



NATURAL HEALTH PRODUCT

BETAINE / BETAINE HYDROCHLORIDE

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 1, 2019

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 ingredient(s)	Source material(s)	Part(s)	Preparation(s)
▶ 1-Carboxy-N,N,N-trimethylmethanaminium inner salt ▶ (Carboxymethyl) trimethylammonium hydroxide inner salt	▶ Betaine ▶ Betaine anhydrous ▶ Trimethylglycine	▶ Betaine ▶ Betaine hydrochloride	<i>Beta vulgaris</i>	Root	Isolate
			N/A	N/A	Synthetic
1-Carboxy-N,N,N-trimethylmethanaminium chloride	Betaine hydrochloride	N/A	<i>Beta vulgaris</i>	Root	Isolate

References: Proper names: Martindale 2014, Moffat et al. 2014, O’Neil et al. 2006; Common names: NHPID 2019; Source information: Allen Jr. 2014, DNP 2014, Moffat et al. 2014, Martindale 2014, FCC 2012, O’Neil et al. 2006.

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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Products containing Betaine as a medicinal ingredient

Helps to support liver function (Kempson et al. 2014; Obeid 2013; Ueland 2011; Lever and Slow 2010; Purohit et al. 2007; Pajares and Perez-Sala 2006; Craig 2004; Patrick 2002; Barak et al. 1996).

Products containing Betaine hydrochloride as a medicinal ingredient or as a source ingredient

Helps to support digestion/Digestive aid (DNP 2014; Moffat et al. 2014; O’Neil et al. 2006).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Liver function

500 - 4,000 milligrams of Betaine, per day (Schwab et al. 2011, Atkinson et al. 2008)

Digestive aid

Table 2. Dose information of Betaine hydrochloride as a medicinal ingredient or as a source ingredient

Medicinal ingredient(s)	Source ingredient(s)	Minimum (mg/day)	Maximum (mg/day)
Betaine	Betaine hydrochloride	137	2,670
Betaine hydrochloride	N/A	180	3,500

References: Allen Jr. 2014, Moffat et al. 2014.



Direction(s) for use

Products containing Betaine hydrochloride (as a medicinal ingredient or as a source ingredient)

Take with food/meal (Allen Jr. 2014; Moffat et al. 2014).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

Products containing Betaine hydrochloride (as a medicinal ingredient or as a source ingredient)

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a peptic ulcer or excess stomach acid (Hendler and Rorvik 2008; O'Neil et al. 2006).

Products providing 600 milligrams or more of Betaine or 780 milligrams or more of Betaine hydrochloride as a medicinal ingredient, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have high cholesterol (Olthof et al. 2005; Swab et al. 2002).

Contraindication(s)

No statement required.

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

No statement required.

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.

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