

# Complaint to TGA - Nature's Own Double Strength Cold Sore Relief

**Acknowledgment:** This information for this complaint was worked up by Monash University 2019 BMS3052 students.

**The product:** Nature's Own Double Strength Cold Sore Relief (ARTG: 224182)

**Dosage Form:** Tablet, **Route of Administration:** Oral, once a day, **Active Ingredients:** lysine hydrochloride 1000 mg

**Sponsor:** Sanofi-Aventis Healthcare Pty Ltd T/A Sanofi Consumer Healthcare

## The promotion

- <https://naturesown.com.au/products/colds-immunity/double-strength-cold-sore-relief/>
- <https://www.chemistwarehouse.com.au/buy/71330/nature-s-own-double-strength-cold-sore-relief-l-lysine-1000mg-100-tablets>
- <https://www.priceline.com.au/nature-s-own-double-strength-cold-sore-relief-l-lysine-1000mg-50-tablets>
- <https://www.goodpricepharmacy.com.au/nature-s-own-double-strength-cold-sore-relief-lysine-1000mg-100-tablets>
- <http://www.epharmacy.com.au/product.asp?id=71330&pname=Nature%27s+Own+Double+Strength+Cold+Sore+Relief+L%2DLysine+1000mg+100+Tablets>
- <https://www.woolworths.com.au/shop/productdetails/780031/nature-s-own-cold-sore-relief-tablets>
- <https://superpharmacyplus.com.au/natures-own-double-strength-cold-sore-relief-l-lysine-1000mg-100-tablets/>
- <https://www.cincottachemist.com.au/natures-own-cold-sore-double-strength-relief-50-tablets>
- Etc.

**The claims** (screen shots appended):

1. "Double Strength Cold Sore Relief" (product name)
2. "A potent formulation of Lysine, an essential amino acid for helping with the symptomatic relief, frequency and severity of cold sores"
3. "Assists to reduce the severity and frequency of cold sores"
4. "Provides relief from the symptoms of cold sores"
5. "Helps provide relief from cold sores & reduce the frequency of outbreak"
6. "Backed by Evidence" (on the bottle)

## The Investigation

An email was sent by a student on 1st September 2019 requesting evidence via their website online form, but no response was received.

### Message

Hi there,

Would you please be able to clarify what you mean by "based off evidence," for your product, Double Strength Cold Sore Relief L-Lysine? Is there any way we can gain access to said, "evidence?"

Kind regards,

Olivia Melone

<https://naturesown.com.au/contact-us/>

Searches were conducted on Ovid MEDLINE and Cochrane to evaluate research on the use of Lysine Hydrochloride for cold sores. Many of the publications were old and of dubious quality. Two recent publications were a 2015 Cochrane Review, "Interventions for prevention of herpes simplex labialis

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(cold sores on the lips)"<sup>1</sup> and 2017 review, "Lysine for Herpes Simplex Prophylaxis: A Review of the Evidence".<sup>2</sup>

The 2015 Cochrane review said, "The available evidence found no preventative effects of lysine".

The 2017 review said, "L-lysine supplementation appears to be ineffective for prophylaxis or treatment of herpes simplex lesions with doses of less than 1 g/d without low-arginine diets. Doses in excess of 3 g/d appear to improve patients' subjective experience of the disease. It concluded, "Longer duration-controlled studies of daily lysine doses exceeding 1.2 g/d are required to definitively test its role in herpes simplex prophylaxis".

**N.B. The Nature's Own product has a recommended dose of 1000mg, once a day.**

### The complaint

I allege the **claims by numerous advertisers concerning Nature's Own Double Strength Cold Sore Relief breach the Therapeutic Goods Advertising Code (No.2) 2018, s.9(a)(b), 10(a)(ii) (claims 1-5, above) and 15(2)(b),(3)(a) (claim 6, above).**<sup>3</sup>

**N.B. The same claims are made on the ARTG Public Summary document which needs revision and compliance with the Therapeutic Goods (Permissible Indications) Determination (No.1) 2019.**<sup>4</sup>

Sincerely

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30 September 2019

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<sup>1</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010095.pub2/full>


<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6419779/>

<sup>3</sup> <https://www.legislation.gov.au/Details/F2018L01524>

<sup>4</sup> <https://www.legislation.gov.au/Details/F2019L00262>

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Screen shots: (19/09/2019)



**ALL PRODUCTS**

## Double Strength Cold Sore Relief

Nature's Own Double Strength Cold Sore Relief is a potent formulation of Lysine, an essential amino acid for helping with the symptomatic relief, frequency and severity of cold sores.

If symptoms persist consult your healthcare professional. Vitamin supplements should not replace a balanced diet.

No added yeast, gluten, lactose, sugar, artificial colours or flavours, artificial sweeteners or preservatives, dairy products or animal-derived ingredients.

TABLET 1/DAY DOUBLE

### Product Benefits

- Assists to reduce the severity and frequency of cold sores
- Provides relief from the symptoms of cold sores
- Convenient 1-a-day dose
- Helps provide relief from cold sores & reduce the frequency of outbreaks

### Dosage

Take 1 tablet daily with food or as recommended by your healthcare professional.

### Cautions


If symptoms persist consult your healthcare professional. Vitamin supplements should not replace a balanced diet.

<https://naturesown.com.au/products/colds-immunity/double-strength-cold-sore-relief/>



<https://www.chemistwarehouse.com.au/buy/71330/nature-s-own-double-strength-cold-sore-relief-l-lysine-1000mg-100-tablets>

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**1/2 PRICE OFF RRP**


**Nature's Own**  
**DOUBLE STRENGTH COLD SORE RELIEF**  
100 TABLETS

Product ID: 2642940  
★★★★★ 4.8 (27) [Write a review](#)

**\$12.99**  
**\$13.00 Off RRP**  
Don't Pay RRP: \$25.99

QTY

 **ADD TO CART**

 **Click & Collect** ⓘ  
Search For A Pickup Store  
[CLICK HERE](#) ✓

**THIS PRODUCT MAY NOT BE RIGHT FOR YOU. ALWAYS READ THE LABEL, WARNINGS AND INSTRUCTIONS FOR USE, BEFORE PURCHASE. VITAMIN AND MINERAL SUPPLEMENTS SHOULD NOT REPLACE A BALANCED DIET.**

**General Information**

Helps to reduce the severity and frequency of cold sores

Nature's Own Double Strength Cold Sore Relief is a potent formulation of Lysine, an essential amino acid for helping with the symptomatic relief, frequency and severity of cold sores.

- Assists to reduce the severity and frequency of cold sores
- Provides relief from the symptoms of cold sores
- Convenient 1-a-day dose
- Helps provide relief from cold sores & reduce the frequency of outbreaks

<https://www.chemistwarehouse.com.au/buy/71330/nature-s-own-double-strength-cold-sore-relief-l-lysine-1000mg-100-tablets>