

COLDZYME®

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

ColdZyme® is a mouth spray that protects against upper respiratory tract viruses causing common cold and flu-like symptoms. ColdZyme® is easy to use and acts fast. ColdZyme® forms a protective moisturizing barrier on the mucous membrane of the oral cavity and throat. The barrier disables viruses and inhibits their ability to spread and multiply.

INTENDED USE

Treat and alleviate common cold and flu-like symptoms.

PRECAUTIONS

- Do not use ColdZyme® if you are hypersensitive/allergic to any of the ingredients.
- Do not use ColdZyme® after surgical intervention in mouth and/or throat until the wound is healed, without consulting your doctor.
- Do not inhale when applying the spray as it may cause irritation of the airways, such as cough and hoarseness.
- Keep ColdZyme® 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, as the symptoms could be due to something else.
- To avoid spread of infectious disease, the product should only be used by one person.
- For optimal effect, do not eat or drink within 20 minutes after use.
- Do not use if pack is damaged or opened.

INDICATION

ColdZyme® can be used when exposed to upper respiratory tract viruses causing common cold and flu-like symptoms, or when experiencing these symptoms.

ColdZyme® is suitable for adults and children over 4 years.

CONTRAINDICATIONS

No known contraindications.

There are no known concerns regarding the use of ColdZyme® during pregnancy or breastfeeding.

POSSIBLE SIDE EFFECTS

No known side effects. Should you experience untoward effects while using ColdZyme®, please consult a doctor for advice. Serious incidents (i.e. serious deterioration of the user's state of health) should be reported to Enzymatica AB (see contact details below) and to your local competent authority.

CLINICAL BENEFITS

- ColdZyme® protects against viruses causing common cold/upper respiratory tract infection/flu-like symptoms.
- ColdZyme® can help shorten the duration of common cold/upper respiratory tract infection/flu-like symptoms if used at an early stage of the infection.
- ColdZyme® alleviates common cold/upper respiratory tract infection/flu-like symptoms, including sore throat.

DIRECTIONS FOR USE

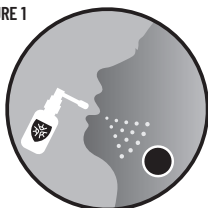
When to use

Use ColdZyme® at possible exposure to upper respiratory tract viruses or as soon as possible after noticing early symptoms of upper respiratory tract infection, such as sore scratchy throat or sneezing. Continue to use ColdZyme® until exposure ceases or symptoms are relieved.

How to use

- Open your mouth and aim the nozzle towards the back of your throat (Figure 1).
- Press down on the pump and spray 2 times (1 dose) every second hour, recommended 6 doses daily during the time you are exposed to upper respiratory tract viruses or until the symptoms are relieved. ColdZyme® can be used for a longer period of time as there is no risk of overdose.

FIGURE 1



HOW DOES IT WORK

ColdZyme® forms an immediate barrier in the mouth and throat with triple action:

Catches: The physical barrier coats the oral cavity and throat, capturing viruses.

Disables: The barrier inhibits the captured viruses' ability to infect cells and multiply.

Protects: The barrier moisturizes and protects the oral cavity and throat.



Catches



Disables



Protects

DESCRIPTION OF DISEASE

Upper respiratory tract viral infections (URTIs), many of which are also known as the common cold or influenza (flu), are the most common diseases in humans, with adults having two to five common colds each year and school children having from seven to ten colds per year. The immune system reacts to the virus through an inflammatory reaction, which causes symptoms such as sore throat, runny nose, cough, sneezing, headache, nasal stuffiness/congestion and cough. Common cold or flu is often self-diagnosed based on symptoms. Many viruses have been associated with URTIs, of which rhinovirus is the most common.¹ The incubation period of an infectious disease is the time between infection and symptom onset. The incubation period varies depending on the type of virus, ranging from half a day to over a week for some viruses.²

¹ Eccles R. Understanding the symptoms of the common cold and influenza. *Lancet Infect Dis.* 2005 Nov;5(11):718-25.

² Lessler J et al. Incubation periods of acute respiratory viral infections: a systematic review. *Lancet Infectious Diseases.* 2009 May;9(5):291-300.

COLDZYME® IS AVAILABLE IN TWO DIFFERENT SIZES

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

THE COLDZYME® PACK CONTAINS

- Mouth spray consisting of bottle, pump, nozzle and protective cap.
- ColdZyme® solution contains glycerol (55%), water, a natural enzyme - cod trypsin, ethanol (< 0.8%), calcium chloride, trometamol and menthol. The solution is sugar-free and contains no preservatives, gluten or lactose. A small spring in the pump may contain traces of cobalt as being an impurity generally present in stainless steel.
- 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



Do not use if package is damaged



Medical device



Unique device identifier



MANUFACTURED BY

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101002 ColdZyme® 20 ml
101101 ColdZyme® 7 ml

BASIC UDI-DI: 7340031ICZMSJE

Summary of Safety and Clinical Performance (SSCP) available in the European database on medical devices (EUDAMED) at: <https://ec.europa.eu/tools/eudamed> by using the Basic UDI-DI.

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