Ostel®-D

COMPOSITION
Ostel®-D 10/400 Tablet: Each film coated tablet contains Sodium Alendronate BP equivalent to Alendronic Acid 10 mg and Vitamin D3 (Colecalciferol BP) 400 IU.
Ostel®-D 70/2800 Tablet: Each film coated tablet contains Sodium Alendronate BP equivalent to Alendronic Acid 70 mg and Vitamin D3 (Colecalciferol BP) 2800 IU.

PHARMACOLOGY
Alendronate Sodium is a bisphosphonate that acts as a specific inhibitor of osteoclast mediated bone resorption. Alendronate is effective when administered at least 30 minutes before breakfast. It transiently distributes to soft tissues following administration but is then rapidly distributed to bone or excreted in the urine. Protein binding in human plasma is approximately 78%. There is no evidence that Alendronate is metabolised in animals or humans. At the cellular level, Alendronate shows preferential localization to sites of bone resorption, specially under osteoclasts. It inhibits osteoclast activity. In addition, bone formation exceeds bone resorption, leading to progressive gains in bone mass. Vitamin D is required for normal bone formation. Vitamin D insufficiency develops when both sunlight exposure and dietary intake are inadequate. Insufficiency is associated with negative calcium balance, increased parathyroid hormone levels, bone loss, and increased risk of skeletal fracture.

INDICATIONS
Treatment of osteoporosis in postmenopausal women.
Treatment of osteoporosis in men.
In the treatment of osteoporosis Ostel®-D increases bone mass and reduces the incidence of fractures, including those of the hip and spine.

DOSAGE AND ADMINISTRATION
Treatment of osteoporosis in post-menopausal women: Ostel®-D 70/2800 tablet once weekly or Ostel®-D 10/400 tablet once daily. Treatment to increase bone mass in men with osteoporosis: Ostel®-D 70/2800 tablet once weekly or Ostel®-D 10/400 tablet once daily. To permit adequate absorption, Ostel®-D must be taken at least 30 minutes before the first food, beverage or medication of the day with plain water only. Other beverages (including mineral water), food and some medications are likely to reduce the absorption of Alendronate. To facilitate delivery to the stomach and thus to reduce the potential for esophageal irritation, Ostel®-D tablet should only be swallowed upon rising for the day with a full glass of water. Patients should not lie down for at least 30 minutes after taking Alendronate until after their first food of the day. Ostel®-D should not be taken at bed time.

SIDE EFFECT

Usually mild and generally do not require discontinuation of therapy. Side effects include esophageal reactions, abdominal pain and distension, diarrhoea or constipation, flatulence, musculoskeletal pain, headache, rash, erythema and transient decreases in serum calcium and phosphate.

PRECAUTION

Hypocalcaemia and other disturbances of mineral metabolism should be corrected before initiation of therapy. Alendronate can cause local irritation of the upper gastro-intestinal mucosa. Caution should be used when Alendronate is given to patients with active upper gastrointestinal problems such as dysphagia, esophageal disease, gastritis, duodenitis or ulcers. Patients should stop taking medicine and consult their physician if they develop esophageal diseases. No dosage adjustment is necessary for the elderly or for patients with mild-to-moderate renal insufficiency (creatinine clearance 35 to 60 ml/min). Ostel-D is not recommended for patients with more severe renal insufficiency (creatinine clearance < 35 ml/min).

CONTRAINDICATION

Abnormalities of the esophagus which delay esophageal emptying, such as stricture or achalasia
Inability to stand or sit upright for at least 30 minutes
Hypersensitivity to any component of this product
Hypocalcaemia

USE IN PREGNANCY AND LACTATION

Alendronate Sodium is pregnancy category C. Overdoses of vitamin-D have shown teratogenic effects in pregnant animals. Ostel®-D should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus. Cholecalciferol and some of its active metabolites pass into breast milk. It is not known whether alendronate is excreted in human milk. Caution should be exercised when Ostel®-D is administered to lactating women.

DRUG INTERACTION

Calcium supplement, antacids and some oral medications will interfere with absorption of Alendronate if taken at the same time. Intravenous ranitidine makes the bioavailability of oral Alendronate double. Incidence of upper gastro-intestinal adverse events associated with NSAID and aspirin appears to be greater with concomitant administration of Alendronate. Mineral oils, orlistat, and bile acid sequestrants (e.g., cholestyramine, colestipol) may impair the absorption of vitamin D. Anticonvulsants, cimetidine, and thiazides may increase the catabolism of vitamin D.

OVERDOSE

Hypocalcemia, hypophosphatemia, and upper gastrointestinal adverse events, such as upset stomach, heartburn, esophagitis, gastritis, or ulcer, may result from oral overdosage. Signs and symptoms of vitamin D toxicity include hypercalcemia, hypercalciuria, anorexia, nausea, vomiting, polyuria, polydipsia, weakness, and lethargy.

STORAGE CONDITION

Store in a cool and dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Ostel®-D 10/400 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister pack.
Ostel®-D 70/2800 Tablet: Each box contains 1 x 8 tablets in Alu-Alu blister pack.