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

Osteoflex Advanced

2. **QUALITATIVE AND QUANTITATIVE:** Glucosamine 1500mg

PHARMACEUTICAL FORM: A White Oblong Caplets

CLINICAL PARTICULARS: Glucosamine is generally used over the counter in the symptomatic treatment of osteoarthritis and joint pain, This product is intended for use in adult

- 3. Posology and method of administration: 2 tablets daily
- 4. Contraindications: Hypersensitivity to any of the active ingredients or excipients
- 5. **Special warnings and precautions: When taken by mouth**: Osteoflex Advanced is possibly safe for most adults when used for up to 10 weeks. Please contact your doctor or pharmacist before use.
- 4.5 Interaction with other medicinal products and other forms of interaction with Antibiotics: Taking Osteoflex Advanced caplets with other drug together might reduce the effectiveness of both medication. Warfarin (Jantoven). Taking glucosamine alone or in combination with the supplement chondroitin might increase the effects of the anticoagulant warfarin. This can increase your risk of bleeding.
- **5. Pregnancy and lactation:** Pregnancy: There is no enough reliable information to know if glucosamine sulfate, glucosamine hydrochloride, or N-acetyl glucosamine is safe to use when pregnant or breast-feeding. Stay on the safe side and avoid use.
- **5a. Lactation:** Any food or drug intake by the mother passes to her infant when she feeds. Hence, if you are taking Glucosamine, then it is wise to consult your medical practitioner before continuing the same. We suggest this is because Glucosamine is not safe for children below 18 years and certainly not safe for infants.

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- 6. **Effects on ability to drive and use machines:** No negative influence on the ability to drive and use machines.
- **7. Undesirable effects:** Administration of Osteoflex Advanced tablets may cause nausea, heartburn. diarrhea, constipation.
 - **8. Overdose Symptoms:** High doses of Osteoflex Advanced can be harmful. Signs of too much Osteoflex Advanced in the body include nausea, dizziness, headaches, upset stomach, vomiting, and loss of appetite. Over dosage with zinc has also been associated with acute renal tubular necrosis and interstitial nephritis. Prolonged high dose zinc supplementation may result in copper deficiency.
 - 9. **Treatment of toxicity following recent ingestion:** If a person suspected to be Osteoflex Advanced 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. The calcium and phosphorus in the milk can help bind the excessiveness of the drug and prevent the stomach and intestines from absorbing it.
 - 10. **Pharmacological properties:** Glucosamine sulfate is a normal component of glycosaminoglycans in the cartilage matrix and synovial fluid. This salt may have a role in slowing cartilage breakdown. The mechanisms of action for glucosamine include maintaining elasticity, strength and resilience of the cartilage, the inhibition of proteolytic enzymes (elastase, hyaluronidase) and promotion of glycosaminoglycan and proteoglycan synthesis. **Mechanism of action:** The mechanisms of action for glucosamine include maintaining elasticity, strength and resilience of the cartilage, the inhibition of proteolytic enzymes (elastase, hyaluronidase) and promotion of glycosaminoglycan and proteoglycan synthesis.

Volume of distribution: Crystalline glucosamine sulfate 1500 mg once daily is recommended in the majority of clinical practice guidelines and was found to be cost effective in pharmacoeconomic analyses

11. **Preclinical safety data:** No data of relevance which is additional to that already included in other sections of the SmPC.

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11. Pharmaceutical Particulars

11.1. List of excipients: Glucosamine Hydrochloride 1500mg, Chondroitin Sulfate 200mg, Hyaluronic Acid 3.3mg, Calcium fructoborate 216mg, MSM (Methylsufanylmethane) 1200mg

Marketing Authorisation Holder

United African Laboratories Ltd. 9 Tebun Bisiriyu Street, Shasha Lagos State