Health Canada Santé Canada

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 PLA and product 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.

Date April 29, 2019

Proper name(s), Common name(s), Source material(s)

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

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
▸ beta-D-galactoside galactohydrolase ▸ beta-galactosidase	▸ beta-galactosidase ▸ Lactase ▸ Tilactase	*Aspergillus flavus* var. *oryzae*	Whole

References: Proper names: IUBMB 1980; Common names: IUBMB 1980; Source material: 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

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).

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.

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 8 2012; 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 µmol/min under the conditions of the assay (FCC 8 2012).

Direction(s) for use

Take with or immediately before a meal/food.

Duration(s) of use

All products

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

Risk information

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have diabetes (Groff and Gropper 2000).

Lactose digestion/Symptoms of lactose intolerance

Consult 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

No statement required.

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) (β-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.

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.

Kirk P, Bourgoin T, Baillargeon G, Ouvrard D, editors. Species 2000 & ITIS Catalogue of Life, 15th March 2012 [Internet]. Reading (GB): Species 2000. [Source database: Species Fungorum 9.0, Sep 2010; Accessed 2012 March 28]. Available from: http://www.catalogueoflife.org

CABI 2012: Centre for Agriculture and Bioscience International. Index Fungorum [Internet]. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2012 March 28]. Available from: http://www.speciesfungorum.org

FCC 8 2012: Food Chemicals Codex, Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2012.

HC 2011: Health Canada. 2011. Canada Vigilance Online Database. Ottawa (ON): Health Canada. [Updated 2011 September 30; Accessed 2012 March 16]. Available from: http://hc- sc.gc.ca/dhp-mps/medeff/databasdon/index-eng.php

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

IUBMB 1980: Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. [Internet]. London (GB): Queen Mary, University of London [β-galactosidase: EC 3.2.1.23. created 1961, modified 1980; Accessed 2012 March 28]. Available from: http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/2/1/23.html

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, Gavaler J. 1987. Does oral enzyme replacement therapy reverse intestinal lactose malabsorption? The American Journal of Gastroenterolgy 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 35 2012: United States Pharmacopeia and the National Formulary (USP 35 - NF 30). Rockville (MD): The United States Pharmacopeial Convention; 2012.