Health Canada Santé Canada

NATURAL HEALTH PRODUCT

CARBON DIOXIDE-RELEASING LAXATIVES

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 February 23, 2024

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[1] Source ingredient(s)
(2R,3R)-2,3-Dihydroxybutanedioic acid potassium salt (1:1)	• Cream of tartar • Potassium acid tartrate • Potassium bitartrate • Potassium hydrogen tartrate	Potassium bitartrate
Carbonic acid sodium salt (1:1)	• Baking soda • Carbonic acid monosodium salt • Sodium bicarbonate • Sodium hydrogen carbonate	Sodium bicarbonate
Disodium dihydrogen pyrophosphate	• Disodium dihydrogen pyrophosphate • Disodium pyrophosphate • Disphosphoric acid disodium salt • Sodium acid pyrophosphate	Disodium pyrophosphate
• Monosodium orthophosphate • Monosodium phosphate • Phosphoric acid, monosodium salt • Phosphoric acid sodium salt (1:1)	• Monosodium orthophosphate • Primary sodium phosphate • Sodium biphosphate • Sodium dihydrogen phosphate • Sodium phosphate,	• Sodium phosphate, monobasic • Sodium phosphate, monobasic, dihydrate • Sodium phosphate, monobasic, monohydrate

• Sodium biphosphate • Sodium dihydrogen phosphate	monobasic	

[1]The ingredients must be pharmacopoeial grade.
References: Proper names: RSC 2024; USP-NF 2023; Gottschalck and McEwen 2006; Sweetman 2002; Common names: RSC 2024; USP-NF 2023; Gottschalck and McEwen 2006; Sweetman 2002; Source information: RSC 2024; USP-NF 2023; Gottschalck and McEwen 2006; Sweetman 2002.

Route of administration

Rectal (US FDA 2023).

Dosage form(s)

Suppository (US FDA 2023).

Use(s) or Purpose(s)

- For relief of occasional constipation and/or irregularity (US FDA 2023).
- Laxative (US FDA 2023).
- Promotes evacuation of the lower bowel (Sweetman 2002).

Note: The above uses can be combined on the product label (e.g., Laxative for the relief of occasional constipation and/or irregularity and promotes evacuation of the lower bowel).

Dose(s)

Subpopulation(s)

Adolescents 12-17 years and Adults 18 years and older (US FDA 2023).

Quantity(ies)

- 1 suppository per day, containing 1.2 - 1.5 grams of Monosodium phosphate + 0.04 -0.05 grams of Disodium dihydrogen pyrophosphate + 1 - 1.5 grams of Carbonic acid sodium salt (1:1) (Sodium bicarbonate) (US FDA 2023).
- 1 suppository per day, containing 0.6 grams of Carbonic acid sodium salt (1:1) (Sodium bicarbonate) + 0.9 grams of (2R,3R)-2,3-Dihydroxybutanedioic acid potassium salt (1:1) (Potassium bitartrate) (US FDA 2023).

Permitted combinations

Products with only one medicinal ingredient are not allowed; medicinal ingredients are permitted

only in the combinations indicated in the Quantities section (US FDA 2023).

Direction(s) for use

- Do not use within 2 hours of another medicine as the desired effect of the other medicine may be reduced (Berardi et al. 2002).
- Remove suppository from wrapper (for suppositories packaged in a wrapper) (US FDA 2021).
- Place under running water for 30 seconds, or in a cup of water for at least 10 seconds before insertion (US FDA 2023).
- Do not lubricate with mineral oil or petrolatum prior to rectal insertion (US FDA 2023).
- Gently insert in the rectum.
- Allow 5-30 minutes to produce bowel movement (US FDA 2023).

Duration(s) of use

Do not use beyond 7 days (US FDA 2023).

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 on a sodium-restricted diet (US FDA 2024).
- **Ask a health care practitioner/health care provider/health care professional/doctor/ physician if** symptoms persist or worsen (US FDA 2021).
- **Ask a health care practitioner/health care provider/health care professional/doctor/ physician** promptly in case of bleeding (US FDA 2021).

Contraindication(s)

Do not use if you have abdominal pain, nausea, fever or vomiting (US FDA 2023).

Known adverse reaction(s)

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.

Storage conditions

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

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 suppository	
Sodium biphosphate	XX g
Disodium dihydrogen pyrophosphate	XX g
Sodium bicarbonate	XX g
Uses • For relief of occasional constipation and/or irregularity. • Laxative. • Promotes evacuation of the lower bowel.	
Warnings	
If applicable: **Allergens: food allergen, gluten (gluten source), sulphites** **Contains aspartame**	
Do not use if you have abdominal pain, nausea, fever or vomiting.	
Ask a health care practitioner before use if you are on a sodium-restricted diet.	
Ask a health care practitioner • if symptoms persist or worsen • promptly in case of bleeding.	
Directions Adults and adolescents 12 and older: • Use 1 suppository per day • Do not use within 2 hours of another medicine as the desired effect of the other medicine may be reduced • Remove suppository from wrapper (for suppositories packaged in a wrapper) • Place under running water for 30 seconds, or in a cup of water for at least 10 seconds before insertion • Do not lubricate with mineral oil or petrolatum prior to rectal insertion • Gently insert in the rectum • Allow 5-30 minutes to produce bowel movement • Do not use beyond 7 days.	
Other information (Add storage information)	
Non-medicinal ingredients List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

References cited

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Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook. 10th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2006.

RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2024 January 12]. Available from: https://merckindex.rsc.org/

Sweetman SC, editor. Martindale: The Complete Drug Reference. 33rd edition. Grayslake (IL): Pharmaceutical Press; 2002.

US FDA 2021. USA Department of Health and Human Services: Food and Drug Administration. Anorectal Drug Products for Over-the-Counter Human Use; 2021. [Accessed 2024 January 12]. Available at: https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2022-09/OTC%20Monograph_M015-Anorectal%20Drug%20Products%20for%20OTC%20Human%20Use%20Posted%20Corrected%2002_23_22.pdf

US FDA 2023. USA Department of Health and Human Services: Food and Drug Administration. Laxative Drug Products for Over-the-Counter Human Use; 2023. [Accessed 2024 January 12]. Available at: https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2023-05/OTC%20Monograph_M007-Laxative%20Drug%20Products%20for%20OTC%20Human%20Use%2005.02.2023.pdf

US FDA 2024: USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 201. Code of Federal Regulations; Labeling Requirements for Over-the-Counter Drugs; 2024. [Accessed 2024 January 12]. Available at: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-C

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