes were observed in the infected control cell cultures which were not treated with the test substances.

Determining the ability of the infected cells to produce the infectious flu A/H5N1 virus

48 hours after the cells were infected, 40 µL of the nutrient media was removed from the holes containing the infected SPEV cell cultures and the concentration of the infectious virus in the samples was determined through titration for infectious activity using a 2-day-old SPEV cell culture monolayer cultivated in 96-hole plates. After reaching the maximum display of cytopathic action, infectious titers were found in all of the test variants. The percentage of healthy cells was determined towards the end of the experiment using methylene-blue.

Results

The results are shown in tables 1 – 3.

Cytotoxic properties of the test substances

Upon visual observation under an optical microscope we were able to see that, in terms of morphological properties, vitality and cytoproliferative activity, the SPEV cell cultures did not differ from similar cells cultivated without treatment by the test substances over a period of 7-8 days' cultivation. On the first day after treatment with the test substances we were able to use the microscope to see a semi-transparent film covering the cell monolayer which disappeared after the 2nd day of observation and which had no effect on the vitality of the SPEV cells for the entire observation period.

Antiviral activity of Nasaleze and Nasaleze Cold

The information shown in table 1 shows that the test substances when treating the cell cultures before infection with the flu A/H1N1 virus (preventive application) in a dose of 2.5 mg per hole, are able to protect most of the

Table 1 : Antiviral properties of the products Nasaleze and Nasaleze Cold with regard to infection with the flu A/H5N1 virus in SPEV cell cultures. Effect on the vitality of infected cells when used for preventive purposes.

Dose of the virus (TCD50)	Products	Percentage of infected cells in the monolayer					
		SPEV+product+virus			SPEV without the product+virus		
		48 hours after infection	72 hours after infection	112 hours after infection	48 hours after infection	72 hours after infection	112 hours after infection
10.0	Nasaleze	100±0	20±5	0	80±10	5±5	0
	Nasaleze Cold	100±0	75±10	0	80±10	5±5	0
1.0	Nasaleze	100±0	85±10	0	95±15	30±5	0
	Nasaleze Cold	100±0	100±0	0	95±15	30±5	0

SPEV cell monolayer against the cytopathogenic effect of the flu A virus within 72 hours after infecting the cells. It was found that up to 85% - 100% of the cells in the monolayer survive when treated with the product Nasaleze Cold, while a total of 30% of the SPEV cells infected with the flu virus which are not treated with the product survive. It was also found that Nasaleze Cold has a slightly greater antiviral effect than original Nasaleze.

At 112 hours after infection, most of the cells in the control and experimental test variants had been killed.

We received similar data when using the test substances immediately after infecting the SPEV cell cultures (table 2). We also found that this depended on the characteristics of the product which was used. So, when infecting the SPEV cells with the flu A virus in a dose of 10.0 $TCID_{50}$ under the effect of the test substance Nasaleze at 72 hours after infection, 25% of the infected cells survived (in the control samples which were not treated with the product 5% of the cells survived in these conditions).

Table 2 : Antiviral properties of the products Nasaleze and Nasaleze Cold with regard to infection with the flu A/H5N1 virus in SPEV cell cultures. Effect on the vitality of infected cells when used for medical and preventive purposes.

Dose of the virus (TCD50)	Products	Percentage of infected cells in the monolayer					
		SPEV+product+virus			SPEV without the product+virus		
		48 hours after infection	72 hours after infection	112 hours after infection	48 hours after infection	72 hours after infection	112 hours after infection
10.0	Nasaleze	100±0	25±5	0	75±10	5±5	0
	Nasaleze Cold	100±0	80±10	0	85±10	5±5	0
1.0	Nasaleze	100±0	85±10	0	95±15	25±5	0
	Nasaleze Cold	100±0	90±0	0	95±15	30±5	0

If the cell cultures were treated with the product Nasaleze Cold, 80% of the cells survived after 72 hours. However, in these conditions cells in all of the test variants had died at 112 hours after infection. Multiple treatments of the cells with the products would most probably be needed in order to achieve a stable antiviral effect.

It was interesting to learn about the effect of these test substances on the ability of the infected SPEV cells to produce the flu A virus in the medium. The results of titration of the samples of the medium collected from the infected cell cultures at 72 hours after infection are shown in table 3.

Table 3 : Antiviral properties of the products Nasaleze and Nasaleze Cold for the flu A/H5N1 virus in SPEV cell cultures. Effect on the concentration of the infectious virus produced by the cells (during preventive use of the products). Virus dose of 1.0 lg TCID50.

Route of administration	Products	Flu A virus titers (lg TCID50/ml) 72 hours after infection	
		SPEV+product+virus	SPEV without the product+virus
		72 hours after infection	72 hours after infection
Preventive	Nasaleze	3.0±0.5	7.5±0.5
	Nasaleze Cold	1.5±0.5	7.5±0.5
Medical and preventive	Nasaleze	4.0±0.5	7.5±0.5
	Nasaleze Cold	3.0±0.5	7.5±0.5

These show that at 72 hours after infection, the Nasaleze test substance was able to reduce the production of the virus by the cells by 10,000+ times when compared with the production of the virus by untreated cells (table 3). In these conditions Nasaleze Cold significantly reduced the infectious activity of the virus (to 6.0 lg $TCID_{50}$). Significant but somewhat lower levels of antiviral activity of the products were shown when using them for medical and preventive purposes (table 3).

These data sets indicate that the test substances Nasaleze and Nasaleze Cold are able to protect the cells from the cytopathogenic effect of the highly pathogenic flu A/H5N1 virus. The factors involved in the antiviral effect of theses natural compounds require further research. At the same time, we should point out the known viricidal qualities (ability to inactivate the infections properties of virions) of phytoncides in the composition of Nasaleze Cold would suggest that it is superior to Nasaleze. However, the data generated clearly shows the antiviral effect of Nasaleze without adding phytoncides. Here we should point out that the test substances, which are presented as microcellular powder, after treatment of the cell monolayer in combination with culture fluid, form a gel-like film layer which is often used in virological research to limit the reproduction of viruses. It is possible that this film may protect the cells against the adsorption of viruses onto their membrane.

Furthermore if the virus still penetrates the cell where it is not protected by the film, the virus which has multiplied and left the cell cannot be passed on to healthy cells which are protected by the film. Therefore, the infection process is significantly slowed down and could even be stopped with multiple applications of the test substances. It is also likely that the toxins and proteins which are formed as a result of the death of the infected cells will be used by the film, swept down into the stomach by normal muco-cilliary clearance mechanisms and will not cause intoxication or allergisation, which are observed during the normal infection process.

Conclusion and Discussion

The test substances Nasaleze and Nasaleze Cold, provided by Pharmaval Inc, are able to protect most cell cultures from the cytopathogenic effect of the flu A/H5N1 virus. Our results indicate the Nasaleze Cold product has more pronounced antiviral properties than the Nasaleze formula. Both substances are however capable of significantly reducing the production of the flu A/H5N1 virus by infected cells over a period of 72 hours after the cells are infected using the equivalent of just 1 daily dose. Moreover, neither test substance showed any cytotoxic properties for SPEV cell cultures.

It is clear that these simple patented natural formulations have some interesting virucidal properties that warrant further investigation and that they could certainly be utilized as an alternative in preventing and perhaps treating active viral infections including the currently well described "avian flu". Our data indicate very strongly that Nasaleze and particularly Nasaleze Cold could be used both as a preventative measure and a treatment option for this pernicious and persistent viral infection.


COLD
Nasaleze®
natural prevention for the common cold

Use of Nasaleze Cold as a prevention method for acute respiratory illnesses in paediatric practice

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Acute viral respiratory infections are the most common childhood pathology. Every year, there are one to eight respiratory infections per child per year. The relevance of using prevention measures for viral respiratory infections is confirmed by the dynamics of incidence of the illness. Based on Rospotrebnadzor (Russian Federal Consumer Rights Protection and Human Health Control Service) data, the incidence of acute infections of the upper respiratory tract in May to December 2009 has grown by 3.5% compared with the same period in 2008 [1]. Children of all age groups are equally involved in the epidemic process. The average illness incidence in children from 0 to 2 years was 38.2% (for the 2008 epidemic season - 36.86%), three to six years - 43.5%, (41.9%), among schoolchildren - 27.3% (26.3%), and in persons over 18 years - 18% (15%) [2]. The highest incidence of the illness is noted among children of pre-school and primary school age. It is possible that adverse external factors also lead to an increase in the incidence of the illness (passive smoking, environmental pollution, living in industrial areas). The aetiology and clinical manifestations of URTI are varied, impeding the diagnosis and treatment of viral infections. Immunity after past URTI is type-specific, which results in repeat cases of illness. [3] The existing prevention methods are sufficiently well-developed but not always effective. Measures include: restricting the child's contact with people suffering from respiratory illnesses, ensuring good sanitation and hygiene, reduction in the use of public transport, extending the time the child spends in the fresh air and immunisation. However, children regularly attend formal establishments and it is possible to get infected at home, by parents, relatives and other children [4].

The high level of incidence, the severity of the diagnosis (especially in children of preschool and primary school age), the possible development of complications and the considerable socio-economic element of URTI result in a need to develop and put into practice effective preventive methods [5].

There are new opportunities for preventing respiratory infections through the use of the locally acting drug Nasaleze Cold. The drug consists of natural components - microdispersed cellulose powder and plant-derived wild garlic extract - which are sprayed from the vial onto the nasal cavity mucosa. A peppermint extract is also included as an auxiliary substance, giving a pleasant taste and odour to the powder. The preparation is a nasal powder spray acting as an "invisible mask", protecting the nasal mucosa from viruses and bacteria [6].

Upon contact with the nasal cavity mucus, the micronised cellulose (polysaccharide-cellulose obtained from plant cellular membrane) forms a gel-like coating that protects the body from microparticles that are inhaled in the air (viruses, bacteria, allergens, pollutants). [7] The wild garlic extract included in the drug composition has been used in medicine for over 5000 years, contains essential oils, a high amount of vitamin C and phytoncides. Phytoncides (from Greek *phytón* - plant and Latin *caedo* - to kill) are biologically active substances formed by plants, which detoxify or suppress the growth and development of microorganisms. The active substances in garlic are allicin and ajoenes, which have a proven anti-bacterial, fungicidal and anti-viral effect (the anti-viral effect is more pronounced in ajoenes). [8] As opposed to anti-biotics and anti-viral drugs, microorganism resistance does not develop for phytoncides.

The product is issued in the form of a dry spray in a special 500 mg bottle that dispenses the exact dose. A gel-like layer is formed on the nasal mucosa, acting as a natural barrier or filter against viruses and bacteria inhaled in the air, and breathing is not affected. Nasaleze Cold can be used prophylactically for daily defence against URTI during an epidemic season, for emergency protection before coming into contact with someone suffering from an infection, in places of mass public gathering or prior to journeys on public transport. Prescription is twice a day.

If required (after sneezing or blowing nose) it is recommended to repeat the spraying to restore the protective coating.

Aims and objectives.

An open comparative randomised study of the efficacy and safety of using microdispersed cellulose powder (Nasaleze Cold) for the prevention of respiratory viral infections in children was carried out over six weeks in the season from December 2009 to January 2010.

The study was based at the outpatient department of the Children's Diseases Clinic of the I.M. Sechenov Medical Academy, Moscow, as well as at the Tula Municipal Centre for Paediatric Respiratory Pathology. Parents of children included in the study were informed about the method of preventing respiratory infections. Monitoring included 63 patients aged three to 14 years who suffered from acute respiratory infections almost every month (from six to 12 times a year). 43 children were prescribed Nasaleze Cold. 20 children in the comparison group received symptomatic treatment. There were 28 girls (44%) and 35 boys (56%) and the average age was 6.8 ± 2.5 years.

Inclusion criteria for the programme were as follows: outpatients three to five years old and outpatients six to 12 years old; informed consent of the patient's parents for taking part in the study; no URTI symptoms; no heightened sensitivity to any of the product's ingredients.

Exclusion criteria for the study were as follows: hypersensitivity and/or contraindications for any ingredients of the investigative product; inability to follow medical recommendations; presence of somatic disorders that may worsen in the course of the patient's participation in the programme; no written consent for taking part in being monitored; patients suffering from severe forms of chronic illnesses; discontinuation of taking part in the programme. The reasons for patients' early withdrawal were: erroneous inclusion in the study; patient's desire to leave the study, deviation from the programme (non-observance of doctor's recommendations with regard to the investigative product); occurrence of severe adverse events calling for withdrawal of the investigative product.

Developing URTI symptoms during the period of observation was not an indication for discontinuing Nasaleze Cold. The patients were monitored for six weeks.

Throughout the observation period, the state of nasal breathing at night and during the day, discharge from the nasal cavity and its characteristics, sneezing and coughing were all evaluated daily on a 5-point scale (where 0 points - no symptoms; 1 point - symptoms appear but do not bother the patient significantly; 2 points - manifestations of the illness cause moderate discomfort, 3 points - symptoms are pronounced, they reduce the patient's activity and affect sleep, 4 points - manifestations of the illness are expressly pronounced, they significantly reduce the patient's activity and negatively affect sleep). Body temperature, intoxication symptoms (headache, lack of energy, drowsiness, restless sleep), tolerance of the drug based on presence/absence of allergic reactions and other side effects were also evaluated.

Parameters were monitored at weeks two and six after starting use of the drug. The Nasaleze Cold medical device was used in accordance with the recommended dosage: one spray into each nostril twice a day. Patients were recommended to re-spray Nasaleze Cold after each time they blew their nose or when likely to come into contact with someone suffering from URTI in order to restore the protective layer.

All patients taking part in the study belonged to the group of children who are frequently ill (URTI 6-10 times/year). The comparison group consisted of 20 children, (control group) comparable in age and gender, not receiving treatment with Nasaleze Cold spray.

Permissible therapy: vitamins and drugs that have to be taken for concurrent conditions, provided they are not included in the list of drugs not permitted for use during the study.

Prohibited therapy during the treatment was taking other nasal medical preparations as well as drugs for prevention of URTI (Grippferron, Viferon, Arbidol etc.)

Study group characteristics.

Data regarding objective and subjective URTI symptoms during and after use of Nasaleze Cold was evaluated. These indicators were compared with the same ones in the group of patients who did not receive preventive treatment with the product and with the same period in the previous year for patients receiving Nasaleze Cold. The results were recorded in the "Patient observation diary".

The average age of patients in the main group (1) and comparison group (2) was 6.9 ± 2.5 and 7.1 ± 3.2 years accordingly. By the start of the study the frequency of URTI for the past three months in both groups was 2.92 ± 1.3 and 2.84 ± 1.78. The frequency of URTI in the previous year in these groups was 2.72±1.11 and 2.79±1.7.

A similar number of children with concurrent allergic conditions and illnesses of the ENT organs was noted in both groups. (Table No. 1)

Table 1. Patient medical history characteristics

GROUPS	MAIN		CONTROL	
	%	Number of children	%	Number of children
Obstructive bronchitis	7.7%	3	10%	2
Bronchial asthma	23%	9	25%	5
Allergic rhinitis	31%	12	30%	6
Atopic dermatitis	10%	4	12.5%	2
Chronic tonsillitis	3.12%	8	5%	1
Adenoids	28.25%	11	25%	5
Chronic rhinopharyngitis	10.2%	4	10%	2

At the start of the study the patients had not received any other drugs for the prevention of URTI.

The patients visited the doctor three times every 2.5 weeks (Table No. 2).

Table 2. Case monitoring timetable for the patients per visit.

Evaluation of efficacy and safety variables was done in accordance with the observation schedule

STUDIES	Visit 1 (prior to starting therapy)	Visit 2 (after 2 weeks)	Visit 3 (after 4 weeks)
Informed consent	✘		
URTI frequency over the past 3 months, URTI frequency the previous year (December, January)	✘		
History of allergic reactions (presence of concurrent allergic conditions, ENT illnesses)	✘		
Patient examination	✘	✘	✘
Inclusion and exclusion criteria	✘		
Evaluation of URTI symptoms' intensity, should they occur (using a 5-point scale, where 0 means 'no symptom' and 4 means 'symptom has maximum intensity')	✘	daily	daily
ENT specialist consultation	✘		✘
Assessment of adverse events		✘	✘
General doctor and patient assessment		✘	✘

Results of the study and discussion:

Analysis of the observation cards has revealed that over the observation period, of the 43 children in the main group, individual intolerance of the drug was observed in three children (6%). All three had allergic conditions: bronchial asthma and perennial allergic rhinitis. In two patients, intensification of all URTI symptoms was observed, coupled with intensified bronchial asthma, which may have been connected with individual sensitivity. Nasal bleeding was noted in one patient on day four of using the drug. The drug was discontinued and the children were withdrawn from further observation. Thus, 40 children remained in the main group and continued to take the drug in accordance with the study protocol.

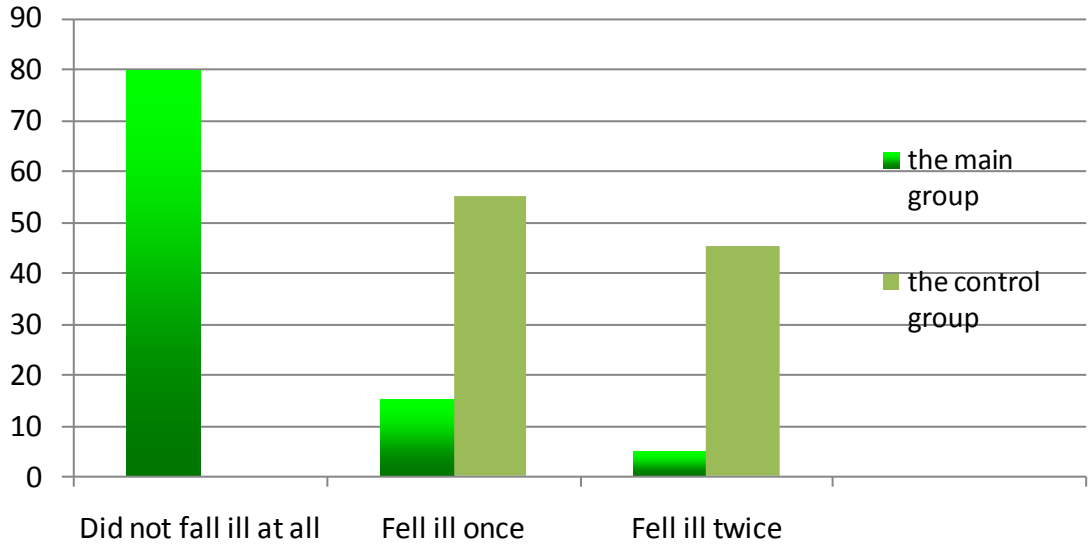
Of these 40 children:

- 32 children (80%) did not fall ill at all
- 6 children (15%) fell ill once
- 2 children (5%) fell ill twice

Table 3. Incidence of illness in children in the main and control groups for the observation period.

INCIDENCE OF ILLNESS	Nasaleze Cold	Control
Did not fall ill at all	32 *(80%)	0 (0%)
Fell ill once	6 (15%)	11 **(55%)
Fell ill twice	2 (5%)	9 *(45%)
TOTAL	40 (100%)	20 (100%)
* - differences are significant, (p<0.05)	** - differences are significant, (p<0.1)	

Fig. No. 1. Incidence of illness in children in the main and control groups for the observation period.



We have analysed the data about the incidence of illness among the children of the main group who received Nasaleze Cold for the same period the previous year. Table No. 2.

Table 4. Comparative analysis of incidence of URTI in 2008 and 2009 for children in the main group.

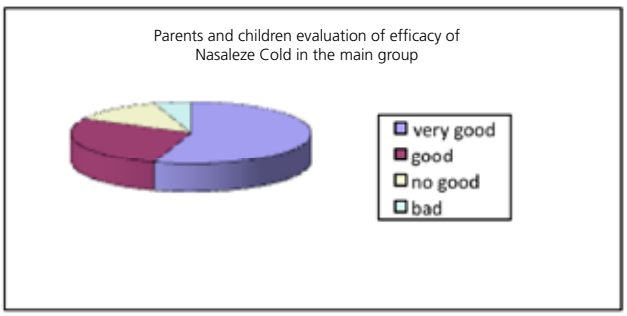
EVALUATION CRITERION	Number of children receiving Nasaleze Cold		
	2008 - 2009 (December, January, February)	2009 - 2010 (December, January, February)	
Number of instances of URTI	2.72 ± 1.11	0.25 ± 0.54	Decreased by 10 times
Duration of URTI (in days)	7.65 ± 3.54	3.24 ± 2.17	Decreased by 2.5 times

Thus, the number of children who did not fall ill in the main group was 80% (32 children); in 17.5% of children, the severity of illnesses decreased. Compared to the same period last year, taking Nasaleze Cold decreased incidence in 90% of patients.

Adverse effects associated with taking Nasaleze Cold were noted in four patients (10%). Five days after taking the drug, children experienced severe nasal discharge (rhinorrhea) and sneezing intensified; these decreased when antihistamines were added to the therapy. Three of these children had bronchial asthma coupled with perennial allergic rhinitis. One child had a medical history of chronic tonsillitis. These children had no catarrhal events registered over the whole observation period, their temperature did not go up, the children did not have URTI and continued taking Nasaleze Cold.

On the whole, the majority of parents (82.5%) and doctors (90%) considered the microdispersed cellulose powder Nasaleze Cold highly effective for the preventive treatment of acute respiratory infections **(Fig. No. 2, 3)**. Good tolerance of Nasaleze Cold was noted by 72.5% of parents and 87.5% of doctors **(Fig. No. 4, 5) .**

Fig. 2, 3. Parent and doctor evaluation of efficacy of Nasaleze Cold in the main group.



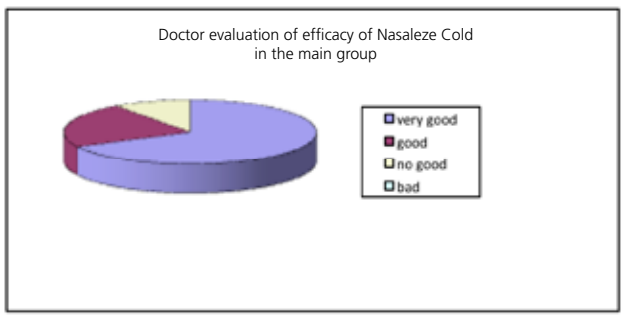
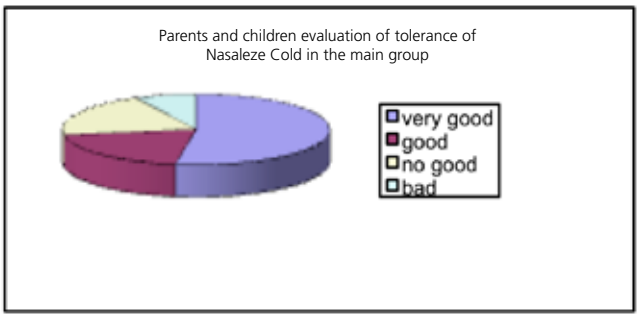
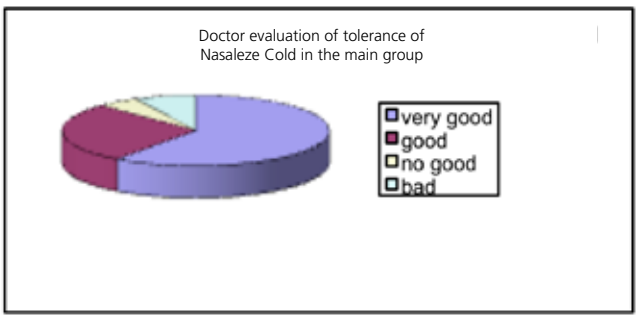


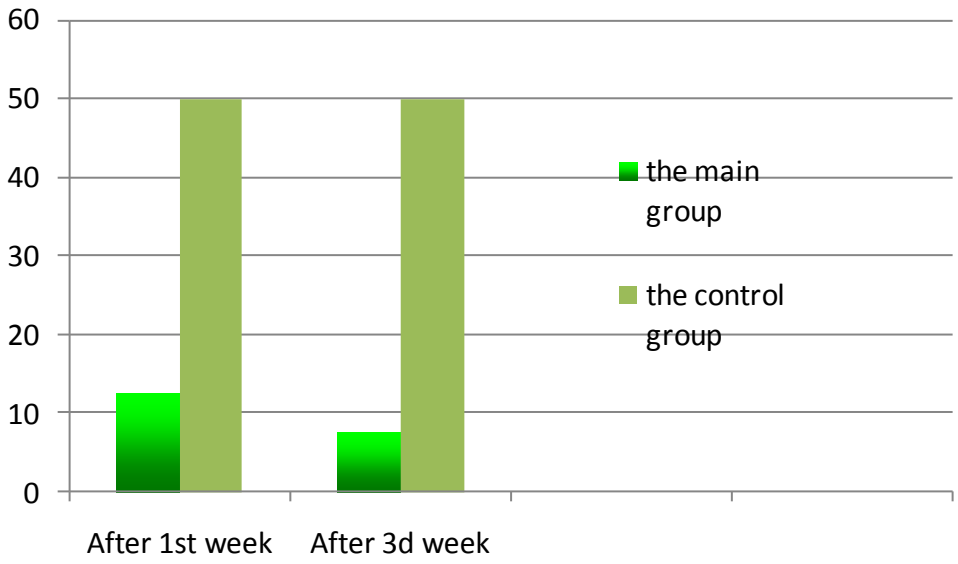
Fig. 4, 5. Parent and doctor evaluation of tolerance of Nasaleze Cold in the main group.





One week after the start of using microdispersed cellulose powder (Nasaleze Cold), five children (12.5%) had fallen ill in the main group, whereas 10 children (50%) had fallen ill in the control group. three weeks after starting use of the drug, in the main group three children – 7.5% (two of them had a repeat illness) fell ill in the main group, and in the control group, again 10 children fell ill – 50% (nine of them had a repeat illness). Fig. No. 6

Fig. No. 6. Illness incidence for children in the main and control groups towards the end of observation weeks one and three.



We have conducted a points-based evaluation of the URTI symptoms in children who fell ill in both groups, a week after the start of the URTI illness, i.e. weeks two and six after the start of observation. In two weeks, children in the main group who fell ill had a less marked manifestation of the main URTI symptoms, the points-based evaluation of which is shown in Fig. 1-7, as compared to the control group: nasal congestion in the daytime decreased from 0.91 ± 0.4 to 0.64 ± 0.6 points; nasal congestion at night decreased from 1.07 ± 0.5 to 0.67 ± 0.6; sneezing – from 0.62 ± 0.6 to 0.51 ± 0.6; headache, lack of energy and drowsiness decreased from 0.43 ± 0.5 to 0.25 ± 0.6; and restlessness during sleep decreased from 0.4 ± 0.5 to 0.23 ± 0.5 ($p<0.05$).

Dynamics of points-based evaluation of subjective URTI symptoms in children of the main and control groups in week two (visit two) and in week six (visit three) of the observation (OY axis – intensity of symptoms expressed in points) ($p<0.05$). Fig. No. 7-13.

Fig. 7. Nasal congestion in the daytime

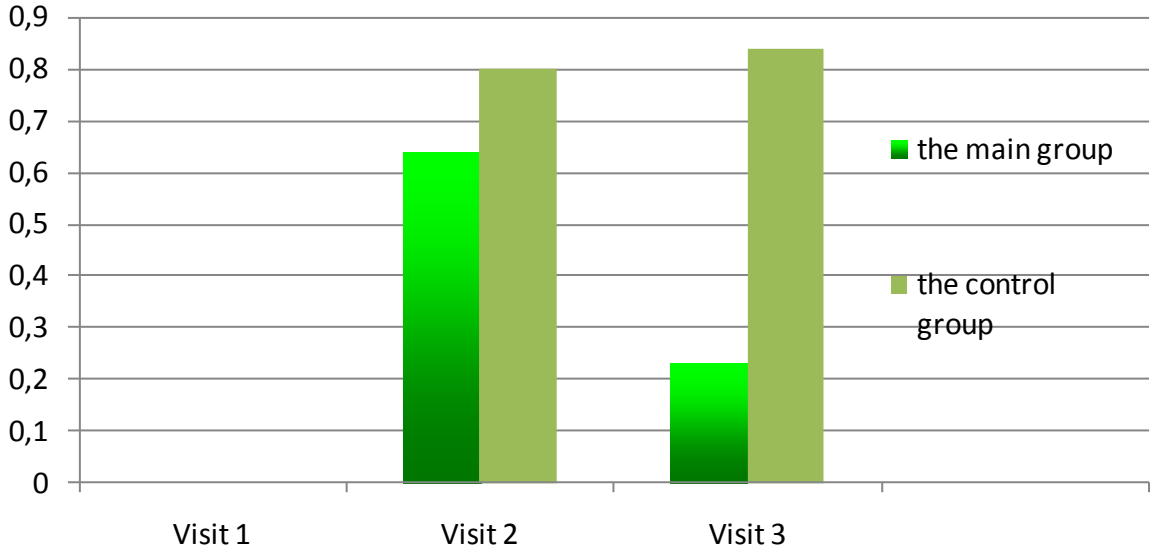


Fig. 8. Nasal congestion at night

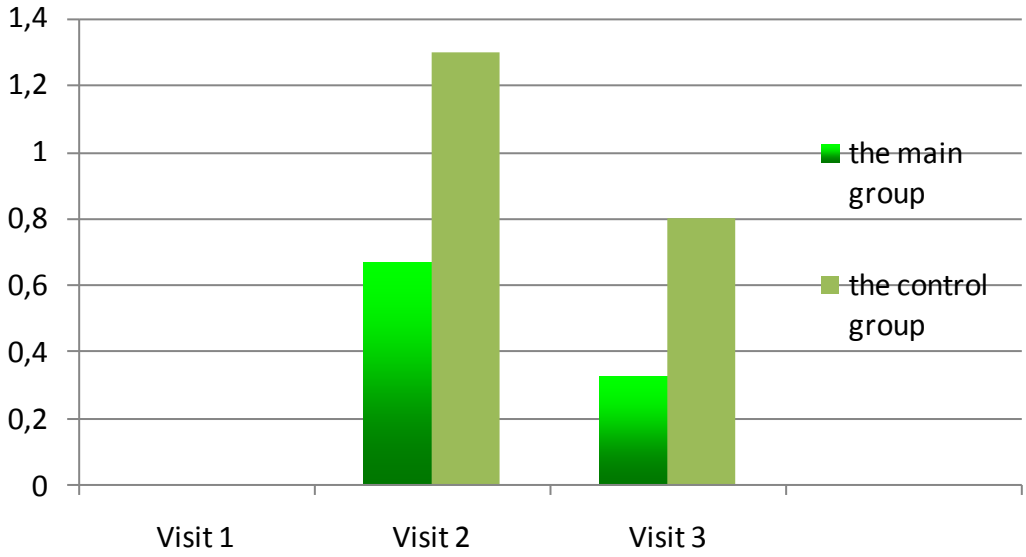


Fig. 9. Sneezing

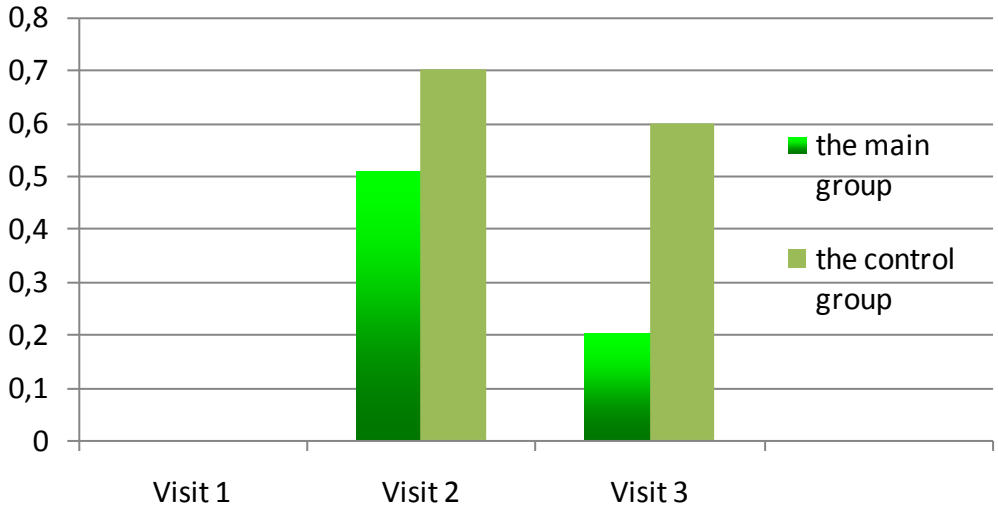


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Fig. 10. Nasal discharge

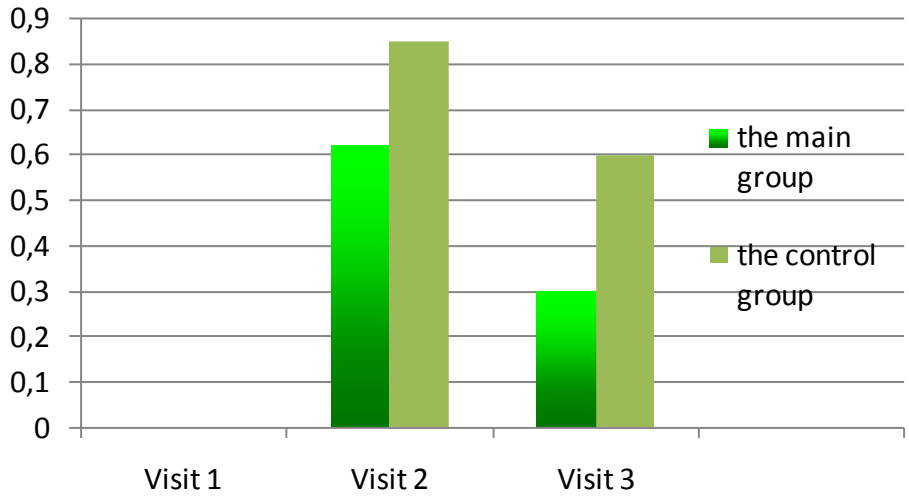


Fig. 11. Cough

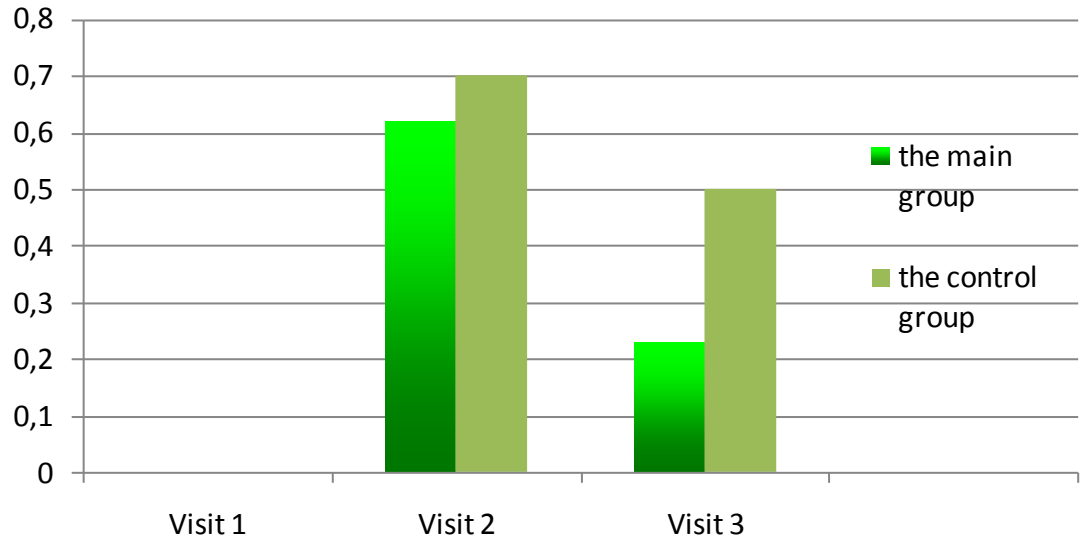


Fig. 12. Headache, lack of energy, drowsiness

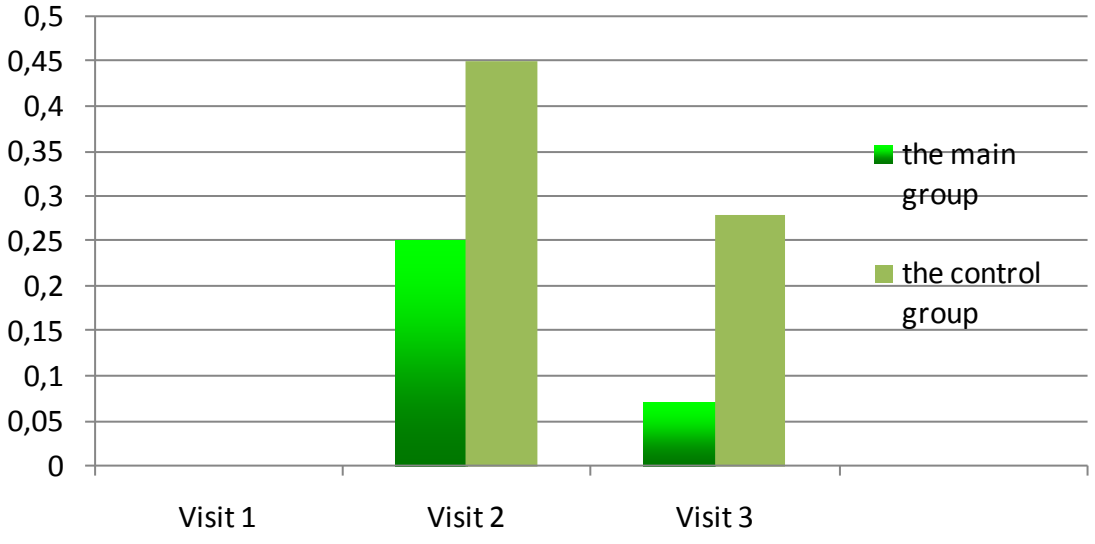
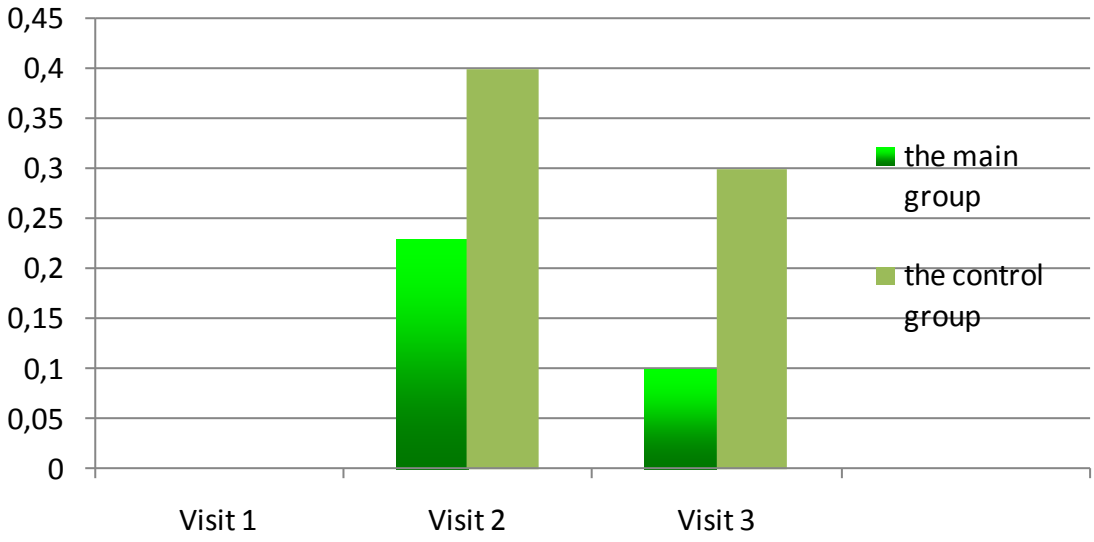


Fig. 13. Restlessness during sleep



In six weeks, a considerable reduction in objective and subjective URTI symptoms was noted as compared with the control group: nasal congestion in the daytime decreased from 0.91 ± 0.4 to 0.23 ± 0.37 points; nasal congestion at night - from 1.07 ± 0.5 to 0.33 ± 0.54; sneezing - from 0.62 ± 0.6 to 0.2 ± 0.44; nasal discharge - from 0.69 ± 0.5 to 0.3 ± 0.28; cough - from 0.64 ± 0.5 to 0.23 ± 0.4; headache, lack of energy and drowsiness - from 0.43 ± 0.5 to 0.07 ± 0.08; restlessness during sleep - from 0.4 ± 0.5 to 0.1 ± 0.09 ($p<0.001$). These data reflect the fact that fewer children had fallen ill by that time in the main group and their illnesses were less severe compared with those of the children in the control group.

Thus, the impact of the microdispersed cellulose powder Nasaleze Cold on objective and subjective URTI symptoms has been clearly demonstrated.

Conclusion:

1. When taking Nasaleze Cold:
   - did not fall ill during the observation period - 32 children (80%)
   - had one episode of URTI - six children (15%)
   - were ill twice - two children (5%).
2. Compared with the same period last year, the illness incidence decreased in 90% of patients, and the duration of URTI (in days) decreased by 2.5 times.
3. Whereas in the control group there were no children who did not fall ill at least once, 11 children (55%) fell ill once, and nine children fell ill twice (45%). Thus, the total number of children who fell ill in the main group is 80% less than in the control group.
4. Tolerance of the drug was noted as very good in the majority of cases; individual intolerance of the drug was observed in three children (6%). In two children, the start of taking the drug caused an intensification of bronchial asthma, of moderate to severe intensity, leading to withdrawal of the drug. In 1 patient, an instance of nasal bleeding was noted on day four of using the drug; this also led to withdrawal of the drug. Thus, Nasaleze Cold must be prescribed with care to children with moderate to severe bronchial asthma for the prevention of URTI. Moreover, presence of nasal bleeding in medical history should be a criterion for excluding patients from the study.

5. Many parents noted the ease of using the drug. The majority of parents (82.5%) rated the microdispersed cellulose powder Nasaleze Cold as a highly effective preventive agent against URTI. Good tolerance of the drug was noted by 72.5% of parents**.**
6. Also, when taking Nasaleze Cold, a clear effect on URTI symptoms in children who fell ill in the main group was noted as compared to control group children. A week from the start of illness, children experienced a definite reduction in such symptoms as nasal congestion in the daytime and at night, nasal discharge, cough, headache, lack of energy; and a tendency towards normal sleep was noted as compared to the control group. A definite reduction in objective and subjective URTI symptoms was also noted in week six of taking the drug.
7. Thus, the use of Nasaleze Cold as a means for preventing the development of respiratory illnesses in children must be recommended for a period of at least one month.

Nasaleze Cold can be recommended for carrying out preventive treatment of cold-related illnesses in children.

Discussion:

Thus, daily use of Nasaleze Cold with a preventive and protective aim: definitely prevents occurrence of respiratory infections (URTI); and protects against re-infection. Use of Nasaleze Cold during the active infection period helps to reduce the duration of the illness; and reduces the severity of URTI. It is important that Nasaleze Cold is not absorbed into the bloodstream, has no systemic action and does not affect immunity. It creates a double natural barrier, mechanical and biological, providing anti-bacterial and anti-viral protection. It is also known that Nasaleze Cold consists of only natural components and is safe for prolonged use throughout the season of cold-related diseases. Microdispersed cellulose powder is well-tolerated, easy to use and may be used in children of any age, starting from the very young. Regular use of inert cellulose powder in the nostrils may effectively prevent and alleviate the symptoms of URTI.

Nasaleze Cold is a modern, effective and safe natural spray for protecting the body against viruses, bacteria and other harmful external factors.

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Could two kitchen favorites ward off swine flu?

As I watched the panic over swine flu build over the last several months, I started to get a little worried. About the flu itself, sure, but I worried even more over what mainstream medicine offered as an answer. Whole camps and schools full of children being given Tamiflu preventatively (it causes some pretty nasty side effects). The CDC going ahead with a vaccine plan despite the lack of evidence for both effectiveness and plan safety.

I couldn't help but wonder if we were going to end up in an even worse spot thanks to these efforts to control the flu. Then my eyes settled on a little bottle on my desk.

A formula I take with me every time I get on a plane—I simply won't travel without it. A formula that is clinically proven to keep viruses and airborne infections from invading the body.

I've been using it to ward off colds successfully for a few years now. And I had to wonder—if this simple formula blocks viral infections from ever taking hold of your system, could it protect us from swine flu?

I immediately opened a new email, eager to find out if my idea had any weight to it.

It turns out my hunch could be right. Nasaleze Cold, the little bottle that's been my constant travel companion, could actually play an important role in protecting your family from swine flu (and all manner of other nasties). Without worrying about the side effects of Tamiflu, and without injecting unproven vaccines into your system.

Proven by thousands of years of use

My email was almost immediately answered by Matt Duxbury, the Export Director for Nasaleze (it's made in the UK). Matt immediately put me in touch with Peter Josling, a UK expert on garlic and colds who actually conducted a clinical study on Nasaleze Cold back before this whole swine flu mess blew up.

Peter commented on the overuse of anti-viral drugs (maybe you've noticed Tamiflu is being given out like candy to schoolchildren whether they're infected or not). He takes comfort in knowing the natural anti-viral ingredients in Nasaleze Cold have been used for thousands of years with no problem.

He went on to tell me that peppermint and wild garlic are both "excellent natural anti-viral agents." Explaining how Nasaleze Cold works, he said it uses a special cellulose (the main component of cell walls in plants) to trap viral particles in the nasal cavity. Unlike liquid nasal sprays (which are usually just drained by the nasal tract anyway), this one uses a cellulose powder, which turns into a gel on contact with the moisture in the nasal cavity.

This gel is similar to normal mucus, acting as a barrier against inhaled pollen, dirt, allergens, and other invaders. It naturally inhibits bacteria and viruses, but only to a certain extent. Of course, Nasaleze Cold goes a step further with the natural anti-viral power of peppermint and wild garlic extract. They destroy the nasties that get trapped in the gel formed by the cellulose.

Nasaleze Cold cuts infections by about 65%

Now, there haven't been any clinical trials on Nasaleze Cold and swine flu, though Matt said they're discussing the possibility. Still, I just had to tell you about it because of Peter's comments and my own personal experience with the formula, and because of Nasaleze Cold's power when it comes to preventing cold viruses from taking hold of your body.

But clinical studies have shown that taking Nasaleze Cold daily or before entering an environment likely to be high in airborne germs can significantly reduce the chances of catching a cold.

And in a pilot study on the formula, 52 volunteers received either a plain cellulose spray or one with powdered garlic extract (Nasaleze Cold). The active treatment group had significantly fewer colds than the group taking plain cellulose (about 65% fewer infections).

They also experienced far fewer "sick days"—126 days of illness in the active group versus 240 days in the control group. And while 11 volunteers in the control group experienced multiple infections, only 2 in the Nasaleze Cold group did.

The only drawback reported by the active group was that they could easily taste the powdered garlic extract, but it didn't keep anyone from using it. [1]

I have to say, while the peppermint does mask the taste a bit, the garlic is definitely there. I did get used to it, though, and in my opinion it's more than worth it.

Dr. Ron Cutler, principal lecturer in microbiology at the University of East London, has also been supportive of Nasaleze Cold. He says, "Nasaleze Cold works by strengthening the nasal barrier against external germs and irritants, it actually helps the nose to filter out germs and dust so preventing the viruses and airborne infections from invading the body. You could say it's an addition to the body's armory to help protect against colds and flu - before they start."

Like I said, my own personal experience with Nasaleze Cold has been nothing but positive—no matter how much the person in the seat behind me coughs, no matter how crowded the plane, I am getting far fewer "travel colds" nowadays. And, believe me, I used to pick up every bug that came my way.

For the latest coverage on swine flu (and all of your other most urgent health concerns), be sure to sign up for the HSI e-Alert. It's delivered to your email inbox five days a week and covers all the late-breaking health news too urgent to wait for the next issue. Visit www.hsibaltimore.com to enroll.

Ordering information for Nasaleze Cold is in the Member Source Directory below.

Nasaleze Cold, Nasaleze International Ltd. Phone +44 -1274 518290; www.nasaleze.com. A bottle of Nasaleze Cold is US$14.95 (with free shipping). Purchase 3 bottles in a "Family Pack" and get a 4th free.

References [1] Hiltunen R, Josling P, et al. (2007) Preventing air-borne infections with an intra nasal cellulose powder formulation. Advances in Therapy 24(6).

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