

## NATURAL HEALTH PRODUCT

### CELLULASE

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** April 29, 2019

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
4-(1,3;1,4)-beta-D-glucan 4-glucanohydrolase	Cellulase	<ul style="list-style-type: none"> <li>▶ <i>Aspergillus niger</i></li> <li>▶ <i>Trichoderma longibrachiatum</i></li> <li>▶ <i>Trichoderma reesei</i></li> </ul>	Whole

References: Proper name: IUBMB 2001; Common name: IUBMB 2001; Source material: CABI 2012, FCC 8 2012, Martindale 2011, Bisby et al. 2010.

#### 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



### **Use(s) or Purpose(s)**

Digestive enzyme (Martindale 2011).

### **Dose(s)**

#### **Subpopulation(s)**

Adults 18 years and older

#### **Quantity(ies)**

Not to exceed 110,000 FCC CU of enzymatic activity, per day (FCC 8 2012; 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 8 2012).

#### **Direction(s) for use**

Take with food/meal.

#### **Duration(s) of use**

Consult a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

#### **Risk information**

##### **Caution(s) and warning(s)**

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant, breastfeeding or 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**

No statement required.

### **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.

### **References cited**

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IUBMB 2001: IUBMB Enzyme Nomenclature [Internet]. London (GB): Queen Mary, University of London. [cellulase: CAS 9012-54-8, EC 3.2.1.4 created 1961, modified 2001; Accessed 2012 March 28]. Available from: <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/2/1/4.html>

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### References reviewed

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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.