

ALPHA-GALACTOSIDASE

This abbreviated labelling standard (AbLS) 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 this AbLS.

Date March 30, 2012

Field	Field content	Reference
Proper name(s)	alpha-D-galactoside galactohydrolase	IUBMB 1961
Common name(s)	alpha-galactosidase/ α -galactosidase	IUBMB 1961
Source material(s)	<i>Aspergillus niger</i> van Tieghem 1867 (Trichocomaceae)	CABI 2012; FCC 7; Bisby et al. 2010
Route(s) of administration	Oral	
Dosage form(s)	The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets. This AbLS is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.	
Use(s) or Purpose(s)	Helps reduce gas production/flatulence following a meal rich in fermentable carbohydrates (such as vegetables, pulses/legumes/beans and whole grains). Helps prevent gastrointestinal intolerance of oligosaccharides/fermentable carbohydrates. Digestive enzyme.	Di Stefano et al. 2007; Pray 2006; Lettieri and Dain 1998; Ganiats et al. 1994 Di Stefano et al. 2007; Pray 2006; Ganiats et al. 1994
Dose(s)	Dose information must include the quantities of both the enzyme preparation and its enzymatic activity: Enzyme activity providing up to 3 000 FCC GalU ¹ per day. For the gastrointestinal intolerance claim: • Enzyme activity providing the equivalent of 260 - 3 000 FCC GalU ¹ per day.	FCC 7; Di Stephano et al. 2007; Lettieri and Dain 1998; Ganiats et al. 1994
Sub-	Adults	

Field	Field content	Reference
population(s)		
Duration(s) of use	For prolonged use, consult a health care practitioner.	
Direction(s) for use	Take with first bite of food/meal.	Pray 2006; CPS 2005; Lettieri and Dain 1998; Ganiats et al. 1994
Risk information	For the gastrointestinal intolerance claim: Consult a health care practitioner if symptoms persist or worsen.	
	Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	
	Consult a health care practitioner prior to use if you have diabetes.	Levine and Weisman 2004; Lettieri and Dain 1998; Ganiats et al. 1994
	Hypersensitivity/allergy has been known to occur, in which case discontinue use.	Pray 2006; CPS 2005; Ganiats et al. 1994
Non-medicinal ingredient(s)	Must be chosen from the current NHPD <i>Natural Health Products Ingredients Database</i> and must meet the limitations outlined in the database.	
Specification(s)	<p>A Finished Product Specifications Form must accompany the application.</p> <p>The finished product must comply with the requirements of the current NHPD <i>Evidence for Quality of Finished Natural Health Products</i> guidance document.</p> <p>The specifications must include testing for enzymatic activity of the medicinal ingredient at the finished product stage using the assay outlined in the Food Chemicals Codex (FCC 7) : α-GALACTOSIDASE ACTIVITY.</p> <p>Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium, isolation process and the percent purity of the medicinal ingredient.</p> <p>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.</p>	

¹. FCC 7: one galactosidase activity unit (GalU) is defined as the quantity of the enzyme that will liberate *p*-nitrophenol at the rate of 1 μ mol/min under the conditions of the assay.

References cited

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>

CPS 2005. Compendium of Pharmaceuticals and Specialties. Beano®. Alpha-D-Galactosidase/Alpha Galactosidase Enzyme. GlaxoSmithKline Consumer Healthcare. Canadian Pharmacists Association; 2005.

Di Stefano M, Miceli E, Gotti S, Missanelli A, Mizzocchi S, Corazza GR. The effect of oral alpha-galactosidase on intestinal gas production and gas-related symptoms. *Digestive Diseases and Sciences* 2007;52(1):78-83.

FCC 7: Food Chemicals Codex, Seventh edition. Rockville (MD): The United States Pharmacopeial Convention; 2012.

Ganiats TG, Norcross WA, Halverson AL, Burford PA, Palinkas LA. Does Beano prevent gas? A double-blind crossover study of oral alpha-galactosidase to treat dietary oligosaccharide intolerance. *The Journal of Family Practice* 1994;39(5):441-445.

IUBMB 1961: IUBMB Enzyme Nomenclature [Internet]. London (GB): Queen Mary, University of London. [α -galactosidase: CAS 9025-35-8, EC 3.2.1.22 created 1961; Accessed 2012 March 28]. Available from: <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/2/1/22.html>

Lettieri JT, Dain B. Effects of beano on the tolerability and pharmacodynamics of acarbose. *Clinical Therapeutics* 1998;20(3):497-504.

Levine B, Weisman S. Enzyme replacement as an effective treatment for the common symptoms of complex carbohydrate intolerance. *Nutrition in clinical care: an official publication of Tufts University* 2004;7(2):75-81.

Pray WS. Non-Prescription Product Therapeutics, 2nd edition. New York (NY): Lippincott Williams & Wilkins; 2006.

References reviewed

Evidence for Quality of Finished Natural Health Products, Version 2.0. Ottawa (ON): Natural Health Products Directorate, Health Canada; 2007. [Accessed 2011 August 2]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php>

The Merck Index Version 14.1. [Internet]. Whitehouse Station (NJ): Merck & Co., Inc. [Published 2006; Updated 2011; Accessed 2011 August 17]. Available from: <http://www.medicinescomplete.com/mc/merck/current/monographs.htm>

Sweetman SC, editor. Martindale: The Complete Drug Reference [Internet]. London (GB): Pharmaceutical Press. [Alpha-galactosidase: latest modification 12-Mar-2011; Accessed 2012 March 28]. Available from: <http://www.medicinescomplete.com>