UNITED AFRICAN LABORATORY LTD

Registered Office 9 Tebun Bisiriyu Str, Shasha, Lagos State. 07063877874 08067757480 Mailing Address: 2 Modupeola Street, Onipetesi Estate, Mangoro, Ikeja, 08033233079

Summary of Product Characteristics

NAME OF THE MEDICINAL PRODUCT

HB12 NIGHT CAPLETS

2. **QUALITATIVE AND QUANTITATIVE:** Haemoglobin 375mg

PHARMACEUTICAL FORM: Caplets

CLINICAL PARTICULARS: Therapeutic indications of HB12 Night Caplet is indicated as a nutritional supplement for; patients with fatty liver, poor memory function, menopausal syndrome, cardiovascular disease, low immunity, pregnancy, anemia, high level of cholesterol, diabetes, night blindness, fertility problems, influenza, vegetarian diet and malabsorption syndromes. This product is intended for use in children and adult.

Melatonin: It is a hormone normally produced in the pineal gland and released into the blood.

- It helps regulate sleep-wake cycle or the circadian rhythm.
- It is also an antioxidants: Removes free radicals and increases the efficiency of Mitochondrial Oxidative Phosphorylation.
- Production of melatonin is stimulated by darkness and inhibited by light. High levels of
 melatonin induce sleep and so consumption of the exogenous melatonin can be used to combat
 insomnia and jet lag.
- 3. Posology and method of administration: One Caplets daily. (Adults)
- 4. **Contraindications:** Hypersensitivity to any of the active ingredients or excipients.
- 5. **Special warnings and precautions:** Before taking this product, tell your doctor or pharmacist if you are allergic to any of it ingredients; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

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Before taking this medication, tell your doctor or pharmacist your medical history, especially of: use/abuse of alcohol, liver problems, stomach/intestinal problems (such as ulcer, colitis). If your brand of multivitamin also contains folic acid, be sure to tell your doctor or pharmacist if you have vitamin B12 deficiency (pernicious anemia) before taking it. Folic acid may affect certain lab tests for vitamin B12 deficiency without treating this anemia. Untreated vitamin B12 deficiency may result in serious nerve problems (such as peripheral neuropathy). Consult your doctor or pharmacist for details.

- 5.1 Interaction with other medicinal products and other forms of interaction with Antibiotics: If you use other drugs or over the counter products at the same time, it reduces the effect of. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. HB12 Night Caplet may interact with the following drugs and products:
- Arsenic trioxide
- Chloramphenicol
- Folic acid
- Furosemide
- Gabapentin
- Hydrochlorothiazide
- Levothyroxine
- Lisinopril
- **5.2 Pregnancy and lactation:** Pregnancy: No adverse effects have been reported with ingestion of normal daily requirements during pregnancy
- 5.3 Lactation: Vitamin B12 has been found distributed into the milk of nursing women in concentrations similar to the maternal blood vitamin B12 concentrations. No adverse effects have been reported to date with intake of normal required doses during lactation.
- 6. **Effects on ability to drive and use machines:** No negative influence on the ability to drive and use machines.

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Undesirable effects: Administration of HB12 Night Caplet may cause Swelling, Rapid weight gain, Diarrhea, Itching or mild rash.

- **8. Overdose Symptoms:** Headache, Nausea and vomiting, Diarrhea, Fatigue or weakness, Tingling sensation in hands and feet.
- **9. Treatment of toxicity following recent ingestion:** If a person suspects HB12 Night Caplet overdose, they can contact their local poison control Centre for advice, unless a poison control representative or a healthcare professional provides alternative advice, the person should drink a glass of milk.

Pharmacological properties: Composition HB12 Night Caplet let. It is effective for the treatment, prevention and control of Scurvy, Anaemia, Wound healing, Vitamin B12 deficiency, Tissue repair and some others.

- **10.1 Volume of distribution:** Cobalamin is distributed to tissues and stored mainly in the liver and bone marrow.
- **10.2** . **Preclinical safety data:** No data of relevance which is additional to that already included in other sections of the SmPC.

11. PHARMACEUTICAL PARTICULARS

11.1. List of excipients: Hemoglobin, Amino acid Chelatd Iron, Vitamin B12, Zinc gluconate, Organic selenium, Melatonin.

Marketing Authorisation Holder

United African Laboratories Ltd.

9 Tebun Bisiriyu Street, Shasha Lagos State.