

LACTASE

This abbreviated labelling standard is a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It includes generalized claims and is not intended to be a comprehensive review of the medicinal ingredient. Wording of the claim on the PLA and label must therefore be identical to the labelling standard.

Date March 30, 2012

Field	Field Content	Reference(s)
Proper name(s)	beta-galactosidase β-D-galactoside galactohydrolase	IUBMB 1980
Common name(s)	lactase beta-galactosidase	IUBMB 1980
Source material(s)	<i>Aspergillus flavus</i> var. <i>oryzae</i> (Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae)	CABI 2012 Bisby et al. 2010
Route(s) of administration	Oral	
Dosage form(s)	<p>The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.</p> <p>This AbLS is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.</p>	
Use(s) or Purpose(s)	<p>Digestive enzyme/lactase to assist in the digestion of foods containing lactose (e.g. dairy foods, milk).</p> <p>Helps prevent symptoms of lactose intolerance (including gas, bloating, cramping and diarrhea).</p>	<p>Ramirez et al.1994 Lin et al.1993 Biller et al. 1987 Moskovitz et al 1987</p>
Subpopulation(s)	Adults	
Dose(s)	<p>Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:</p> <ul style="list-style-type: none"> • Enzyme preparation, per dosage unit; and • Preparations containing the equivalent of: Minimum: 3 000 FCC ALU lactase, per day. Maximum: 18 167 FCC ALU lactase, 3 times per day. 	<p>FCC 7 Ramirez et al.1994 Lin et al.1993</p>
Duration(s) of use	No statement required.	
Risk information	Discontinue use and consult a health care practitioner if symptoms persist or worsen.	

Field	Field Content	Reference(s)
	Consult a health care practitioner prior to use if you have diabetes.	Groff and Gropper 2000
	Headaches, heartburn, bloating and hypersensitivity (e.g. allergy) have been known to occur; in which case, discontinue use.	HC 2011
Non-medicinal ingredients	Must be chosen from the current NHPD <i>Natural Health Products Ingredients Database</i> and must meet the limitations outlined in the database.	
Specifications	<p>The finished product must comply with the minimum specifications outlined in the current NHPD <i>Compendium of Monographs</i>.</p> <p>The medicinal ingredient must comply with the specifications outlined in the Food Chemicals Codex (FCC): FCC 7: Lactase (Acid) (β-Galactosidase) activity (ALU)</p> <p>The medicinal ingredient may comply with the specifications (quality specifications only) outlined in the United States (USP) pharmacopoeial monograph listed below: USP 34: Lactase</p>	

References

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, 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. 2011. *Index Fungorum* [Internet]. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2012 March 28]. Available from: <http://www.speciesfungorum.org>

FCC 7: Food Chemicals Codex, Seventh edition. Rockville (MD): The United States Pharmacopoeial 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, 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 34: United States Pharmacopeia and the National Formulary (USP 34 - NF 29). Rockville (MD): The United States Pharmacopeial Convention; 2011.