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)**

- 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 (≥ 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**

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**

**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

**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).

**References cited**


Tripathi V, Vashishtha B. Bioactive compounds of colostrum and its application. Food Reviews International 2006;22(3):225-244.

References reviewed


He F, Tuomola E, Arvilommi H, Salminen S. Modulation of human humoral immune response through orally administered bovine colostrum. FEMS Immunology and Medical Microbiology 2001;31(2):93-96.


