

Betaine / Betaine hydrochloride

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BETAINE / BETAINE HYDROCHLORIDE Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 78 KB) 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 Beta vulgaris Root Isolate N/A N/A Synthetic 1-Carboxy-N,N,N-trimethylmethanaminium chloride Betaine hydrochloride N/A Beta vulgaris 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 any age category listed in this monograph for the specified route of administration are listed 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. References Cited Allen Jr. LV (Editor). Remington: The Science and Practice of Pharmacy. Philadelphia College of Pharmacy. Royal Pharmaceutical Society; 2014. [Accessed 2019 May 8]. Available from: <http://www.medicinescomplete.com/mc/rem/current/> Atkinson W, Elmslie J, Lever M, Chambers ST, George PM. Dietary and supplementary betaine: acute effects on plasma betaine and homocysteine concentrations under standard and postmethionine load conditions in healthy male subjects. American Journal of Clinical Nutrition 2008;87:577-585. Barack AJ, Beckenhauer HC, Tuma DJ. Betaine,

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The effects of chronic betaine supplementation on exercise performance, skeletal muscle oxygen saturation and associated biochemical parameters in resistance trained men. *Journal of Strength and Conditioning Research* 2011;25(12):3461-3471. Van Guldener C, Janssen MJFM, De Meer K, Donker AJM, Stehouwer CDA. Effect of folic acid and betaine on fasting and postmethionine-loading plasma homocysteine and methionine levels in chronic haemodialysis patients. *Journal of Internal medicine* 1999;245:175-183. White P, Marble A, Bogan IK, Smith RM. Enlargement of the liver in diabetic children. *Archives of Internal Medicine* 1938;62(5):740-750. Ziesel SH. Betaine supplementation and blood lipids: fact or artifact? *Nutrition Reviews* 2006;64(2):77-79. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

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.

STORAGE CONDITION(S)

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.

REFERENCES

Route of Administration Oral

Ingredient name(s)	Common name(s)	Source information		
Ingredient(s)	Source material(s)	Part(s)	Preparation(s)	
N,N,N- trimethylmethanaminium chloride	Betaine hydrochloride	Betaine hydrochloride	Beta vulgaris	Root
	N/A	Synthetic		
N,N,N- trimethylmethanaminium chloride	Betaine hydrochloride	N/A	Beta vulgaris	Root

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