



## NATURAL HEALTH PRODUCT

### BOVINE COLOSTRUM

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

August 28, 2018

#### 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)	Preparation(s)
Bovine colostrum	Bovine colostrum	<i>Bos taurus</i>	Colostrum	Dried and not from hyper-immunized cattle

References: Proper name: Martindale 2010, Kim et al. 2009, Cesarone et al. 2007, Shing et al. 2007; Common name: Martindale 2010, Kim et al. 2009, Cesarone et al. 2007, Shing et al. 2007; Source material: Kim et al. 2009, Cesarone et al. 2007, Shing et al. 2007.

#### 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)

- ▶ Helps to support immune function within the upper respiratory tract (Davison and Diment 2009; Cesarone et al. 2007; Crooks et al. 2006; Patel and Rana 2006; Brinkworth and Buckley 2003; Mero et al. 2002).
- ▶ Helps to support the immune system (Davison and Diment 2009; Cesarone et al. 2007; Crooks et al. 2006; Patel and Rana 2006; Brinkworth and Buckley 2003; Mero et al. 2002).

### Dose(s)

#### Subpopulation(s)

Adults 18 years and older

#### Quantity(ies)

0.4 - 10 grams of dried colostrum, per day (Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007; Shing et al. 2006).

#### Direction(s) for use

No statement required.

### Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use (Cesarone et al. 2007; Brinkworth and Buckley 2004; Brinkworth et al. 2004; Coombes et al. 2002; Antonio et al. 2001).

### 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 or breastfeeding, or if you have diabetes, a history of cancer, or suffer from an immune system disorder (e.g. Crohn's disease, myasthenia gravis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, HIV/AIDS, etc.) (Kim et al. 2009; Rowlands 2009; Salvioli et al. 2009; Tripathi et al. 2006; Albers et al. 2005; Mero et al. 2002; Mero et al. 1997).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking medications to suppress the immune system (immunosuppressive medications) (Albers et al. 2005).



### **Contraindication(s)**

Do not use this product if you have a known allergy/hypersensitivity to cow's milk (HC 2011).

### **Known adverse reaction(s)**

No statement required.

### **Storage conditions**

No statement required.

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### **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.

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