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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

July 11, 2012

Proper name(s)

alpha-D-galactoside galactohydrolase (UBMB 1961)

Common name(s)

alpha-galactosidase/ α-galactosidase (IUBMB 1961)

Source material(s)

Aspergillus niger van Tieghem 1867 (Trichocomaceae) (CABI 2012; FCC 8; 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 monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Use(s) or Purpose(s)

Statement(s) to the effect of:

- 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 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).

Dose(s)

Subpopulation(s)

Adults (≥ 19 years)

Quantity(ies)

Note

- Dose information must include the quantities of both the enzyme preparation and its enzymatic activity.
- 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 8).

Digestive enzyme and reduction of flatulence:
Enzyme activity providing up to 3000 FCC GalU per day.

Prevent gastrointestinal intolerance:
Enzyme activity providing the equivalent of 260 - 3000 FCC GalU per day (FCC 8; Di Stephano et al. 2007; Lettieri and Dain 1998; Ganiats et al. 1994).

Directions for use

Take with first bite of food/meal (Pray 2006; CPS 2005; Lettieri and Dain 1998; Ganiats et al. 1994).

Duration of use

For prolonged use, consult a health care practitioner.
Risk information

Statement(s) to the effect of:

Caution(s) and warning(s)

All products:
- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- If you have diabetes, consult a health care practitioner prior to use (Levine and Weisman 2004; Lettieri and Dain 1998; Ganiats et al. 1994).

Prevent gastrointestinal intolerance:
If symptoms persist or worsen, consult a health care practitioner.

Contraindication(s)

No statement required

Known adverse reaction(s)

Hypersensitivity/allergy has been known to occur, in which case discontinue use (Pray 2006; CPS 2005; Ganiats et al. 1994).

Non-medicinal ingredients

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

Specifications

- The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.
- 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) : α-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.
References cited


References reviewed
