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 July 5, 2021

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	▶ Monosodium orthophosphate ▶ Primary sodium phosphate ▶ Sodium biphosphate ▶ Sodium dihydrogen	▶ Sodium phosphate, monobasic ▶ Sodium phosphate, monobasic, dihydrate ▶ Sodium phosphate,

▶ Phosphoric acid sodium salt (1:1) ▶ Sodium biphosphate ▶ Sodium dihydrogen phosphate	phosphate ▶ Sodium phosphate, monobasic	monobasic, monohydrate

[1]The ingredients must be pharmacopoeial grade.
References: Proper names: Gottschalck and McEwen 2006, USP 29 2006, Sweetman 2002, O'Neil et al. 2001; Common names: Gottschalck and McEwen 2006, USP 29 2006, Sweetman 2002, O'Neil et al. 2001; Source information: Gottschalck and McEwen 2006, USP 29 2006, Sweetman 2002, O'Neil et al. 2001.

Route of administration

Rectal (FDA 1985)

Dosage form(s)

Suppository (FDA 1985)

Use(s) or Purpose(s)

- For relief of occasional constipation and/or irregularity (FDA 1985)
- Laxative (FDA 1985)
- Promotes evacuation of the lower bowel (Sweetman 2002).

Dose(s)

Subpopulation(s)

Adolescents 12-17 years and Adults 18 years and older (FDA 1985)

Quantity(ies)

- One 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) (FDA 1985).
- One 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) (FDA 1985).

Permitted combinations

Products with only one medicinal ingredient are not allowed; medicinal ingredients are permitted only in the combinations indicated in the Quantities section (FDA 1985).

Direction(s) for use

- Do not take this product 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) (FDA 1990).
- Place under running water for 30 seconds, or in a cup of water for at least 10 seconds before insertion (FDA 1985).
- Do not lubricate with mineral oil or petrolatum prior to rectal insertion (FDA 1985).
- Gently insert in the rectum.
- Allow 5-30 minutes to produce bowel movement (FDA 1985).

Duration(s) of use

Do not use this product beyond 7 days (FDA 1985).

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 on a sodium-restricted diet (FDA 2018).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen (FDA 1990).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician promptly in case of bleeding (FDA 1990).

Contraindication(s)

Do not use this product if you have abdominal pain, nausea, fever or vomiting (FDA 1985).

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 (NHPR).

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.

References cited

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-care. 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

FDA 2018: USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 201. Labeling Requirements for Over-the-Counter Drugs; 2018. [Accessed 2019 July 9]. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=201&showFR=1&subpartNode=21:4.0.1.1.2.3

FDA 1990. USA Department of Health and Human Services: Food and Drug Administration. 55 CFR Part 346. Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph; 1990. FR Citation: 55FR31776 [Accessed 2019 July 9]. Available at: https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-anorectal-drug-products

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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.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th edition. Whitehouse Station (NJ): Merck and Co., Inc; 2001.

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

USP 29: United States Pharmacopeia and the National Formulary (USP 29/NF 24). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2006.