

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 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 on the label.

Date

January 10, 2025

Proper name(s), Common name(s), Source information

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

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
Bovine colostrum	Bovine colostrum	<i>Bos taurus</i>	Colostrum ¹	Dry

References: Proper name: Brayfield and Cadart 2024; Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007; Common name: Brayfield and Cadart 2024; Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007; Source information: Kim et al. 2009; Cesarone et al. 2007; Shing et al. 2007.

¹Not from hyper-immunized cattle.

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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.



Use(s) or Purpose(s)

- Helps maintain/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 maintain/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).

Note: The terms ‘Helps’ or ‘Helps to’ can be used interchangeably on the label.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Method of preparation: Powdered

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

Ask 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)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding,**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes, a history of cancer, or an immune system disorder** (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).



- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if** you are taking medications to suppress the immune system (Albers et al. 2005).

Contraindication(s)

Do not use if you have a known allergy/hypersensitivity to cow's milk (HC 2012).

Known adverse reaction(s)

No statement required.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each scoop Bovine colostrum (<i>Bos taurus</i> – colostrum) XX g
Uses <ul style="list-style-type: none"> • Helps to support immune function within the upper respiratory tract. • Helps to support the immune system.
Warnings
Allergens: Milk
If applicable¹: Other allergens: food allergen, gluten (source of gluten), sulphites Contains aspartame
Do not use if you have a known allergy to cow's milk.
Ask a health care practitioner before use if • you are pregnant or breastfeeding • you have diabetes, a history of cancer, or an immune system disorder • you are taking medications to suppress the immune system.
Directions Adults 18 years and older: • Take X scoop(s), X time(s) per day • Ask a health care practitioner for prolonged use.
Other information (Add storage information).
Non-medicinal ingredients List all NMIs.
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

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