



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

December 8, 2015

Medicinal ingredients

Proper name(s)	Common name(s)	Source material(s)
1-Carboxy- <i>N,N,N</i> -trimethylmethanaminium inner salt (Moffat et al. 2014; O'Neil et al. 2006) (Carboxymethyl)trimethylammonium hydroxide inner salt (Martindale 2014; O'Neil et al. 2006)	Betaine	<ul style="list-style-type: none">▶ <i>Beta vulgaris</i> root (FCC 2012)▶ Betaine (anhydrous) (DNP 2014; Moffat et al. 2014; Martindale 2014; FCC 2012; O'Neil et al. 2006)▶ Betaine hydrochloride (Allen Jr. 2014; DNP 2014; Martindale 2014; O'Neil et al. 2006)
1-Carboxy- <i>N,N,N</i> -trimethylmethanaminium chloride (O'Neil et al. 2006) (Carboxymethyl)trimethylammonium chloride (O'Neil et al. 2006)	Betaine hydrochloride	<ul style="list-style-type: none">▶ <i>Beta vulgaris</i> root (FCC 2012)▶ Betaine hydrochloride (Allen Jr. 2014; DNP 2014; Martindale 2014; O'Neil et al. 2006)



Note: For products making the digestive claim, the medicinal ingredient must be represented as betaine hydrochloride. For products making only the liver function claim, the medicinal ingredient must be represented as betaine.

Route(s) of administration

Oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s) Statement(s) to the effect of

All products

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).

Medicinal Ingredient: Betaine hydrochloride

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

Dose(s) Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Liver function

Medicinal Ingredient	Minimum (mg/day)	Maximum (mg/day)	References
Betaine	500	4000	Schwab et al. 2011; Atkinson et al. 2008
Betaine hydrochloride	650; not to exceed 1000 mg per single dose	3500	Allen Jr. 2014; Moffat et al. 2014; Atkinson et al. 2008

Digestive aid

Medicinal Ingredient	Minimum (mg/day)	Maximum (mg/day)	References
Betaine hydrochloride	180 mg; not to exceed 1000 mg per single dose	3500	Allen Jr. 2014; Moffat et al. 2014

Directions for use

Products providing betaine hydrochloride (as a medicinal ingredient or as a source ingredient)

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

Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

All products

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Products providing betaine hydrochloride (as a medicinal ingredient or as a source ingredient)

If you have a peptic ulcer or excess stomach acid, consult a health care practitioner prior to use (Hendler and Rorvik 2008; O'Neil et al. 2006).

Products providing ≥ 600 mg betaine and/or ≥ 780 mg betaine hydrochloride per day

If you have high cholesterol, consult a health care practitioner prior to use (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 Statement(s) to the effect of

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 Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID. In addition, the medicinal ingredient may comply with the specifications outlined in the Betaine monograph, published in the Food Chemicals Codex (FCC 2012), or the Betaine Hydrochloride monograph, published in the United States Pharmacopeia (USP 34).

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