

NATURAL HEALTH PRODUCT

ALPHA-GALACTOSIDASE

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)
alpha-D-galactoside galactohydrolase	alpha-Galactosidase	<i>Aspergillus niger</i>	Whole

References: Proper name: UBMB 1961; Common name: UBMB 1961; Source material: CABI 2012, FCC 8 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
- ▶ 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).

The following combined use(s) or purpose(s) is/are also acceptable:

- ▶ Digestive enzyme that helps reduce gas production 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).
- ▶ Digestive enzyme that helps prevent gastrointestinal intolerance of oligosaccharides/fermentable carbohydrates (Di Stefano et al. 2007; Pray 2006; Ganiats et al. 1994).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Digestive enzyme (not for combined claims)

Not to exceed 3,000 FCC GalU of enzyme activity, per day (FCC 8 2012; 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 8 2012; 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 $\mu\text{mol}/\text{min}$ under the conditions of the assay (FCC 8 2012).

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

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 are pregnant, breastfeeding or have diabetes (Levine and Weisman 2004; Lettieri and Dain 1998; Ganiats et al. 1994).

Prevention of gastrointestinal intolerance/Reduction of flatulence

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 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

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 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.

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