

## NATURAL HEALTH PRODUCT

### LACTASE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

#### Notes

- Text in parentheses is additional optional information which can be included on the label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label.

#### Date

January 31, 2025

#### Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<ul style="list-style-type: none"> <li>• beta-D-galactoside galactohydrolase</li> <li>• beta-galactosidase</li> </ul>	<ul style="list-style-type: none"> <li>• beta-galactosidase</li> <li>• Lactase</li> <li>• Tilactase</li> </ul>	<i>Aspergillus flavus</i> var. <i>oryzae</i>	Whole

References: Proper names: IUBMB 1980; Common names: IUBMB 1980; Source information: CABI 2012; Bisby et al. 2010.

#### Route of administration

Oral

#### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

**Note:** Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when lactase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application.

## Use(s) or Purpose(s)

- Digestive enzyme
- Digestive enzyme/lactase to assist in the digestion of foods containing lactose (e.g., dairy foods, milk) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987).
- Helps prevent symptoms of lactose intolerance (including gas, bloating, cramping and diarrhea) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987).

**Note:** The above uses can be combined on the product label (e.g., Digestive enzyme that helps prevent symptoms of lactose intolerance).

## Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

*Digestive enzyme*

Not to exceed 54,000 FCC ALU of enzymatic activity, per day; and 18,000 FCC ALU per single dose (FCC 2024; Ramirez et al. 1994; Lin et al. 1993).

*Lactose digestion/Symptoms of lactose intolerance*

3,000 – 54,000 FCC ALU of enzymatic activity, per day; not to exceed 18,000 FCC ALU per single dose (FCC 2024; Ramirez et al. 1994; Lin et al. 1993).

### Notes

- The Quantity per dosage unit must be the enzymatic activity (FCC unit). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity.
- One lactase unit (ALU) is defined as that quantity of enzyme that will liberate *o*-nitrophenol at a rate of 1  $\mu\text{mol}/\text{min}$  under the conditions of the assay (FCC 2024).

### Direction(s) for use

Take with or immediately before a meal/food.

## Duration(s) of use

*All products*

Ask a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

## Risk information

### Caution(s) and warning(s)

*All products*

**Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Groff and Gropper 2000).**

*Lactose digestion/Symptoms of lactose intolerance*

**Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.**

### Contraindication(s)

No statement required.

### Known adverse reaction(s)

**Stop use if** gastro-intestinal disturbance and/or hypersensitivity/allergy occur (HC 2011).

## Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

## Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

## Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.
- Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.
- The specifications must include testing for enzymatic activity of the medicinal ingredient at appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): Lactase (Acid) ( $\beta$ -Galactosidase) activity (ALU).
- Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of the shelf life indicated on the product

label.

**EXAMPLE OF PRODUCT FACTS:**

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

<b>Product Facts</b>
<b>Medicinal ingredient</b> in each capsule beta-galactosidase ( <i>Aspergillus flavus</i> var. <i>oryzae</i> – whole) <span style="float: right;">XX FCC ALU</span>
<b>Uses</b> • Digestive enzyme to assist in the digestion of foods containing lactose. • Helps prevent symptoms of lactose intolerance (including gas, bloating, cramping and diarrhea).
<b>Warnings</b>
<b>If applicable<sup>1</sup>:</b> <b>Allergens: food allergen, gluten (gluten source), sulphites</b> <b>Contains aspartame</b>
<b>Ask a health care practitioner before use if you have diabetes.</b>
<b>Stop use if</b> gastro-intestinal disturbance or allergy occur.
<b>Ask a health care practitioner if</b> symptoms persist or worsen <sup>2</sup> .
<b>Directions</b> Adults 18 years and older: • Take X capsule(s), X time(s) per day • Take with or immediately before a meal • Ask a health care practitioner for prolonged use.
<b>Other information</b> (Add storage information)
<b>Non-medicinal ingredients</b> List all NMIs
<b>Questions?</b> (Call) 1-XXX-XXX-XXXX

<sup>1</sup>This section can be removed from the table if the product contains no allergen or aspartame.

<sup>2</sup>The qualifier ‘For lactose digestion/symptoms of lactose intolerance:’ may be included on the label to inform consumers.

**References cited**

Biller JA, King S, Rosenthal A, Grand RJ. 1987. Efficacy of lactase-treated milk for lactose-intolerant pediatric patients. *The Journal of Pediatrics* 111: 91-94.

Bisby F, Roskov Y, Culham A, Orrell T, Nicolson D, Paglinawan L, Bailly N, Appeltans W, Kirk P, Bourgoin T, Baillargeon G, Ouvreard D, editors. *Species 2000 & ITIS Catalogue of Life*. Reading (GB): Species 2000. [Source database: Species Fungorum 9.0, Sep 2010; Accessed 2024 November 21]. Available from: <http://www.catalogueoflife.org>

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HC 2011: Health Canada. 2011. Canada Vigilance Online Database. Ottawa (ON): Health Canada. [Updated 2011 September 30; Accessed 2024 November 21]. Available from: <http://hc-sc.gc.ca/dhp-mps/medeff/databasdon/index-eng.php>

Groff J, Gropper S. 2000. Advanced Nutrition and Human Metabolism, 3<sup>rd</sup> edition. Belmont (CA): Wadsworth/Thomson Learning.

IUBMB 1980: Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. London (GB): Queen Mary, University of London [ $\beta$ -galactosidase: EC 3.2.1.23. created 1961, modified 1980; Accessed 2024 November 21]. Available from: <https://iubmb.qmul.ac.uk/enzyme/EC3/0201a.html#023>

Lin MY, Dipalma JA, Martini MC, Gross CJ, Harlander SK, Savaiano DA. 1993. Comparative effects of exogenous lactase (beta-galactosidase) preparations on in vivo lactose digestion. *Digestive Diseases and Sciences* 38(11):2022-2027.

Moskovitz M, Curtis C, Gavalier J. 1987. Does oral enzyme replacement therapy reverse intestinal lactose malabsorption? *The American Journal of Gastroenterology* 82(7):632-635.

Ramirez FC, Lee K, Graham DY. 1994. All lactase preparations are not the same: results of a prospective, randomized, placebo-controlled trial. *The American Journal of Gastroenterology* 89(4):566-570.

USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2024.