

COLDZYME®

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

ColdZyme® is a mouth spray against common cold. It is easy to use and has fast onset of action. ColdZyme® creates a protective barrier against common cold viruses by coating the mucous membrane in the oral cavity. The barrier traps the common cold viruses, deactivates and hinders them from spreading and multiplying.

INTENDED USE

Treat and alleviate common cold.

PRECAUTIONS

- Do not use ColdZyme® if you are hypersensitive/allergic to any of the ingredients.
- Do not use the product during pregnancy or breastfeeding, as there is no clinical information available.
- Do not use the product after surgical intervention in mouth and/or throat until wound is healed, without consulting your doctor.
- Do not inhale when applying the spray as it may cause irritation of the airways, resulting in cough and hoarseness.
- Keep out of reach of children, to prevent accidents with small parts.
- Consult a doctor if you have a high fever or if your symptoms are more severe than those of a normal common cold; they could be due to something else.
- To avoid spread of disease, the product should only be used by one user.

INDICATION

To be used when exposed to common cold viruses or early on when common cold symptoms occur. ColdZyme® is suitable for adults and children over 4 years.

CONTRAINDICATIONS

- No known contraindications.

POSSIBLE SIDE EFFECTS

- No known side effects.

Should you experience untoward effects while using ColdZyme®, please consult a doctor for advice.

CLINICAL BENEFITS

- ColdZyme® protects against common cold viruses.
- ColdZyme® can help shorten the duration of a common cold if used at an early stage of the infection.
- ColdZyme® alleviates common cold symptoms and soothes sore throat.

DIRECTIONS FOR USE

When to use

Start using ColdZyme® as soon as possible after noticing symptoms of common cold or at possible exposure to common cold viruses. Continue to use ColdZyme® until the symptoms are relieved.

How to use

1. Open your mouth and aim the nozzle towards your throat (Figure 1).
2. Press down on the pump and spray 2 times (1 dose) every second hour up to 6 times daily during the time you are exposed to the cold virus or until symptoms are relieved.

FIGURE 1



HOW DOES IT WORK

ColdZyme® consists of two major ingredients, glycerol and cod trypsin, which together provide an effective barrier that acts in three ways:

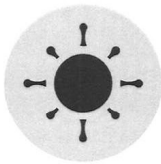
Traps: Glycerol creates an osmotically active transient barrier that traps viruses.

Deactivates: Trypsin inhibits the viruses' ability to bond, deactivating their ability to infect cells.

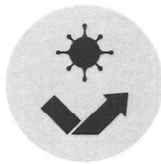
Protects: The ColdZyme® barrier protects the oral cavity and throat.



TRAPS



DEACTIVATES



PROTECTS

DESCRIPTION OF DISEASE: THE COMMON COLD

The common cold is one of the most common infectious diseases caused by viruses that enter the body via the nose, mouth and throat¹. The common cold is caused by a diverse set of viruses (nearly 200¹) where rhinoviruses are the major pathogens. The incubation time is approximately 48 hours, depending on the type of virus (range 0.5 to 4.5 days²).

The immune system reacts to the cold virus through an inflammatory reaction. The inflammatory reaction causes symptoms such as sore throat, cough, runny nose and sometimes fever and sneezing.

- A common cold usually lasts 7-10 days¹
- An adult usually has 2-5 colds per year³
- A child usually has 7-10 colds per year³

COLDZYME® IS AVAILABLE IN TWO DIFFERENT SIZES

- ColdZyme® 20 ml - menthol
- ColdZyme® 7 ml - menthol

¹Heikkinen, et al. "The common cold." The Lancet 361.9351 (2003): 51-59

²Lessler, Justin et al. Incubation periods of acute respiratory viral infections: a systematic review, The Lancet Infectious Diseases, Volume 9, Issue 5, 291-300.

³Hull D, et al. Effects of creating a non-specific, virus-hostile environment in the nasopharynx on symptoms and duration of common cold. Acta Otorhinolaryngol Ital. 2007 Apr; 27(2): 73-7.

THE COLDZYME® PACK CONTAINS

- Mouth spray consisting of bottle, pump, nozzle and protective cap.
- ColdZyme® solution contains glycerol, water, a natural enzyme - cod trypsin, ethanol (<1 %), calcium chloride, trometamol and menthol. The solution is sugar-free and contains no preservatives, gluten or lactose.
- These instructions for use.

CARE AND STORAGE

- Use before the expiration date indicated on the product label and pack.
- Store at or below 25°C.
- Return unused product to your pharmacy.

EXPLANATION OF SYMBOLS



Consult instructions for use



Upper limit of temperature



Use by date



Batch code



Catalogue number



Manufacturer



Caution, consult instructions for use

MANUFACTURED BY

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101002 ColdZyme 20 ml
101101 ColdZyme 7 ml



MEDICAL DEVICE