

STEM BROMELAIN

This abbreviated labelling standard (AbLS) is a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It includes generalized claims and is not intended to be a comprehensive review of the medicinal ingredient. Wording of the claim on the PLA and label must therefore be identical to this AbLS.

Date March 30, 2012

Field	Field content	Reference
Proper name(s)	stem bromelain	IUBMB 1992
Common name(s)	stem bromelain/ pineapple stem bromelain/ bromelain	IUBMB 1992
Source material(s)	pineapple (<i>Ananas comosus</i> (L.) Merr. var. <i>comosus</i> (Bromeliaceae)) stem	USDA 2011
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 AbLS is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.	
Use(s) or Purpose(s)	Digestive enzyme.	
Dose(s)	<p>Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:</p> <ul style="list-style-type: none"> • Enzyme preparation providing up to 1500 mg per day; not to exceed 540 mg per dose; and • Enzyme activity providing up to 133 928 538 FCC PU^{1, 2} per day³; not to exceed 44 642 846 FCC PU per dose. 	<p>Kerkhoffs et al. 2004; Walker et al. 2002; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978</p> <p>Glade et al. 2001; Gutfreund et al. 1978</p>
Sub-population(s)	Adults	
Duration(s) of use	For prolonged use, consult a health care practitioner.	
Direction(s) of use	Take with food/meal.	

Field	Field content	Reference
Risk information	Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	
	Consult health care practitioner prior to use if you have gastrointestinal lesions/ulcers, are taking anticoagulant agents, anti-inflammatory agents or antibiotics or before having surgery.	Sweetman 2011 Brinker 2010 Blumenthal et al. 2000
	Hypersensitivity/allergy has been known to occur, in which case discontinue use.	Sweetman 2011 Brinker 2010 Murray and Pizzorno 2006 Blumenthal et al. 2000 Baur and Fruhmman 1979
	Nausea, vomiting, and diarrhoea have been known to occur, in which case discontinue use (and consult a health care practitioner).	Sweetman 2011 Brien et al. 2006 Blumenthal et al. 2000
Non-medicinal ingredient(s)	Must be chosen from the current NHPD <i>Natural Health Products Ingredients Database</i> and must meet the limitations outlined in the database.	
Specification(s)	<p>A Finished Product Specifications Form must accompany the application.</p> <p>The finished product must comply with the requirements of the current NHPD <i>Evidence for Quality of Finished Natural Health Products</i> guidance document.</p> <p>The specifications must include testing for enzymatic activity of the medicinal ingredient at the finished product stage using the assay outlined in the Food Chemicals Codex (FCC 7) : PLANT PROTEOLYTIC ACTIVITY.</p> <p>Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium, isolation process and the percent purity of the medicinal ingredient.</p> <p>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.</p>	

- ¹. FCC 7: one papain unit (PU) is defined as that quantity of enzyme that liberates the equivalent of 1 µg of tyrosine per hour under the conditions of the assay.
- ². One gelatin digestion unit (GDU) is approximately equivalent to 15 000 FCC papain unit (1 GDU ≈ 15 000 FCC PU).
- ³. For multi-ingredient products containing both Papain and Bromelain, the combined proteolytic activity should not exceed the maximum proteolytic activity of 7 200 000 FCC PU per day (as per the NHPD Papain AbLS).

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