

PAPAIN

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 and common names	papain	IUBMB 2000
Source material(s)	leaf latex of papaya (<i>Carica papaya</i> L. (Caricaceae)) fruit of papaya (<i>Carica papaya</i> L. (Caricaceae))	Merck 2011 USDA 2011 Morton 1987
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)	Dose information must include the quantities of both the enzyme preparation and its enzymatic activity: <ul style="list-style-type: none"> Enzyme preparation of the latex from the leaf and/or unripe fruit of papaya, providing up to 1200 mg per day; not to exceed 400 mg per dose; and Enzyme activity providing up to 7 200 000 FCC PU^{1,2} per day; not to exceed 2 400 000 FCC PU per dose³. 	Dörr and Herrman 2007; Martin et al. 2002; Dale et al. 2001; Morton 1987 Martin et al. 2002 Dale et al. 2001
Sub-population(s)	Adults	
Duration(s) of use	For prolonged use, consult a health care practitioner.	
Direction(s) of use	Take with food/a meal.	
Risk information	Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	

Field	Field content	Reference
	Consult a health care practitioner prior to use if you have gastrointestinal lesions/ulcers, are taking anticoagulant agents, anti-inflammatory agents or other enzyme products, are having surgery.	
	Hypersensitivity/allergy has been known to occur, in which case discontinue use.	HC 2011 Sweetman 2011 US FDA 2008
	Consult a health care practitioner prior to use if you have allergy to latex or fruits (such as avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, and tomato).	US FDA 2008 APhA 2006 Brehler et al. 1997
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 medicinal ingredient may comply with the specifications outlined in the United States Pharmacopeia (USP 34): Papain.</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 their 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 FCC papain unit is approximately equivalent to one USP papain unit (1 FCC PU ≈ 1 USP 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 (2 400 000 FCC PU per dose).

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