

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



•	Sodium biphosphate	monobasic	
•	Sodium dihydrogen		
	phosphate		

<sup>&</sup>lt;sup>1</sup>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)

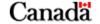
Adolescents 12-17 years and Adults 18 years and older (US FDA 2023).

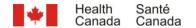
## Quantity(ies)

- 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

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 Selfcare. 13<sup>th</sup> edition. Washington (DC): American Pharmaceutical Association; 2002.

Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook. 10<sup>th</sup> 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. 33<sup>rd</sup> 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-

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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-

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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

USP-NF 2023: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2023.

