

NATURAL HEALTH PRODUCT

L-CARNITINE

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 the statements are synonymous. Either term or statement may be selected by the applicant.

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Proper name(s)

- ▶ (L-3-Carboxy-2-hydroxypropyl) trimethylammonium hydroxide, inner salt (USP 35)
- ▶ (R)-3-carboxy-2-hydroxy-N,N,N-trimethyl-1-propanaminium hydroxide, inner salt (USP 35)
- ▶ L-Carnitine (Merck 2012)

Common name(s)

- ▶ L-Carnitine (Merck 2012)
- ▶ Levocarnitine (Merck 2012; USP 35)

Source material(s)

- ▶ L-Carnitine tartrate (EFSA 2012; Wall et al. 2011)
- ▶ L-Carnitine fumarate (EFSA 2003)

Route(s) of administration

Oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, 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

L-Carnitine from L-Carnitine tartrate

- ▶ Aids in the muscle recovery process by reducing muscle tissue damage associated with a resistance training regimen (Ho et al. 2010; Spiering et al. 2008; Spiering et al. 2007; Kraemer et al. 2006; Kramer et al. 2003; Volek et al. 2002).
- ▶ Helps support muscle tissue repair in individuals involved in resistance training (Ho et al. 2010; Spiering et al. 2008; Spiering et al. 2007; Kraemer et al. 2006; Kramer et al. 2003; Volek et al. 2002).
- ▶ Helps improve physical performance when used in conjunction with a training regimen (Wall et al. 2011; Cha et al. 2001; Arenas et al. 1994; Huertas et al. 1992; Arenas et al. 1991; Vecchiet et al. 1990; Marconi et al. 1985).
- ▶ Helps delay fatigue during physical activity (Cha et al. 2011; Wall et al. 2011; Karahan et al. 2010).
- ▶ Helps support fat metabolism (Brass 2000; Stephens et al. 2007; Karlic and Lohninger 2004; Müller et al. 2002).
- ▶ Helps support fat oxidation (Wall et al. 2011; Stephens et al. 2007; Wutzke and Lorenz 2004; Müller et al. 2002).

L-Carnitine from all sources

- ▶ Antioxidant (Cao et al. 2011; Arkadeb et al. 2008; Gomez-Amores et al. 2007).
- ▶ Workout support/supplement (Wall et al. 2011; Cha et al. 2001; Arenas et al. 1994; Huertas et al. 1992; Arenas et al. 1991; Vecchiet et al. 1990; Marconi et al. 1985).

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

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Muscle recovery, Muscle tissue repair

1-4 g per day, not to exceed 2 g per single dose (Ho et al. 2010; Spiering et al. 2008; Spiering et al. 2007; Kraemer et al. 2006; Kramer et al. 2003; Volek et al. 2002; Benvenga et al. 2001; Ahmet et al. 2000; Harper et al. 1988).

Physical performance, Fatigue



2-4 g per day, not to exceed 2 g per single dose (Wall et al. 2011; Benvenga et al. 2001; Cha et al. 2001; Ahmet et al. 2000; Arenas et al. 1994; Huertas et al. 1992; Arenas et al. 1991; Vecchiet et al. 1990; Harper et al. 1988; Marconi et al. 1985).

Fat oxidation

1 g, three times per day (Wall et al. 2011; Stephens et al. 2007; Wutzke and Lorenz 2004; Müller et al. 2002).

Fat metabolism, Antioxidant, Workout support/supplement

Up to 4 g per day, not to exceed 2 g per single dose (Brass 2000; Karlic and Lohninger 2004; Benvenga et al. 2001; Ahmet et al. 2000; Harper et al. 1988).

Directions for use

Muscle recovery, Muscle tissue repair, Workout support/supplement, Physical performance, Fatigue

Take 2-4 hours prior to exercise (Harper et al. 1988).

Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

- ▶ If you are pregnant or breastfeeding, consult a healthcare practitioner prior to use (CPS 2008).
- ▶ If you have a liver disease, a kidney disease, or a seizure disorder, consult a healthcare practitioner prior to use (CPS 2008; Bain et al. 2006; Shils et al. 2006).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

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