# Cellulase



Cellulase (PDF Version - 62 KB) 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 June 27, 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) 4-(1,3;1,4)-beta-D-Glucan 4-glucanohydrolase Cellulase Aspergillus flavus var. oryzae Aspergillus niger Trichoderma longibrachiatum Trichoderma reesei Whole References: Proper name: IUBMB 2024; Common name: IUBMB 2024; Source information: CABI 2025; Brayfield and Cadart 2024; FCC 2024; Kirk 2024. 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 cellulase 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 (Brayfield and Cadart 2024). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Not to exceed 110,000 FCC CU of enzymatic activity, per day (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 cellulase unit (CU) is defined as the amount of activity that will produce a relative fluidity change of 1 in 5 minutes in a defined carboxymethyl cellulose substrate under the conditions of the assay (FCC 2024). Direction(s) for use Take with a meal/food. 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. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs. 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 appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): CELLULASE 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 their shelf life indicated on the product label. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2024. [Accessed 2024 August 14]. Available from: https://www.medicinescomplete.com/#/browse/martindale CABI 2025: Centre for Agriculture and Bioscience International. 2011. Index Fungorum. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2025. [Accessed 2025 January 13]. 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. FCC 2024: Food Chemicals Codex. 14th edition. Rockville (MD): The United States Pharmacopeial Convention; 2024. 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. IUBMB 2024: IUBMB Enzyme Nomenclature. London (GB): Queen Mary, University of London; 2024. [Accessed 2024 August 14]. Available from: https://iubmb.qmul.ac.uk Kirk PM. Species Fungorum Plus (version Apr 2024). In Bánki O, Roskov Y, Döring M, Ower G, Hernández Robles DR, Plata Corredor CA, Stjernegaard Jeppesen T, Örn A, Pape T, Hobern D, Garnett S, Little H, DeWalt RE, Ma K, Miller J, Orrell T,R, Aalbu R, Abbott J, Aedo C, et al., Catalogue of Life (Version 2024-12-19). Catalogue of Life, Amsterdam, Netherlands; 2024. [Accessed 2015 January 13]. Available from: https://doi.org/10.48580/dg9ld-4hj References Reviewed Elms J, Fishwick D, Walker J, Rawbone R, Jeffrey P, Griffin P, Gibson M, Curran AD. Prevalence of sensitisation to cellulase and xylanase in bakery workers. Occupational and Environmental Medicine 2003;60(10):802-804. Vanhanen M, Tuomi T, Tupasela O, Keskinen H, Tuppurainen M, Hytönen M, Tarvainen K, Kanerva L, Nordman H. Cellulase allergy and challenge tests with cellulase using immunologic assessment. Scandinavian Journal of Work, Environment & Health 2000;26(3):250-256. Report a problem on this page Date modified: 2019-03-01

## MEDICINAL INGREDIENT(S)

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

## DOSAGE FORM(S)

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 cellulase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application.

## 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.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs.

## 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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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 appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): CELLULASE 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 their shelf life indicated on the product label.

| Proper name(s) | Common name(s) | Source information | |
|---|---|---|---|
| Source material(s) | Part(s) | | |
| 4-(1,3;1,4)-beta-D-Glucan 4-glucanohydrolase | Cellulase | Aspergillus flavusvar.oryzaeAspergillus nigerTrichoderma longibrac | |