Chymotrypsin

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CHYMOTRYPSIN (PDF Version - 76 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) Chymotrypsin alpha-Chymotrypsin Chymotrypsin Bos taurus Sus scrofa Pancreas References: Proper name: IUBMB 2025; Common names: IUBMB 2025; Source information: FCC 2024; ITIS 2024; USP-NF 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 chymotrypsin 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 480,000 USP chymotrypsin units of enzymatic activity, per day; and 160,000 USP chymotrypsin units per single dose (USP-NF 2024; Dörr and Herrmann 2007; Martin et al. 2002; Dale et al. 2001). Notes The Quantity per dosage unit must be the enzymatic activity (FCC or USP units). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity. One USP Chymotrypsin Unit is defined as the activity causing a change in absorbance at the rate of 0.0075/min under the conditions of the assay (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. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have gastrointestinal lesions/ulcers or are having surgery. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners or anti-inflammatory medications. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Brayfield and Cadart 2024). 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): CHYMOTRYPSIN 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. References cited Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2024. [Accessed 2024 July 30]. Available from: https://www.medicinescomplete.com/#/browse/martindale CPS 2008: Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008. Dale PS, Tamhankar CP, George D, Daftary GV. Co-medication with hydrolytic enzymes in radiation therapy of uterine cervix: evidence of the reduction of acute side effects. Cancer Chemotherapy and

Pharmacology 2001;47(Suppl):S29-S34. Dörr W, Herrmann T. Efficacy of Wobe-Mugos® E for reduction of oral mucositis after radiotherapy: results of a prospective, randomized, placebo-controlled, triple-blind phase III multicenter study. Strahlentherapie und Onkologie 2007;183:121-127. FCC 2024: Food Chemicals Codex. 14th edition. Rockville (MD): The United States Pharmacopeial Convention; 2024. ITIS 2024: Nicolson D, Alexander S, Hodson A, Mitchell D, Orrell, T & Perez-Gelabert D. The Integrated Taxonomic Information System (version 2024-11-19). 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 2025 January 13]. Available from: https://doi.org/10.48580/dglq4-4ky IUBMB 2025: IUBMB Enzyme Nomenclature. London (GB): Queen Mary, University of London [chymotrypsin: CAS 9004-07-3, EC 3.4.21.1 created 1961 as EC 3.4.4.5

and EC 3.4.4.6, transferred 1972 to EC 3.4.21.1; Accessed 2025 June 8]. Available from: https://iubmb.qmul.ac.uk/enzyme/EC3/4/21/1.html Martin T, Uhder K, Kurek R, Roeddiger S, Schneider L, Vogt HG, Heyd R, Zamboglou N. Does prophylactic treatment with proteolytic enzymes reduce acute toxicity of adjuvant pelvic irradiation? Results of a double-blind randomized trial. Radiotherapy and Oncology 2002;65:17-22. USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2024. References reviewed Cichoke AJ. Pancreatic Enzymes. In: Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine, 3rd edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006; p. 1131-1146. 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 chymotrypsin 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 gastrointestinal lesions/ulcers or are having surgery.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners or anti-inflammatory medications. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Brayfield and Cadart 2024).

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): CHYMOTRYPSIN ACTIVITYWhere 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.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Chymotrypsin	alpha-ChymotrypsinChymotrypsin	Bos taurusSus scrofa	Pancreas