LACTASE

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 10, 2012

Proper name(s)

◦ beta-galactosidase (IUBMB 1980)
◦ β-D-galactoside galactohydrolase (IUBMB 1980)

Common name(s)

◦ lactase (IUBMB 1980)
◦ beta-galactosidase (IUBMB 1980)

Source material(s)

Aspergillus flavus var. oryzae (Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae) (CABI 2012; 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

- Digestive enzyme/lactase to assist in the digestion of foods containing lactose (e.g. dairy foods, milk) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987).

- Helps prevent symptoms of lactose intolerance (including gas, bloating, cramping and diarrhea) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987).

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 lactase unit (ALU) is defined as that quantity of enzyme that will liberate o-nitrophenol at a rate of 1 µmol/min under the conditions of the assay.

For digestive aid:

- Enzyme preparation, per dosage unit; and
- Preparation providing up to the equivalent of $1.8 \times 10^4$ FCC ALU lactase, 3 times per day.

For lactose digestion:

- Enzyme preparation, per dosage unit; and
- Preparation containing the equivalent of (FCC 8; Ramirez et al. 1994; Lin et al. 1993):
  - Minimum: $3 \times 10^3$ FCC ALU lactase, per day.
  - Maximum: $1.8 \times 10^4$ FCC ALU lactase, 3 times per day.

Directions for use

Take with or immediately before a meal/food.

Duration of use

For digestive aid:
For prolonged use, consult a health care practitioner.
Risk information
Statement(s) to the effect of:

Caution(s) and warning(s)

- If you have diabetes, consult a health care practitioner prior to use (Groff and Gropper 2000).
- If symptoms persist or worsen, discontinue use and consult a health care practitioner.

Contraindication(s)
No statement required.

Known adverse reaction(s)

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 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 appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC):
  Lactase (Acid) (β-Galactosidase) activity (ALU)
- The medicinal ingredient may comply with the specifications (quality specifications only) outlined in the current United States (USP) pharmacopoeial monograph: Lactase
- 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


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


