



## 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 the statements are synonymous. Either term or statement may be selected by the applicant.

#### Date

March 25, 2013

#### Proper name(s)

Bovine colostrum (Martindale 2010; Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007)

#### Common name(s)

Bovine colostrum (Martindale 2010; Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007)

#### Source material(s)

Colostrum from *Bos taurus* (Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007)

#### Note

Sources of colostrum should not be from hyper-immunized cattle.

#### 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 monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

**Use(s) or Purpose(s)** Statement(s) to the effect of

- ▶ 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)** Statement(s) to the effect of

**Subpopulation(s)**

adults ( $\geq 19$  years)

**Quantity(ies)**

0.4-10 g dried powder, per day (Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007; Shing et al. 2006).

**Directions for use**

No statement required.

**Duration of use** Statement(s) to the effect of

For prolonged use, consult a health care practitioner (Cesarone et al. 2007; Brinkworth and Buckley 2004; Brinkworth et al. 2004; Coombes et al. 2002; Antonio et al. 2001).

**Risk information** Statement(s) to the effect of

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

- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- ▶ If you have a history of cancer, consult a healthcare practitioner prior to use (Rowlands 2009; Salvioli et al. 2009; Mero et al. 2002).
- ▶ If you have diabetes, consult a health care practitioner prior to use (Kim et al. 2009; Tripathi et al. 2006; Mero et al. 1997).



- ▶ If you have liver or kidney disease or if you have been instructed to follow a low protein diet, consult a health care practitioner prior to use (Shils et al. 2006).
- ▶ If you suffer from an immune system disorder (e.g. Crohn's disease, myasthenia gravis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, HIV/AIDS, etc.) or if you are taking immunosuppressants (Albers et al. 2005), consult a health care practitioner prior to use.

### **Contraindication(s)**

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

### **Note**

The list of priority allergens is maintained at: [http://hc-sc.gc.ca/fn-an/label-etiquet/allergen/guide\\_ligne\\_direct\\_indust-eng.php](http://hc-sc.gc.ca/fn-an/label-etiquet/allergen/guide_ligne_direct_indust-eng.php)

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

No statement required.

### **Storage conditions**

No statement required.

### **Non-medicinal ingredients**

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

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