

Fruit Bromelain/Stem Bromelain

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FRUIT BROMELAIN/STEM BROMELAIN Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 74 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 PLA and product 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. Date March 28, 2024 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) Fruit bromelain Fruit bromelain Juice bromelain Pineapple fruit bromelain Ananas comosus var. bracteatus Ananas comosus var. comosus Fruit Stem bromelain Bromelain Pineapple stem bromelain Stem bromelain Ananas comosus var. bracteatus Ananas comosus var. comosus Stem References: Proper names: IUBMB 1992; Common names: IUBMB 1992; Source information: USDA 2023. 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. Use(s) or Purpose(s) Used in Herbal Medicine to help relieve minor pain, swelling and inflammation (Walker et al. 2002, Blumenthal 1998). Digestive enzyme. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Minor pain, swelling and inflammation relief 480,000 - 130,000,000 FCC PU of enzymatic activity per day; Not to exceed 45,000,000 FCC PU per single dose (Kerkhoffs et al. 2004; Walker et al. 2002; Glade et al. 2001; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978). Digestive enzyme Not to exceed 130,000,000 FCC PU of enzymatic activity per day and 45,000,000 FCC PU per single dose (Kerkhoffs et al. 2004; Walker et al. 2002; Glade et al. 2001; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978). Notes One papain unit (PU) is defined as that quantity of enzyme that liberates the equivalent of 1 microgram of tyrosine per hour under the conditions of the assay (FCC 8 2012). One gelatin digestion unit (GDU) is approximately equivalent to 15,000 FCC papain unit (1 GDU \approx 15,000 FCC PU). Dose information may include the quantities of both the enzyme preparation and its enzymatic activity. The enzymatic activity quantity may be indicated in the Quantity/Unit field and its quantity of enzyme preparation in mg or ml in the Additional Quantity/Unit field. Direction(s) for use Digestive enzyme (optional for minor pain, swelling and inflammation relief) Take with food Combination rules For multi-ingredient products containing fruit bromelain and stem bromelain, the combined proteolytic activity should not exceed the maximum proteolytic activity of 130,000,000 FCC PU per day and 45,000,000 FCC PU per single dose. The same combination rule applies with combination of fruit bromelain and/or stem bromelain with papain. Duration(s) of Use All products Ask a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use. Risk Information Caution(s) and warning(s) All products 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 (Varilla et al. 2021; Martindale 2011; Brinker 2010; Blumenthal et al. 2000; Heinecke et al. 1972). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners, anti-inflammatory agents or antibiotics (Pereira et al. 2023; Varilla et al. 2021; Martindale 2011; Brinker 2010; Blumenthal et al. 2000). Minor pain, swelling and inflammation relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Martindale 2011; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmman 1979). When using this product you may experience gastrointestinal discomfort/disturbances (Martindale 2011; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmman 1979). 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): PLANT PROTEOLYTIC 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 Baur X, Fruhmenn G. Allergic reactions, including asthma, to the pineapple protease bromelain following occupational exposure. *Clinical Allergy* 1979;9(5):443-450. Blumenthal M. The Complete German Commission E monographs: Therapeutic guide to herbal medicines. Boston (MA): American Botanical Council; 1998. Blumenthal M, Goldberg A, Brinckmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Brien S, Lewith G, Walker AF, Middleton R, Prescott P, Bundy R. Bromelain as an adjunctive treatment for moderate-to-severe osteoarthritis of the knee: a randomized placebo-controlled pilot study. *QJM: An International Journal of Medicine* 2006;99(12): 841-850. Brinker F. Herb Contraindications and Drug Interactions, 4 th edition. Sandy (OR): Eclectic Medical Publications; 2010. FCC 8 2012: Food Chemicals Codex. Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2012. 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. Gutfreund AE, Taussig SJ, Morris AD. Effect of oral bromelain on blood pressure and heart rate of hypertensive patients. *Hawaii Medical Journal* 1978;37(5):143-146. Heinicke RM, van der Wal L, Yokoyama M. Effect of bromelain (ananase®) on human platelet aggregation. *Experientia* 1972;28(7):844-845. IUBMB 1992: IUBMB Enzyme Nomenclature. London (GB): Queen Mary, University of London. [Accessed 2024 March 7]. Available from: <https://iubmb.qmul.ac.uk/enzyme/EC3/4/22/> Kerkhoffs GM, Struijs PA, de Wit C, Rahlfs VW, Zwipp H, van Dijk CN. A double blind, randomized, parallel group study on the efficacy and safety of treating acute lateral ankle sprain with oral hydrolytic enzymes. *British Journal of Sports Medicine* 2004;38:431-435. Klein G, Kullich W. Short-term treatment of painful osteoarthritis of the knee with oral enzymes: a randomized, double-blind study versus diclofenac. *Clinical Drug Investigation* 2000;19(1):15-23. Martindale 2011: Sweetman SC, editor. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2012. [Accessed 2023 October 16]. Available from: <http://www.medicinescomplete.com> Murray MT, Pizzorno JE. Bromelain. In: Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. p.791-795. Pereira IC, Satiro Vieira EE, de Oliveira Torres LR, Cavalcanti Carneiro da Silva F, de Castro E Sousa JM, Torres-Leal FL. Bromelain supplementation and inflammatory markers: A systematic review of clinical trials. *Clinical Nutrition ESPEN* 2023;55:116-127. Singer F, Singer C, Oberleitner H. Phlogenzym versus diclofenac in the treatment of activated osteoarthritis of the knee. A double-blind prospective randomized study. *International Journal of Immunotherapy XVII* 2001;(2/3/4):135-141. USDA 2023: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2023 October 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Varilla C, Marcone M, Paiva L, Baptista J. Bromelain, a Group of Pineapple Proteolytic Complex Enzymes (*Ananas comosus*) and Their Possible Therapeutic and Clinical Effects. A Summary. *Foods* 2021; 10(10):2249. Walker AF, Bundy R, Hicks SM, Middleton RW. Bromelain reduces mild acute knee pain and improves well-being in a dose-dependent fashion in an open study of otherwise healthy adults. *Phytomedicine* 2002;9:681-686. References Reviewed Baur X. Studies on the specificity of human IgE-antibodies to the plant proteases papain and bromelain. *Clinical & Experimental Allergy* 1979;9(5):451-457. Berardi RR, Kroon LA, McDermott JH, Newton GD, Oszko MA, Popovich NG, Remington TL, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 15 th edition. Washington (DC): APhA Publications; 2006. Repchinsky C, editor-in-chief. Patient Self-Care: Helping Patients Make Therapeutic Choices, 1 st edition. Ottawa (ON): Canadian Pharmacists Association; 2002. 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MEDICINAL INGREDIENT(S)

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

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.

RISK INFORMATION

Caution(s) and warning(s) All products 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 (Varilla et al. 2021; Martindale 2011; Brinker 2010; Blumenthal et al. 2000; Heinecke et al. 1972). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners, anti-inflammatory agents or antibiotics (Pereira et al. 2023; Varilla et al. 2021; Martindale 2011; Brinker 2010; Blumenthal et al. 2000). Minor pain, swelling and inflammation relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Martindale 2011; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmenn 1979). When using this product you may experience gastrointestinal discomfort/disturbances (Martindale 2011; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmenn 1979).

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

STORAGE CONDITION(S)

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): PLANT PROTEOLYTIC 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

Route of Administration Oral

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Fruit bromelain	Fruit bromelainJuice bromelainPineapple fruitAnanas comosusvar.bracteatusAnanas comosusvar. comosus		Fruit
Stem bromelain	BromelainPineapple stem bromelainStem bromelainAnanas comosusvar.bracteatusAnanas comosusvar. comosus		Stem