

# Zinc Gluconate Glycine (Cold-Eeze®)

## Introduction

Of the 62 million common colds requiring medical attention in the United States each year, more than 80% affect school-age children. Controlled clinical trials have demonstrated the effectiveness of Zinc Gluconate Glycine lozenges (Cold-Eeze®) in reducing the duration of the common cold.

In September 1999, the medical staff at the Heritage Center, a placement facility for adolescents in Provo, Utah, introduced Zinc Gluconate Glycine lozenges (Cold-Eeze®) to help aid in the symptomatic relief of the common cold. The prophylactic use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) became standard practice at the Center in December 2000. In May 2001, the Heritage Center reported to Quigley Corporation, the makers of Zinc Gluconate Glycine lozenges (Cold-Eeze®), that the Center's medical records showed a considerable decrease in cold episodes. In June 2001, the Center began working with Synergy Research, Inc. (SRI) — an independent Contract Research Organization — to initiate a retrospective study of the data. Heritage Center provided SRI with medical charts for subjects in residence from 1998 to 2001. SRI, working with the Heritage Center, designed a clinical trial protocol and a comprehensive case report form in order to capture the data directly from the medical charts. SRI independently supervised and collected the retrospective study data according to criteria detailed in the study protocol.

The retrospective study had two (2) objectives. The primary objective was to determine the effectiveness of Zinc Gluconate Glycine lozenges (Cold-Eeze®) in reducing the duration and severity of the common cold in a school age population of males and females. The secondary objective was to ascertain the benefits — if any — of a prophylactic administration of Zinc Gluconate Glycine lozenges (Cold-Eeze®) to reduce the occurrence of the common cold in the same population.

## Design and Methodology

The study subjects were males and females, between the ages of 12 and 18, enrolled at the Heritage Center. Medical data for January 1998 through August 2001 was reviewed. Demographic information, medical history, diagnoses, cold signs and/or symptoms, and concomitant medication data were assembled, reviewed and transcribed onto case report forms.

A cold episode was identified by the presence of two (2) or more pre-specified signs and/or symptoms occurring on the same day. Symptoms consisted of: sneezing, runny nose, stuffy nose, sore throat, cough, headache, muscle ache, chest congestion, postnasal drip

and oral temperature  $\geq 100.6^\circ\text{F}$ . These signs and/or symptoms were used to determine the start date of a cold. Use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) and concomitant medications (antibiotics, analgesics, cold preparations, anti-tussives) were also recorded. Cold resolution was determined by subject self-report noted in the medical chart, cessation of Zinc Gluconate Glycine lozenges (Cold-Eeze®), if applicable, or other cold therapy because it was no longer needed, or medical staff documentation noting resolution of signs and/or symptoms.

Zinc Gluconate Glycine lozenges (Cold-Eeze®) were not distributed to residents of the Center from January 1998 to September 1999 when cold signs and/or symptoms were identified to staff at the Heritage Center. These subjects were used to establish the average duration of common cold signs and/or symptoms in the absence of Zinc Gluconate Glycine lozenge (Cold-Eeze®) therapy.

In September 1999, the Center began dispensing four (4) lozenges daily to residents who exhibited cold signs and/or symptoms. Prophylactic daily administration of one (1) Zinc Gluconate Glycine lozenge (Cold-Eeze®) to all residents was initiated in November 2000. Zinc Gluconate Glycine lozenges (Cold-Eeze®) during this time period continued to be dispensed to symptomatic residents.

Results from the data prior to September 1999 were compared with the data from September 1999 until April 2001. Due to the time period of a given subject's residency, a resident's medical data could contribute to both data groups.

The primary objective of this retrospective study was to determine the effectiveness of Zinc Gluconate Glycine lozenges (Cold-Eeze®) in reducing the duration and severity of the common cold. To this end, the study compared the duration of colds during the period of time Zinc Gluconate Glycine lozenges (Cold-Eeze®) were not used with the subsequent time when Zinc Gluconate Glycine lozenges (Cold-Eeze®) were used on a regular basis.

The secondary objective was to determine the benefits — if any — of a prophylactic administration of Zinc Gluconate Glycine lozenges (Cold-Eeze®) to reduce the occurrence of the common cold. The study compared the period of time when the prophylactic administration of Zinc Gluconate Glycine lozenges (Cold-Eeze®) was implemented with the period of time when it was used only for symptomatic treatment.

Throughout the study, adverse events documented, as related to Zinc Gluconate Glycine lozenges (Cold-Eeze®), were recorded to evaluate its safety.

## Summary of Clinical Results

### The Effect of Cold-Eeze® on Cold Duration

The use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) resulted in a statistically significant reduction in the duration of cold episodes,

from a median of 10.0 days without Zinc Gluconate Glycine lozenges (Cold-Eeze®) to a median of 6.0 days when Zinc Gluconate Glycine lozenges (Cold-Eeze®) were administered to treat colds ( $p < 0.0001$ ).

Other statistics reflected a total of 315 cold episodes prior to the implementation of Zinc Gluconate Glycine lozenge (Cold-Eeze®) therapy with a mean duration of  $8.4 \pm 3.8$  days. A total of 243 cold episodes were recorded after institution of Zinc Gluconate Glycine lozenge (Cold-Eeze®) treatment and their average duration was  $7.5 \pm 3.0$  days ( $p < 0.0027$ ).

### The Effect of the Prophylactic Use of Cold-Eeze® on the Number of Colds Per Year

The prophylactic use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) resulted in a statistically significant reduction in the number of cold episodes, from a median of 1.3 colds per year without Zinc Gluconate Glycine lozenges (Cold-Eeze®) to a median of 0 colds when Zinc Gluconate Glycine lozenges (Cold-Eeze®) were prophylactically administered ( $p < 0.0001$ ).

### The Relationship of Cold-Eeze® and Antibiotic Usage

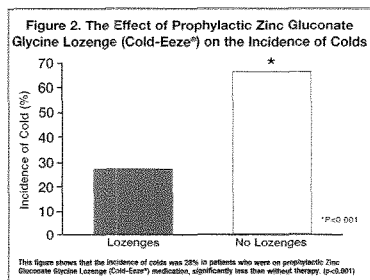
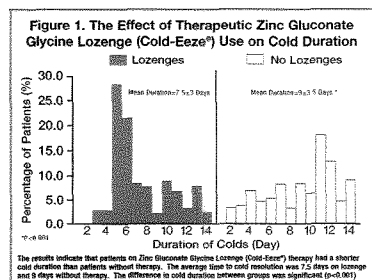
The use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) suggested a significant reduction in the use of antibiotics. A gross comparison of all subjects in all groups suggested that the use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) may have contributed to a substantial reduction in antibiotic use.

## Conclusion

The statistical results of this retrospective study provide strong support for the treatment of, or prophylaxis against, the common cold in school-age children using Zinc Gluconate Glycine lozenges (Cold-Eeze®). First, treatment with Zinc Gluconate Glycine lozenges (Cold-Eeze®) significantly reduced the duration of cold signs and/or symptoms when taken four (4) times per day during a cold episode. Second, prophylaxis with Zinc Gluconate Glycine lozenges (Cold-Eeze®) significantly decreased the incidence of colds when taken one (1) time per day. Third, use of Zinc Gluconate Glycine lozenges (Cold-Eeze®) greatly reduced the use of antibiotics at the Heritage Center from September 1999 to August 2001.

In conclusion, this retrospective study indicates that Zinc Gluconate Glycine lozenges (Cold-Eeze®) significantly reduce cold duration and the use of antibiotics in school-age children, and when administered prophylactically, can significantly decrease the frequency of colds in this population.

**AUTHORS:** Betty Howell McElroy, M.D., P.A., Medical Director, Heritage Center  
Shelly Porter Miller, MMS, PA-C, Heritage Center  
Tanya Howell, Clinical Research Associate, Synergy Research



**Table 1. Effects of therapeutic Zinc Gluconate Glycine lozenge (Cold-Eeze®) use on cold duration**

|                           | Zinc Gluconate Glycine (Cold-Eeze®) used Therapeutically |       |
|---------------------------|--|-------|
|                           | Yes  | No    |
| Number of Colds Evaluated | 232  | 239   |
| Mean                      | 7.5*   | 9.0** |
| Median                    | 6.0*   | 10.0* |
| Standard Deviation        | 3.0  | 3.5   |

A Cold duration in days \*  $p < 0.0027$  \*\*  $p < 0.0001$  (Wilcoxon sign-rank test)

**Table 2. Effects of prophylactic Zinc Gluconate Glycine lozenge (Cold-Eeze®) use on number of colds**

|                           | Zinc Gluconate Glycine (Cold-Eeze®) used Prophylactically |        |
|---------------------------|---|--------|
|                           | Yes   | No     |
| Number of Colds Evaluated | 119   | 377    |
| Mean                      | 0.9*  | 1.7*   |
| Median                    | 0.0*  | 1.3*** |
| Standard Deviation        | 1.9   | 1.9    |

B Number of colds.  $p < 0.001$  (t-test) \*\*\*  $p < 0.0001$  (Wilcoxon sign-rank test)