

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF DRUG PRODUCT**

OSAM-D Tablets

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film-coated tablet contains:

Ossein Mineral Complex 830mg corresponds to:

Calcium ...177.6mg"

Phosphorus ...82.2mg"

Residual mineral salts ... 24.9mg

Collagen ...224.0mg

Other proteins ...66.4mg

Trace elements ...F, Mg, Fe, Zn, Cu, Ni.

\*Corresponds to approx. 440mg Hydroxyapatite.

Vitamin D BP ...400IU

### **3. PHARMACEUTICAL FORM**

Cream-colored oblong shaped film coated tablets plain on both sides.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

OSAM-D (Ossein Mineral Complex + Vitamin D) tablets are indicated for the treatment of:

- Increased mineral requirements during pregnancy and lactation.
- Osteoporosis
- Osteomalacia
- Prophylaxis against dental caries
- As adjuvant in fractures with delayed callus formation.

#### **4.2 Posology and method of administration**

Adult dose:

1 to 2 tablets daily before meals with water / juice or as recommended by the physician.

In Osteoporosis: Increased dosage as prescribed by the physician.

#### **4.3 Contraindications**

None

#### **4.4 Special warnings and special precautions for use**

- Precaution should be taken in patients with known hypersensitivity to Vitamin D or any of its derivatives.
- Precaution should be taken in patients who are having excess intake of Vitamin D that may lead to hypercalcemia for excess bone loss.

#### **4.5 Interaction with other medicaments**

A physician's consultations necessary if OSAM-D (Ossein Mineral Complex + Vitamin D) is to be used along with these drugs:

*Antacids:* Hypermagnesemia (high blood magnesium levels) may develop when Ossein Mineral Complex + Vitamin D is taken with magnesium-containing antacids particularly in patients with chronic renal failure.

*Anti-Seizure drugs:* Decreased Vitamin D effects may occur with the use of certain anti-seizure drugs, as they may induce hepatic microsomal enzymes and accelerate the conversion of Vitamin D to inactive metabolites.

*Cholestyramine/Colestipol:* As much time as possible should be allowed between the ingestion of these drugs and Ossein Mineral Complex + Vitamin D as the intestinal absorption of Vitamin D may be impaired with the use of these agents.

*Corticosteroids:* Use of corticosteroids can cause osteoporosis and calcium depletion with long-term administration.

*Digoxin:* Ossein Mineral Complex + Vitamin D should be used with caution in patients taking digoxin, because hypercalcemia (which may result with excess vitamin D use) may precipitate abnormal heart rhythms.

*Orlistat:* It can reduce Vitamin D level in patient.

*Rifampin:* It increases vitamin D metabolism and reduces Vitamin D blood levels.

*Thiazides:* Concurrent administration of thiazide diuretics and Vitamin D to hypoparathyroid patients may cause hypercalcemia, which may be transient or may require discontinuation of Ossein Mineral Complex + Vitamin D.

#### **4.6 Pregnancy and Lactation**

It fulfils mineral requirements during pregnancy and lactation.

#### **4.7 Effects on ability to drive and use machine**

There will be no effects on ability to drive and use machine.

#### **4.8 Undesirable effects**

Ossein Mineral Complex + Vitamin D is well tolerated in recommended doses.

### **5. PHARMACEUTICAL PARTICULARS**

#### **5.1 List of excipients**

Corn Starch, Lactose Regular, Glycine 100%, Sodium Starch Glycolate, Butylated Hydroxyanisole, Cross Povidone (Kollidon-CL), Aerosil 200, Magnesium Stearate, Purified Water, Opadry Yellow II 85G32558

#### **5.2 Incompatibilities**

None

#### **5.3 Shelf-life**

3 Years.

The expiration dates refer to the product correctly stored in the required conditions.

#### **5.4 Special precautions for storage**

Store below 30°C.

Protect from sunlight & moisture.

The expiration date refers to the product correctly stored at the required conditions.

#### **5.5 Nature and contents of container**

OSAM-O (Ossein Mineral Complex + Vitamin D) Tablets are available in blister pack of 30's.

#### **5.6 Instructions for use/handling**

- To be sold on prescription of a registered medical practitioner only.
- Keep out of the reach of children.

### **6. MARKETING AUTHORISATION HOLDER**

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