UNITED AFRICAN LABORATORY LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the Medicinal Product:** Ultra Coq10
2. **Qualitative and Quantitative:** Coenzyme Q10 (200mg), Vitamin E (Di-alpha-tocopheryl acetate) 20mg
3. **Pharmaceutical Form:** Capsule
4. **Clinical Particulars:**

4.1 Therapeutic indications: Coenzyme Q10 is primarily indicated for treating genetic Coenzyme Q10 deficiencies, reducing migraine frequency, and improving sperm quality in male infertility. It is also widely used as an adjunctive therapy to manage congestive heart failure and mitigate statin-induced muscle pain.

4.2 Posology and method of administration: The recommended dose is one capsule once daily, preferably taken with a meal containing fat.

4.3 Contraindications: Coenzyme Q10 is strictly contraindicated in patients with a known hypersensitivity to Coenzyme Q10/Vitamin E or any inactive excipients in the formulation (such as soy or peanut oil used in specific softgels)**.**

4.4 Special warnings and precautions:

- **Diabetes Mellitus:** Coenzyme Q10 can improve insulin sensitivity and modestly lower blood glucose levels. Patients on anti-diabetic medication or insulin require close blood glucose monitoring to prevent hypoglycemia.
- **Hepatic or Biliary Insufficiency:** Coenzyme Q10 is metabolized by the liver and eliminated primarily via bile. Use with caution in patients with hepatic impairment or biliary obstruction, as accumulation may occur.
- **Chemotherapy and radiotherapy:** Because Coenzyme Q10 and Vitamin E possess antioxidant activity, concomitant use with certain anticancer treatments should be discussed with the treating oncologist. The clinical significance of possible interference with oxidative mechanisms of some anticancer therapies has not been established.
- **Bleeding disorders and surgery:** Vitamin E may have effects on platelet function and haemostasis, particularly at higher doses. Caution should therefore be exercised in patients with bleeding disorders and in patients receiving anticoagulant or antiplatelet medicines. Patients scheduled for major elective surgery should inform their healthcare professional that they are taking this product. Consideration should be given to

discontinuation before surgery based on individual bleeding risk and concomitant medicines.

4.5 Interaction with other medicinal products and other forms of interaction with Antibiotics:

- **Anticoagulants (e.g., Warfarin):** Coenzyme Q10 has been reported to reduce the anticoagulant effect of warfarin in some patients, although controlled clinical evidence is conflicting. Vitamin E may also influence haemostasis, particularly at higher doses. Patients receiving anticoagulants should therefore be monitored clinically and, where appropriate, by coagulation testing when this product is initiated or discontinued.
- **Antihypertensives:** Coenzyme Q10 may exert a synergistic blood pressure-lowering effect. Dosage adjustments of antihypertensive drugs may be necessary to avoid hypotension.
- **HMG-CoA Reductase Inhibitors (Statins):** Statins (e.g., atorvastatin, simvastatin) inhibit the mevalonate pathway, which is shared by cholesterol and Coenzyme Q10 synthesis. This significantly decreases endogenous tissue and plasma concentrations of Coenzyme Q10.
- **Chemotherapeutic agents:** The antioxidant properties of Coenzyme Q10 and Vitamin E may theoretically interact with treatments whose therapeutic effects partly depend on oxidative mechanisms. Patients receiving chemotherapy or radiotherapy should seek advice from their treating specialist before using this product.

4.6 Pregnancy and lactation

- **Pregnancy:** There are insufficient clinical data on the use of the combination of Coenzyme Q10 and Vitamin E during pregnancy. As a precautionary measure, use during pregnancy should be undertaken only when considered clinically necessary and following an assessment of the potential benefits and risks.
- **Breast-feeding**: It is not known whether supplementation with Coenzyme Q10 at the dose contained in this product results in clinically relevant exposure in breast-fed infants. Vitamin E is naturally present in breast milk. A decision should be made whether to discontinue breast-feeding or to discontinue/avoid treatment, taking into account the benefit of breast-feeding for the child and the benefit of treatment for the mother.

4.7 Effects on ability to drive and use machines: Coenzyme Q10/Vitamin E capsules have no or negligible influence on the ability to drive and use machines. Patients who experience dizziness or other symptoms that may impair concentration should avoid driving or operating machinery until the symptoms resolve.

4.8 Undesirable effects: Adverse reactions are typically mild and transient, classified below by system organ class:

- **Gastrointestinal disorders (Common):** Nausea, dyspepsia, epigastric discomfort, diarrhea, loss of appetite.
- **Nervous system disorders (Rare):** Dizziness, headache, insomnia.

- **Skin and subcutaneous tissue disorders (Rare):** Allergic skin rash, photosensitivity.

4.9 Overdose Symptoms: Coenzyme Q10 has generally demonstrated a wide safety margin. Excessive intake may result in gastrointestinal symptoms, including nausea, abdominal discomfort and diarrhoea. Excessive intake of Vitamin E may result in gastrointestinal disturbances and, at substantially high exposures, may increase the risk of bleeding, particularly in patients receiving anticoagulant or antiplatelet therapy.

5. Pharmacological properties:

5.1 Pharmacodynamic Properties: Coenzyme Q10 and Vitamin E provide complementary antioxidant activity. Coenzyme Q10 additionally contributes to mitochondrial electron transport and cellular energy metabolism, whereas Vitamin E primarily provides protection against oxidative damage to membrane lipids and other lipid-containing cellular structures.

5.2 Mechanism of Action:

- **Coenzyme Q10:** Coenzyme Q10 is an essential lipid-soluble electron carrier of the mitochondrial respiratory chain. It accepts electrons from Complexes I and II and transfers them to Complex III, contributing to the generation of the proton gradient required for ATP synthesis. In its reduced form, ubiquinol, Coenzyme Q10 acts as an antioxidant within biological membranes and lipoproteins. It helps limit lipid peroxidation and can participate in the regeneration of other antioxidants, including alpha-tocopherol.
- **Vitamin E (D-alpha-tocopheryl acetate):** Vitamin E is incorporated into lipid membranes and acts primarily as a chain-breaking antioxidant. It reacts with lipid peroxyl radicals, thereby interrupting lipid peroxidation and protecting membrane lipids from oxidative damage. Vitamin E can subsequently be regenerated to its reduced form through interactions with other antioxidant systems, including those involving Coenzyme Q10.

5.3 Volume of distribution: Following absorption, Coenzyme Q10 is incorporated into chylomicrons and enters the systemic circulation primarily via the lymphatic system. In the blood, more than 95% of Coenzyme Q10 is bound to lipoproteins, predominantly low-density lipoproteins (LDL). It is widely distributed into tissues with high metabolic energy requirements. It shows preferential accumulation in the myocardium, liver, kidneys, and skeletal muscle. The apparent volume of distribution (V_d) is high, estimated at approximately 20.4 L/kg, reflecting extensive intracellular uptake and partitioning into lipophilic cellular membranes. Coenzyme Q10 crosses the blood-brain barrier in limited amounts.

5.4 Preclinical safety data: Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction and development.

6. **PHARMACEUTICAL PARTICULARS**

6.1 List of excipients: Bioperine, Phospholipids, Microcrystaline Cellulose.

6.2 Shelf Life: 3 years

6.3 Special Precaution for Storage: Store in a cool dry dark place below 30 °C

7. **Marketing Authorisation Holder**
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