

# Pilot study: Does ColdZyme® Mouth Spray reduce upper respiratory tract infection (URTI) incidence or duration in endurance athletes?

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## Introduction

Infection of the upper respiratory tract (URTI) and the associated symptoms (URS) are the most frequent presentations to General Practitioners. URS are the most common ailment reported by athletes to medicine clinics at major sporting events (Derman et al., 2013). Infection is more likely (infection risk) when immunological defences are lowered. Moderate exercise or training loads are associated with enhanced immunity and lowered URS whereas intensive training and high training loads are associated with increased susceptibility to URTI/URS. Endurance athletes in particular have a high incidence of upper respiratory tract infection (URTI), and such infections can compromise training and/or competition performance (Pyne et al., 2005).

ColdZyme® Mouth Spray (ColdZyme) is a CE-marked medical device in the form of a mouth spray that forms a barrier in the throat against common cold viruses. The aims of this study were to assess the effects of ColdZyme on URTI incidence and symptom ratings in endurance athletes under free-living conditions.

## Methods

**Design and Participants:** Prospective, open label pilot study.

Thirty nine endurance-trained, competitive athletes were randomised to control (no treatment) or ColdZyme. They were monitored over the study period (December 2017 – February 2018) via training and illness symptom logs (Jackson common cold questionnaire). A total of 35 completed (n = 17 control; n = 18 ColdZyme).

**Figure 1:** Device and instructions for use (IFU)



**How To Use – for symptoms**  
Start to use ColdZyme® as soon as possible after noticing symptoms of a cold. Continue to use it until the symptoms are relieved. If the symptoms are not better within 10 days of starting the treatment, consult your doctor or health care provider. Instructions for use of ColdZyme® when you have cold symptoms:

- Open your mouth and aim the nozzle towards your throat (Figure 1).
- Press on the pump and spray 2 puffs (1 dose) every two hours while you are awake.
- Spray one dose after brushing your teeth before bedtime for longer protection during the night.
- Continue the treatment until the symptoms are relieved.

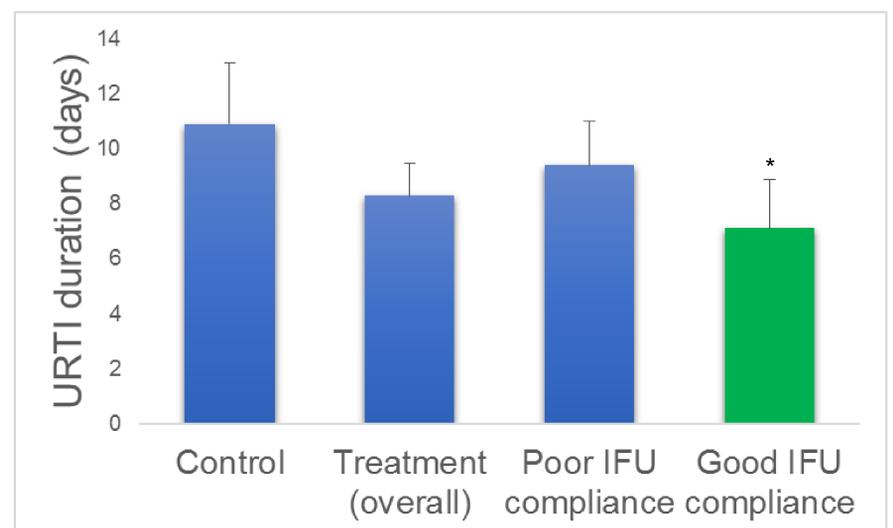
**How To Use – preventively**  
If you do not have any symptoms of a cold but are likely to be subjected to a cold virus, such as when someone near you has a cold, you can use ColdZyme® for preventive purposes. Do not use the product for a continuous period of more than 30 days. Instructions for use of ColdZyme® for preventive purposes:

- Open your mouth and aim the nozzle towards your throat (Figure 1).
- Press down on the pump and spray 2 puffs (1 dose) every two hours during the time you are exposed to the cold virus.
- One dose in the morning and evening is recommended as a general preventive measure. The spray can also be used after brushing your teeth before bedtime.

## Results and Discussion

At least one episode was recorded during the study period in 91% of all participants (94% control, 89% treatment). Fifty episodes were recorded in total over the study period with no difference between groups in the mean incidence rate (episodes/person:  $1.4 \pm 0.7$  Control,  $1.6 \pm 0.9$  Treatment,  $P = 0.266$ , all values are mean  $\pm$  SD).

Episode duration was  $10.9 \pm 10.2$  days in Control and  $8.3 \pm 6.3$  days in Treatment ( $P = 0.098$ ). When use compliance was examined, those in the treatment group with good compliance to the product instructions for use (IFU) were observed to have significantly lower ( $P = 0.038$ ) episode duration ( $7.1 \pm 6.6$  days), but incidence was not different. This pilot study indicates that, when used correctly, ColdZyme can shorten the duration a common cold. The present findings with endurance athletes agree with those from a recent study (Clarsund et al., 2014) in which healthy adults were inoculated with Rhinovirus. Clarsund et al. (2014) observed a 54% reduction in illness duration with ColdZyme mouth spray treatment.



**Figure 2:** URTI duration (days).

Values show mean and SEM for clarity. \* Significantly different to Control ( $P = 0,038$ )

The incidence of URTI is higher than 'normal' in many athletes and such infections can compromise training and/or competition performance (Pyne et al., 2005). Strategies to reduce the risk of contracting these illnesses will be of benefit, and strategies to manage or treat ill athletes can optimise their recovery and limit the risks of spreading infection to others (i.e. team mates). ColdZyme did not influence self-reported URTI incidence but the duration was significantly lower in the treatment group when the device was used in accordance with the manufacturer instructions for use (IFU).

### Acknowledgements:

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### References

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- Pyne D.B., Hopkins W.G., Batterham A.M., Gleeson M. & Fricker PA. (2005), Br J Sports Med. 39(10):752-6.