SCHEDULING STATUS:

PROPRIETARY NAME AND DOSAGE FORM:

L-CARNITINE tablets

Read all of this leaflet carefully because it contains important information for you.

- L-CARNITINE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use L-CARNITINE carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share L-CARNITINE with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT L-CARNITINE CONTAINS:

The other ingredients are: Dicalcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone (PVP).

2. WHAT L-CARNITINE IS USED FOR:

- L-CARNITINE aids in the muscle recovery process by reducing muscle tissue damage associated with a resistance training regimen.
- L-CARNITINE helps support muscle tissue repair in individuals involved in resistance training.
- L-CARNITINE helps improve physical performance when used in conjunction with a training regimen.
- L-CARNITINE helps delay fatigue during physical activity, helps support fat metabolism and fat oxidation.

3. BEFORE YOU TAKE L-CARNITINE:

Do not take L-CARNITINE:

• If you are hypersensitive (allergic) to the active ingredient or any of the other ingredients of L-CARNITINE (see "WHAT L-CARNITINE CONTAINS").

Take special care with L-CARNITINE:

- If you have a liver disease, a kidney disease, or a seizure disorder, consult a healthcare provider prior to use.
- If you have any bleeding disorders. L-CARNITINE can increase the effect of warfarin and your chances of bruising and bleeding.
- If you have an underactive thyroid. L-CARNITINE can make thyroid hormone replacement therapy less effective.
- If you have a seizure disorder. L-CARNITINE can increase the risk of seizures in people who previously had one.
- If you are pregnant or breastfeeding your baby (see "PREGNANCY AND BREASTFEEDING").

Taking L-CARNITINE with food and drink:

• L-CARNITINE should be taken with food.

Pregnancy and Breastfeeding:

- Do not take L-CARNITINE if you are pregnant or breastfeeding your baby.
- If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking this medicine.

Driving and using machinery:

 It is unlikely that L-CARNITINE will affect your ability to drive a vehicle or operate machinery requiring your attention.

Important information about some of the ingredients of L-CARNITINE:

• Sugar free.

Taking other medicines with L-CARNITINE:

• Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are on any of the following medicine or treatment, you should discuss the use of **L-CARNITINE** with your doctor or pharmacist first:

- Warfarin or other blood thinning medication. These medicines can increase the risk of bleeding.
- Thyroid hormone replacements such as thyroxine and levothyroxine. L-CARNITINE can make these
 medicines less effective.
- Valproic acid (antiseizure medication). L-CARNITINE can increase the risk of seizures in people who previously had one.

4. HOW TO TAKE L-CARNITINE:

- Do not share medicines prescribed to you with any other person.
- Always take L-CARNITINE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- Do not exceed the recommended dosage.
- For oral use only.
- Always take L-CARNITINE with enough liquid (water).

The usual dose is:

• Adults: Take 2 tablets in the morning with breakfast and 1 tablet in the afternoon with lunch, or as prescribed by your healthcare provider.

If you take more L-CARNITINE than you should:

- Large doses are reported to cause stomach cramps, nausea (feeling sick), vomiting, diarrhoea (runny loose stool), skin rash, fishy body odour or muscle weakness.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest
 hospital or poison control centre.

If you forget to take/missed a dose of L-CARNITINE:

- Take the missed dose as soon as you remember.
- Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

• L-CARNITINE can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

If any of the following happens, stop taking L-CARNITINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **L-CARNITINE**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

• Less frequent: seizures (fits) in people with seizure disorders.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Frequency unknown: Nausea (feeling nauseous).
- Frequency unknown: Abdominal cramps or stomach pains.
- Frequency unknown: Vomiting.
- Frequency unknown: Diarrhoea (runny, loose stool).
- Less frequent: Skin rash.
- Less frequent: Fishy body odour.
- Less frequent: Muscle weakness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF L-CARNITINE:

- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Store in the original package/container.
- Protect from light and moisture.
- Do not store in the bathroom.
- Keep tightly closed.
- Do not use after the expiry date stated on the container.
- Do not use L-CARNITINE if you notice any discolouration of the tablets.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF L-CARNITINE:

100 tablets, packed inside a white plastic container with a silver screw cap.

8. IDENTIFICATION OF L-CARNITINE:

Oblong, white tablets.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

To be allocated upon registration.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Brunel Laboratoria (Pty) Ltd 1 Van Tonder Street Sunderland Ridge Centurion 0157 info@brunel.co.za www.brunel.co.za

11. DATE OF PUBLICATION:

To be allocated upon registration.

12. DATE OF REGISTRATION:

To be allocated upon registration.

13. COMPLEMENTARY MEDICINE:

Complementary Medicine – Health Supplement. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

The Professional Information for **L-CARNITINE** is available on <u>http://www.brunel.co.za/l-carnitine-tablets-100/</u> or can be requested from the contact details above.

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