LIPASE

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 12, 2012

Proper name(s)

Triacylglycerol acylhydrolase/ triacylglycerol lipase (IUBMB 1961)

Common name(s)

Lipase (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

**Dose(s)**

**Subpopulation(s)**

Adults (≥ 19 years)

**Quantity(ies)**

Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:

- Enzyme preparation per dosage unit; and
- Enzyme activity providing up to $1.1 \times 10^5$ FCC LU per day, in divided doses, not to exceed $3.0 \times 10^4$ FCC LU per dose (FCC 8; Glade et al. 2001).

**Note**

One FCC lipase unit (LU) is defined as the quantity of enzyme that will liberate 1 μmol of butyric acid per minute under the conditions of the test (FCC 8).

**Directions for use**

All products:
Take with food/meal.

For enteric-coated products:
Swallow whole/do not crush or chew (CPS 2008).

**Duration of use**

For prolonged use, consult a health care practitioner.

**Risk information** Statement(s) to the effect of:

**Caution(s) and warning(s)**

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
Contraindication(s)
No statement required.

Known adverse reaction(s)
Hypersensitivity/allergy has been known to occur, in which case, discontinue use (Martindale 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 the appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): LIPASE 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

