Tolerase® L

The freedom to enjoy dairy

Tolerase® L is an acid lactase that converts lactose into glucose and galactose. The enzyme originates from a special strain of the fungus Aspergillus oryzae. Its activity in an acidic environment (pH 3.5 – 5.5) makes this lactase particularly effective to digest lactose in the stomach and is therefore ideal for use in dietary supplements as a digestive aid for lactose intolerant individuals.

Lactose intolerance

Lactose is a milk sugar, naturally present in dairy products. It is digested by the enzyme lactase into glucose and galactose, which are absorbed in the bloodstream. Lactose-intolerant people lack this enzyme and as a result are unable to digest lactose fully.

If undigested, lactose reaches the large intestine where it is degraded by its microflora. The resulting by-products may cause symptoms of lactose intolerance including diarrhea, abdominal cramps, flatulence and nausea. When lactose-intolerant people stop consuming dairy products, their intake of calcium tends t o be lower, which can put their bone health at risk.

About 75% of the world's population is lactose intolerant, meaning that they cannot drink milk or consume dairy products without experiencing these uncomfortable symptoms.

The prevalence of lactose intolerance varies across the world. In general, people from Western countries are less prone to lactase deficiency, but still up to 30% of the population is unable to digest lactose. In Latin America, Africa and Asia lactose intolerance is much more frequent. For instance, in China almost all the population is lactose intolerant.

Tolerase® L

- ✓ A highly efficacious and safe enzyme with a positive opinion from the European Food Safety Authority: "contributes to breaking down lactose" with an approved claim by the European Commission "**Lactase enzyme improves lactose digestion in individuals who have difficulty digesting lactose.**"
- ✓ Feel the benefit: helps to eliminate lactose intolerance discomforts like bloating, gas, diarrhea and abdominal cramps that occur after consuming dairy products
- ✓ Regulatory compliance in key markets
- ✓ Low cost in use
- ✓ Consistently high activity level (min. 100,000 ALU*/gram), allowing small tablet size
- ✓ Excellent tableting properties:
  - Off-white to light brown color
  - Superior flowability
  - Suitable for direct compression
  - Bland taste
- ✓ Strong scientific substantiation for acid lactase
- ✓ Manufactured by dsm-firmenich, a global leader in food enzymes

dsm-firmenich

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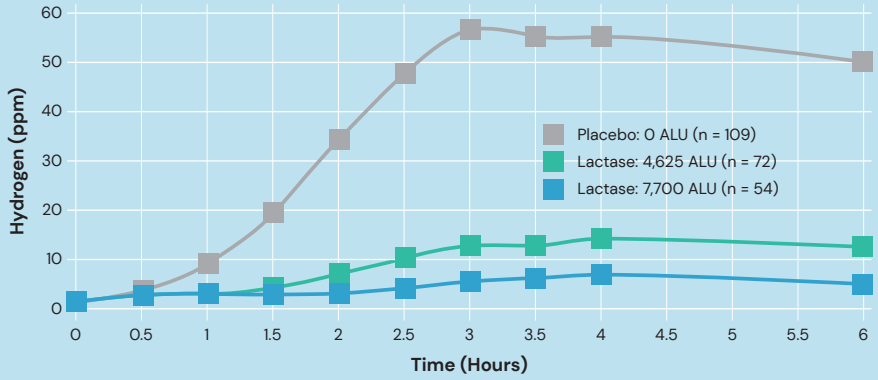
Efficacy

Lactase from *Aspergillus oryzae* has a high activity in an acidic environment (pH 3.5 – 5.5) making the enzyme particularly suitable to digest lactose in the stomach. The use of this enzyme to degrade lactose is well established, both scientifically and commercially.

There are numerous scientific references indicating efficacy of acid lactase in lactose-intolerant people, e.g.: *Barillas & Solomons (1987), DiPalma and Collins (1989), Gao et al. (2002), Guzek et al. (2008), Portincasa et al. (2008), and Ojetti et al. (2010).*

Hydrogen breath test

If lactose is not digested in the small intestine, it enters the large intestine. Here it can be fermented by naturally-present microbes. Lactose fermentation results in the production of volatile fatty acids and gasses, as carbon dioxide (CO_2) and hydrogen (H_2). A part of the hydrogen is expired by breath. Therefore, the hydrogen breath test has been developed as a method to identify lactose intolerance.



Portincasa et al., 2008 – Eur. J. Clin. Invest. 38(11):835-844.

Study design

- 109 lactose-intolerant participants (age 38 ± 1 y).
- Participants received 500 ml of milk (containing approx. 25 g of lactose). With the milk they all received a placebo or lactase.Lactase was provided in two different doses.
- Breath samples were taken for hydrogen analyses, an indicator of poor lactose digestion and absorption.

Results

- Hydrogen expiration in breath was clearly lower after lactase treatments.
- The breath hydrogen, measured as area under the curve, was reduced by 76% (low lactase dose) and 88% (normal lactase dose).
- Symptom score ([severity of] bloating, abdominal pain, and bowel movements) reduced by 76% (low lactase dose) and 88% (normal lactase dose).

Conclusion

- Lactase from A*spergillus oryzae* effectively broke down lactose, resulting in less expired hydrogen and a strong reduction of symptoms.

Claims and labelling

Tolerase® L is available as:

- Authorized EU Health Claim Regulation (EU) 432/2012
- US FDA GRAS notified
- ANVISA BRAZIL approved

The scientific evidence for acid lactase is well-established and lactase is on the list of authorized claims by the European Commission:

"Contributes to breaking down lactose"

Depending on the local regulatory requirements and interpretation, claim wording might be modified.

Composition

Tolerase® L is an acid lactase (β-galactosidase) originating from the food-grade fungus *Aspergillus oryzae*. Its activity is ≥100,000 ALU/g.

Tolerase® L is a granulated product with excellent flowability and compressibility for use in tablets and capsules. Tolerase® L has an off-white to light brown colour, high solubility and a bland taste.

Applications and dosage

The dose of Tolerase® L is dependent of the amount of lactose and the size of the meal consumed. In general, a larger meal remains in the stomach for longer and therefore less enzyme is required than when the same amount of lactose is consumed with a light meal or just a glass of milk.

The EFSA recommended dose is 4,500 ALU with each lactose-containing meal. The dose may have to be adjusted to individual needs for lactase supplementation and consumption of lactose-containing products.

For more information on Tolerase® L,
visit **www.dsm.com/human-nutrition**
or e-mail **info.dnp@dsm.com**

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