Health Canada Santé Canada

NATURAL HEALTH PRODUCT

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 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 May 30, 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)
• Triacylglycerol acylhydrolase • Triacylglycerol lipase	Lipase	• *Aspergillus flavus* var. *oryzae* • *Aspergillus niger* • *Rhizopus oryzae*	Whole

References: Proper name: IUBMB 2025; Common name: IUBMB 2025; Source information: CABI 2025, FCC 2024, 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 lipase 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

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 110,000 FCC LU of enzymatic activity, per day; and 30,000 FCC LU per single dose (FCC 2024; Glade et al. 2001).

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 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 2024).

Direction(s) for use

All products

Take with a meal/food.

Enteric-coated products

Swallow whole. Do not crush or chew (CPS 2008).

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)

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Brayfield and Cadart 2025).

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): 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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, Labelling of Natural Health Products for more details.

Product Facts
Medicinal ingredient in each capsule Triacylglycerol lipase (*Aspergillus niger* – whole) XX FCC LU (YY mg)
Uses Digestive Enzyme.
Warnings
If applicable[1]: **Allergens: food allergen, gluten (gluten source), sulphites** **Contains aspartame**
Ask a health care practitioner before use if you are pregnant or breastfeeding.
Stop use if allergy occurs.
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day • Take with food • Swallow whole. Do not crush or chew[2] • Ask a health care practitioner for prolonged use.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

[1]This section can be removed from the table if the product contains no allergen or aspartame.

[2]Enteric-coated products.

References cited

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Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2025. [Accessed 2025 April 25]. Available from: https://www.medicinescomplete.com/#/browse/martindale

CABI 2025: Centre for Agriculture and Bioscience International. Index Fungorum. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International). [Accessed 2025 April 25]. Available from: http://www.speciesfungorum.org

CPS 2008: Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008.

Glade MJ, Kendra D, Kaminski MV. Improvement in protein utilization in nursing-home patients on tube feeding supplemented with an enzyme product derived from *Aspergillus niger* and bromelain. Nutrition 2001;17(4):348-350.

FCC 2024: Food Chemicals Codex. 14th edition. Rockville (MD): The United States Pharmacopeial Convention; 2024.

IUBMB 2025: Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. London (GB): Queen Mary, University of London [lipase: CAS 9001-62-1, EC 3.1.1.3 created 1961; Accessed 2025 April 25]. Available from: https://www.qmul.ac.uk/sbcs/iubmb/

References reviewed

Cichoke AJ. Pancreatic Enzymes. In: Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. p. 1131-1146.