PROTOCOL FOR LIFE BALANCE®

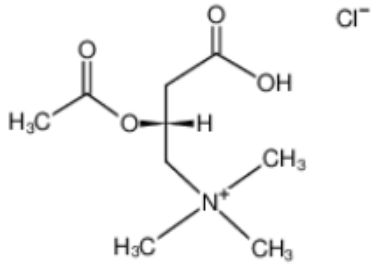
Dietary Supplement Information
for Physicians with Naturokinetics®
**PRODUCT CODE: P0076**
**CATEGORY: NEUROLOGICAL SUPPORT***

# Acetyl-L-Carnitine 500 mg

## TECHNICAL SUMMARY

Acetyl-L-Carnitine (ALC) is a naturally occurring compound that plays a critical role in fat metabolism and cellular energy production.* ALC readily crosses the blood-brain barrier and promotes healthy nerve cell function by maintaining normal mitochondrial bioenergetics, stabilizing cell membranes, and contributing to the production of acetylcholine, an important neurotransmitter that plays a role in learning and memory.* ALC also supports the brain's natural defenses against free radical attack.*

**Structure Formula:** ALC is an acetylated form of L-carnitine, present in the product in hydrochloride form.




**Chemical name:** (R)-3-Acetoxy-4-(trimethylammonio) butyrate hydrochloride

**Allergen and Additive Disclosure:** Not manufactured with yeast, wheat, gluten, soy, milk, egg, fish, shellfish, or tree nut ingredients. Produced in a GMP facility that processes other ingredients containing these allergens.

**Delivery Form:** Vegetable Capsules

## ROLE AS NUTRIENT/FUNCTION

L-carnitine is present in cells and tissues as both free carnitine and acylcarnitines, including acetyl-L-carnitine. L-carnitine is required for energy production.* It facilitates the transport of fatty acids across the inner mitochondrial membrane for subsequent β-oxidation (known as "carnitine shuttle").* In skeletal and cardiac muscle, fatty acids are the predominant substrate for energy production. In the brain, fatty acids become key energy substrates under metabolically compromised conditions. The acetyl moiety of ALC can be used to maintain acetyl-CoA levels, another factor in energy production.* ALC also acts as a partial direct cholinergic agonist and can be converted into acetylcholine, which is a factor in its effects on the neurological and brain tissue.*

## NATUROKINETICS®

**Liberation:** The disintegration of the vegetable capsule using a USP testing method of disintegration occurs between zero and 60 minutes.

**Absorption:** Orally administered ALC is released from the vegetable capsule in the stomach and then absorbed by the small intestines via a sodium cation-dependent active transport system.

**Supplement Facts**

Serving Size 2 Veg Capsules
Servings Per Container 50

| Amount Per Serving | |
|---|---|
| Acetyl-L-Carnitine (from Acetyl-L-Carnitine HCl) | 1 g (1,000 mg)* |

* Daily Value not established.

Other ingredients: Hypromellose (cellulose capsule), Magnesium Stearate (vegetable source) and Stearic Acid (vegetable source).

- **Transports Fatty Acids & Boosts Cellular Energy***
- **Brain and Nerve Cell Function***

**SUGGESTED USAGE: Take 1-2 capsules 1 to 2 times daily as needed, or as directed by your healthcare practitioner.**

Oral administration of 2 g/d ALC for 50 days has been shown to significantly increase plasma levels of ALC in association with a modest increase of total L-carnitine availability.

In a clinical study in healthy individuals, a single 500 mg dose of orally administered acetyl-L-carnitine has been shown to increase plasma ALC levels. In this study, the endogenous baseline concentration of ALC was 1.3 µg/mL, $C_{max}$ and $T_{max}$ were determined to be 1.19 µg/mL and 3.1 h, respectively.

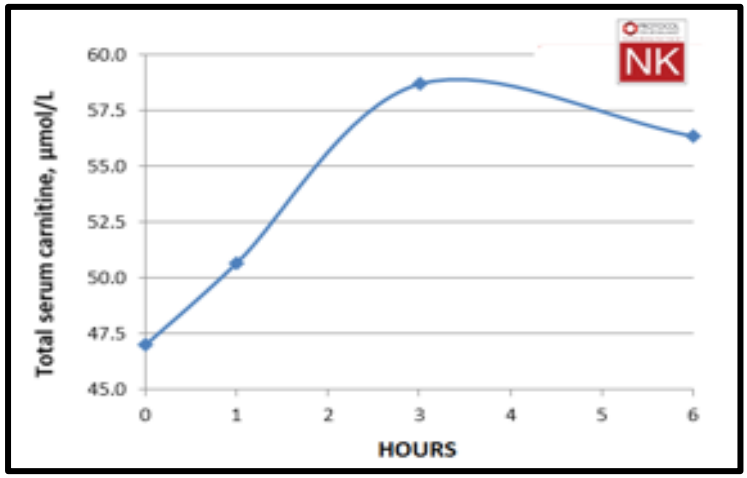



**Fig.1.** Average total serum carnitine level before, 1, 3 and 6 hours following a single administration of two Acetyl-L-Carnitine capsules providing 1,000 mg of Acetyl-L-Carnitine, in healthy adult volunteers.

The absorption of Protocol For Life Balance® Acetyl-L-Carnitine capsules was studied in healthy adult volunteers (Fig.1). Supplemental ALC is shown to increase the levels of available total serum carnitine over a 6-hour period.

**Distribution:** ALC enters the total carnitine body pool, which is comprised of exogenous (approx. 75%) and endogenous carnitine (free and acyl-esters). It is transported into cardiac and skeletal muscle tissue via

carnitine transporters, and then intracellularly, into mitochondria. Carnitine crosses the blood-brain barrier where it selectively accumulates in hypothalamus.

**Metabolism:** During or immediately after uptake into intestinal cells, ALC is de-acetylated and a portion of it is immediately re-acetylated.

**Elimination:** Carnitine is eliminated from the body primarily by renal excretion of non-esterified carnitine and acylcarnitine esters. However, under normal conditions only a very small fraction (usually <5%) of filtered carnitine is excreted. Carnitine that is not absorbed in the small intestine is almost completely degraded by the endogenous flora of the large intestine.

## CLINICAL VALIDATION

- **Cardiovascular Support**.* The utility of ALC in supporting myocardial function is based on the notion that the aging process is accompanied by significant carnitine depletion in the myocardium.* In aging individuals, myocardial depletion is also associated with a marked decline in ejection fraction as compared with myocardium with normal carnitine tissue levels.*

## SAFETY INFORMATION

**Tolerability:** Orally, ALC is generally well tolerated. It may cause mild GI discomfort, and restlessness. One of its metabolites can cause the urine, breath, and sweat to have a fishy odor.

**Caution:** ALC may interact with anticoagulant medications. This product is intended to be used by healthy adults. Caution is advised for use in individuals taking thyroid hormones or have thyroid disorder. Some medications may increase the need for ALC, including AZT, certain antibiotics, isotretinoin, and some anti-seizure medications carbamazepine, phenobarbital, phenytoin, and valproic acid.

**Contraindications:** ALC may interfere with thyroid metabolism and should be avoided in patients with hypothyroidism. Caution is advised for individuals with a propensity to seizures, as an increase in seizure frequency and severity could occur.

## INTERACTIONS

**Drug Interactions.** Acenocoumarol, warfarin: caution is required when associated with ALC (might increase INR). Some drugs (anti-epileptic, anti-retroviral therapy) might interact with ALC metabolism and decrease ALC plasma levels.

**Supplement Interactions.** Avoid using D-carnitine because it might compete with L-carnitine in active transport systems. Taking D-carnitine might cause symptoms of L-carnitine deficiency, and theoretically acetyl-L-carnitine deficiency.

**Interference with Lab Tests.** None known.

## STORAGE

The product has a shelf-life of 2 years when stored at a room temperature without exposure to direct sunlight and excessive moisture.