



ColdGuard™ in the prevention and management of the common cold

Stephani Schmidt
Amazeza Information Services

Republished with permission: *S Afr Pharm J* 2020;87(3):56-58

The common cold

The common cold is a mild upper respiratory viral illness caused by several families of viruses (more than 200 subtypes of viruses), for example rhinoviruses, adenoviruses, human coronaviruses and respiratory syncytial virus. Rhinoviruses are the most common cause, accounting for 30 to 50 percent of common colds.¹

Initial symptoms include nasal discharge, nasal congestion/obstruction and a sore throat (dry or “scratchy” throat). Other symptoms include cough, sneezing, headache, fever (low grade, if present) and pressure or discomfort in the ears and face.¹ It may also trigger asthma exacerbations. Colds typically last for 3 to 10 days, but may persist for longer, especially in smokers.¹

Preschool children have an average of about five to seven colds per year and adults an average of about two to three episodes per year.¹

Despite being a mild illness, the common cold is associated with a significant economic burden as assessed by expenditures for treatment and by loss of productivity and subsequent loss of earnings.¹ According to Sexton et al. “colds account for approximately 40 per cent of all time lost from jobs among employed people”.¹

Focus on ColdGuard™

ColdGuard™ works by forming a protective coating (barrier) on the mucous membrane of the throat. The two main ingredients are glycerol, which forms an osmotically active barrier, and cod trypsin.²

The role of cod trypsin

The history of cod trypsin, a marine enzyme from the deep-sea cod, started in 1970, when an Icelandic scientist, professor Jon Bragi Bjarnason, noticed that the hands of employees at a large fish-cleaning plant were “unusually soft and unscathed”. Considering that they are cleaning fish, directly from the cold

Atlantic Ocean, one would have thought that their hands would be dry, cracked and chapped.³

Following investigation, it was found that certain cold-adapted marine organisms contained an enzyme with protective properties. The enzyme (cod trypsin) that forms in the pancreas of cod (Atlantic cod [*Gadus morhua*]) is extracted as a by-product of cod processing.^{3,4}

In order for cold viruses to gain entry into epithelial cells they need to bind to specific receptors on the cells. Proteins on the surface of cold viruses allow viruses to bind to cellular receptors.^{5,6} The effect of ColdGuard™ is thought to be partially due to the ability of trypsin to cleave (degrade) proteins on the surface of viruses (“it cleaves proteins on the carbonyl side of the amino acids arginine and lysine”).⁵ This inhibits the viruses’ ability to infect host cells – it acts on the cold virus itself, reducing its ability to bind to cells in the mucous membrane and cause a common cold.^{2,5}

Efficacy

Antiviral activity

ColdZyme® (ColdGuard™) has demonstrated broad antiviral activity *in vitro*.^{5,7} In a virucidal efficacy suspension test, Stefansson et al. evaluated the virus deactivating ability of ColdGuard™ against several common cold viruses. Results from their study are presented in Table 1.^{5,7}

Table 1: The virus deactivating ability of ColdGuard™^{5,7}

Virus	Per cent deactivation
Rhinovirus type 1A	91.7
Rhinovirus type 42	92.8
Human influenza A virus (H3N2)	96.9
Respiratory syncytial virus	99.9
Adenovirus type 2	64.5
Human coronavirus	99.9

COLDPREV study

The primary objective of this pilot study was to evaluate the effect of ColdGuard™ on viral loads in the oropharynx, after challenge with rhinovirus. Healthy volunteers (number (*n*) = 46) were assigned to self-administer six doses of either ColdGuard™ or placebo as a pre-treatment on the day prior to inoculation of the rhinovirus. They were then infected with rhinovirus 16 via nasal inoculation. After inoculation, subjects continued using six doses of either ColdGuard™ or placebo daily, for 10 days.⁸

The secondary objective was to evaluate the effect of ColdGuard™ on the reduction in the number of days with symptoms in those who experienced a symptomatic cold.

Treatment with ColdGuard™ resulted in a reduction in:

- Viral load. Total viral load in the oropharynx in the ColdGuard™ group was significantly lower compared to the placebo group (median of 3.87 versus 11.8 log copies/ml).⁸
- The number of days with common cold symptoms. ColdGuard™ group experienced a significantly shorter duration of common cold symptoms compared to the placebo group (3.0 days versus 6.5 days).⁸

Other studies

ColdGuard™ was compared to no treatment (control group) in 267 patients with naturally occurring common colds. Treatment with ColdGuard™ significantly reduced symptoms such as sore throat, nose congestion and headache and improved quality of life. The use of symptom-relieving “rescue” medication throughout the first week was 23% lower in the ColdGuard™ group compared to the control group.⁹

Davidson et al. evaluated the effects of ColdGuard™ on self-reported upper respiratory tract infection in competitive endurance athletes ($n = 123$) under free-living conditions. Athletes were randomised to receive placebo ($n = 61$) or ColdGuard™ ($n = 62$) for a three-month study period. The duration of colds in the ColdGuard™ group (7.7 ± 4.0 days) was significantly shorter compared to the untreated group (10.4 ± 8.5 days).¹⁰

Preliminary results from an open-label, observational study showed that the number of cold-related sick days decreased by 29% among elderly care personnel ($n = 111$) who used ColdGuard™ over a 5-month period, compared to historical data.¹¹ In addition, among those who experienced a common cold, 63% reported the symptoms to be milder than previous colds.¹¹

In a small study, preschool staff members ($n = 15$) were instructed to use ColdGuard™ according to the instructions on the device over a six-month period. They found that the average sick-leave days decreased from 7.4 (historical data) to 4.1 days.¹²

Dosage and directions for use

ColdGuard™ is presented as a device that deposits a viscous solution that mainly consists of glycerol and cod trypsin onto the throat.⁸ It is applied via the mouth to target the throat, creating a temporary protective barrier against common cold viruses.²

It may help to:

- Prevent a common cold. Individuals who are not experiencing any signs or symptoms of a common cold, but are at risk of being exposed; for example, those who are in contact with someone who has a cold should use ColdGuard™ during the time of exposure.²
- Shorten the duration of a common cold. Those who are already experiencing symptoms of a common cold, should start treatment as soon as possible after noticing the symptoms and continue until the symptoms have been cleared.^{2,5,8,12}

ColdGuard™ is suitable for use in adults and children from four years of age.² One dose (two sprays), should be used, every two hours, for up to six times a day. The nozzle should be aimed towards the back of the throat when it is sprayed.²

Safety

According to the instructions for use leaflet there are no known contraindications and no known side-effects.²

Important prescribing points

- ColdGuard™ is intended to reduce the probability of catching a cold by blocking viruses at their point of entry.^{2,5} It may help to reduce the duration of a cold, if used at an early stage of the illness.^{2,5} In addition, it is also intended to improve common cold symptoms.^{2,9}
- ColdGuard™ is sugar free and does not contain gluten or preservatives.²
- As a precaution, individuals who are allergic or hypersensitive to any of the ingredients should avoid using ColdGuard™.²
- Inhaling the spray may cause transient asthma-like symptoms such as hoarseness and coughing.² The patient should be advised to not inhale when ColdGuard™ is applied.²
- ColdGuard™ should not be used for more than 30 consecutive days; there is currently no data regarding the long-term use.²
- Individuals with a high fever or those who are experiencing symptoms that are more severe than a common cold should consult a healthcare professional, in order to exclude other illnesses.²
- It is important to note that “there is no available data for ColdGuard™ on other types of coronaviruses, e.g. the SARS-CoV-2 virus responsible for the ongoing coronavirus disease 2019 (COVID-19) pandemic.”^{3,7}

References

1. Sexton DJ, McClain MT. The common cold in adults: Diagnosis and clinical features. PostTW, editor. UpToDate. Waltham, MA: UpToDate Inc. Available from: <http://www.uptodate.com>. (accessed 21 May 2020)
2. ColdGuard™ instructions for use. Abex Pharmaceutica (Pty) Ltd. Available from: https://coldguard.co.za/wp-content/uploads/2020/03/COL_IFU_B-ColdGuard-7ml-IFU_South-Africa.pdf. (accessed 21 May 2020).
3. ColdGuard™ [homepage on the internet]. Available from: <https://coldguard.co.za/about/>. (accessed 25 May 2020).
4. Enzymatica. Barrier technology. [homepage on the internet]. Available from: <https://www.enzymatica.se/en/about-us/barrier-technology/>. (accessed 27 May 2020).
5. Stefansson B, Gudmundsdottir A, Clarsund M. A medical device forming a protective barrier that deactivates four major common cold viruses. *Virology Research Reviews*. 2017;5. Available from: <https://www.oatext.com/a-medical-device-forming-a-protective-barrier-that-deactivates-four-major-common-cold-viruses.php>. (accessed 25 May 2020).
6. Heikkinen T, Järvinen A. The common cold. *Lancet*. 2003;361: 51-59.
7. Stefansson B, Gudmundsdottir Á, Clarsund M. ColdZyme forms a protective barrier in the throat that deactivates five major common cold viruses. Swedish Otolaryngology Congress, Apr 2018. Abstract available from: <https://www.enzymatica.se/files/Main/18091/2752911/999769.pdf>. (accessed 27 May 2020).
8. Clarsund M, Fornbacke M, Uller L, Johnston SL, Emanuelsson CA. A randomized, double-blind, placebo-controlled pilot clinical study on ColdZyme® Mouth Spray against rhinovirus-induced common cold. *Open Journal of Respiratory Diseases*. 2017 Oct 16;7(4):125-35.
9. Lindberg F. Multi-symptom relief and improvement of quality of life - a comparative multicenter trial on ColdZyme® Mouth Spray in common cold. Abstract available from: <https://www.enzymatica.se/files/Main/PDF/>