



**Ostel®**

Alendronate Sodium  
**Bone Calcium Regulator**

### **COMPOSITION**

Ostel® Tablet : Each tablet contains alendronate sodium INN 13.05 mg, which is equivalent to alendronic acid 10 mg.

### **PHARMACOLOGY**

Oral bioavailability of 10 mg tablet is 0.78% when administered after an overnight fast and 2 hours before breakfast. Ostel® 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. Protein binding in human plasma is approximately 78%. There is no evidence that Ostel® is metabolised in animals or humans.

Mechanism of action:

At the cellular level Ostel® (alendronate) shows preferential localization to sites of bone resorption, especially under osteoclasts. It does not interfere with osteoclast recruitment or attachment, but it inhibits osteoclast activity. It reduces bone turnover i.e. the number of sites at which bone is remodeled. In addition, bone formation exceeds bone resorption at these remodeling sites leading to progressive gains in bone mass.

### **INDICATION**

Treatment and prevention of osteoporosis in post menopausal women.  
For the prevention of osteoporosis  
For the treatment of glucocorticoid induced osteoporosis  
Treatment of Paget's disease of bone

### **DOSAGE AND ADMINISTRATION**

Osteoporosis in post-menopausal women: 10 mg once daily.

Prevention and treatment of osteoporosis: 10 mg once daily.

Glucocorticoid induced osteoporosis: 10 mg once daily.

Paget's disease induced of bone : 40 mg once daily for 6 months.

To permit adequate absorption, Ostel® 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 Ostel®. To facilitate delivery to the stomach and thus to reduce the potential for esophageal irritation, Ostel® 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

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Ostel® until after their first food of the day. Patients should not chew or suck on the tablet. Ostel® 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.

**CONTRAINDICATION AND PRECAUTION**

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 and other disturbances of mineral metabolism should be corrected before initiation of therapy.

Alendronate can cause local irritation of the upper gastro-intestinal mucosa. Because there is a potential for worsening of the underlying disease, 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 such as difficulty or pain upon swallowing, retrosternal pain, new or worsening heart burn.

No dosage adjustment is necessary for the elderly or for patients with mild-to-moderate renal insufficiency (creatinine clearance 35 to 60 ml/min). Alendronate is not recommended for patients with more severe renal insufficiency (creatinine clearance <35 ml).

**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.

**USE IN PREGNANCY AND LACTATION**

Alendronate has not been studied in pregnant and breast feeding women and should not be given to them.

Safety and effectiveness in paediatric patients have not been established.

## Ostel®

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### **STORAGE CONDITION**

Store at temperature below 30° C

### **HOW SUPPLIED**

Ostel® Tablet : Box containig 3 x10 tablets in blister pack.



**BONE CALCIUM REGULATOR THERAPEUTIC CLASS**

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**Oxilar®**

Raloxifene Hydrochloride  
**Bone Calcium Regulator**

### **COMPOSITION**

Oxilar® tablet : Each film-coated tablet contains Raloxifene Hydrochloride INN equivalent to Raloxifene 60 mg.

### **PHARMACOLOGY**

Raloxifene is a selective estrogen receptor modulator (SERM) that belongs to the benzothiophene class of compounds. It reduces resorption of bone and decreases overall bone turnover as evidenced by reductions in serum and urine levels of bone turnover markers, radiocalcium kinetics studies for decreased bone resorption and increases in bone mineral density (BMD).

Decrease in estrogen levels after oophorectomy or menopause lead to increase in bone resorption and bone loss. Initially bone resorption is rapid because the compensatory increase in bone formation is inadequate to offset resorptive losses. The imbalance between resorption and formation is related to loss of estrogen, and may also involve age-related impairment of osteoblasts or other precursors.

Raloxifene's biological actions, like those of estrogen, are mediated through estrogen receptor binding, which results in differential expression of multiple estrogen-regulated genes in different tissues.

Clinical data indicate that Raloxifene has estrogen-like effects on bone (increase in BMD) and on lipid (decrease in total and LDL cholesterol levels) metabolism. Raloxifene is an estrogen antagonist and lacks estrogen-like effects in uterine and breast tissues.

### **INDICATIONS AND USES**

Oxilar® is indicated for the treatment and prevention of osteoporosis in post-menopausal women.

### **DOSAGE AND ADMINISTRATION**

The recommended dosage is 60 mg daily, which may be administered any time of day without regard to meals.

### **PRECAUTIONS**

Raloxifene should be avoided in women with active venous thromboembolism, or a history of thromboembolic disorders. It should be discontinued at least 72 hours prior to periods of prolonged immobilization, such as post-surgical recovery. Raloxifene should be used with caution in women with congestive heart failure or active malignancy, who may be at

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## Oxilar®

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increased risk of thrombo-embolic disease. It should be used with caution in hepatic impairment and severe renal impairment. It should not be given to women with undiagnosed vaginal bleeding.

### **SIDE EFFECT**

The most common adverse effects of Raloxifene are hot flushes and leg cramps. Raloxifene is associated with an increased risk of venous thrombo-embolic events, particularly during the first 4 months of treatment. Peripheral edema has also been reported.

### **CONTRAINDICATION**

Raloxifene is contraindicated in women with active or a history of venous thromboembolic events, including deep vein thrombosis, pulmonary embolism and retinal vein thrombosis; hypersensitivity to Raloxifene or other constituents of the drug.

### **DRUG INTERACTION**

Cholestyramine reduces the systemic absorption of Raloxifene. Raloxifene may reduce the anticoagulant effect of warfarin. Patients on warfarin should undergo monitoring when Raloxifene therapy is initiated. No clinically important interactions have been reported when Raloxifene is co-administered with digoxin, non-steroidal anti-inflammatory drugs, oral antibiotics, benzodiazepines, analgesics, or histamine receptor blockers.

### **USE IN PREGNANCY AND LACTATION**

Raloxifene should not be given to pregnant and lactating women.

### **STORAGE CONDITION**

Keep at a cool and dry place, protected from light and moisture.

### **HOW SUPPLIED**

Oxilar® tablet: Box containing 1x10's tablet in blister pack.

