

Galactosidase, alpha-

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Alpha-Galactosidase (PDF Version - 75 KB) 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 10, 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) alpha-D-Galactoside galactohydrolase alpha-Galactosidase *Aspergillus niger* Whole References: Proper name: UBMB 1961; Common name: UBMB 1961; Source information: FCC 2024; 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 alpha-Galactosidase 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 Helps prevent gastrointestinal intolerance of oligosaccharides/fermentable carbohydrates (Di Stefano et al. 2007; Pray 2006; Ganiats et al. 1994). Helps reduce gas production/flatulence following a meal rich in oligosaccharides/fermentable carbohydrates (such as vegetables, pulses/legumes/beans and whole grains) (Di Stefano et al. 2007; Pray 2006; Lettieri and Dain 1998; Ganiats et al. 1994). Note: The above uses can be combined on the product label (e.g., Digestive enzyme that helps prevent gastrointestinal intolerance of oligosaccharides/fermentable carbohydrates). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Digestive enzyme Not to exceed 3,000 FCC GalU of enzyme activity, per day (FCC 2024; Di Stephano et al. 2007; Lettieri et Dain 1998; Ganiats et al. 1994). Prevention of gastrointestinal intolerance/Reduction of flatulence 260 - 3,000 FCC GalU of enzymatic activity, per day (FCC 2024; Di Stephano et al. 2007; Lettieri and Dain 1998; Ganiats et al. 1994). 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 FCC galactosidase activity unit (GalU) is defined as the quantity of the enzyme that will liberate p-nitrophenol at the rate of 1 µmol/min under the conditions of the assay (FCC 2024). Direction(s) for use Take with first bite of food/meal (Pray 2006; CPS 2005; Lettieri and Dain 1998; Ganiats et al. 1994). Duration(s) of Use 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 are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Levine and Weisman 2004; Lettieri and Dain 1998; Ganiats et al. 1994). Prevention of gastrointestinal intolerance/Reduction of flatulence 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 hypersensitivity/allergy occurs (Pray 2006; CPS 2005; Ganiats et al. 1994). 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 the appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): ALPHA-GALACTOSIDASE ACTIVITY. 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. 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, 15 th March 2012. Reading (GB): Species 2000. [Source database: Species Fungorum 9.0, Sep 2010; Accessed 2024 November 15]. Available from: <http://www.catalogueoflife.org> CABI 2012: Centre for Agriculture and Bioscience International. 2011. Index Fungorum. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2024 November 15]. 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 2024: Food Chemicals Codex. 14 th edition. Rockville (MD): The United States Pharmacopeial Convention; 2024. 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. London (GB): Queen Mary, University of London. [α -galactosidase: CAS 9025-35-8, EC 3.2.1.22 created 1961; Accessed 2024 November 15]. 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 Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2024. [Accessed 2024 November 21]. Available from: <https://www.medicinescomplete.com/#/browse/martindale> RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2024 November 15]. Available from: <https://merckindex.rsc.org/> Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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

DOSAGE FORM(S)

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 alpha-Galactosidase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application.

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 are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Levine and Weisman 2004; Lettieri and Dain 1998; Ganiats et al. 1994). Prevention of gastrointestinal intolerance/Reduction of flatulence 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 hypersensitivity/allergy occurs (Pray 2006; CPS 2005; Ganiats et al. 1994).

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 CONDITION(S)

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 the appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): ALPHA-GALACTOSIDASE ACTIVITY. 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.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
alpha-D-Galactoside galactohydrolase	alpha-Galactosidase	Aspergillus niger	Whole