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.

Date

September 27, 2013

Proper name(s)

- (L-3-Carboxy-2-hydroxypropyl) trimethylammonium hydroxide, inner salt (USP 35)
- (R)-3-carboxy-2-hydroxy-N,N,N-trimethyl-1-propanamininium 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).

**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).

**References cited**


Volek JS, Kraemer WJ, Rubin MR, Gomez AL, Ratamess NA, Gaynor P. L-carnitine L-tartrate


References reviewed


