

Alendon®

Tablet

Description

Alendon is a preparation of Alendronic acid, a biphosphonate used in the treatment and prevention of osteoporosis in post-menopausal women.

Indications

Alendon is indicated for the :

- ♦ Treatment and prevention of osteoporosis in post-menopausal women
- ♦ Treatment of osteoporosis, Alendon increases bone mass and reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures)
- ♦ Prevention of osteoporosis, Alendon may be considered in post-menopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and to reduce the risk of future fracture
- ♦ Treatment to increase bone mass in men with osteoporosis
- ♦ Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who have low bone mineral density. Patients treated with glucocorticoids should receive adequate amounts of calcium and vitamin D
- ♦ Treatment of Paget's disease of bone in men and women

Dosage and Administration

Treatment of osteoporosis in post-menopausal women

The recommended dose is one Alendon 70 tablet (70 mg) once weekly or one Alendon tablet (10 mg) once daily.

Treatment to increase bone mass in men with osteoporosis

The recommended dose is one Alendon tablet (10 mg) once daily. Alternatively, one Alendon 70 tablet (70 mg) once weekly may be considered.

Prevention of osteoporosis in post-menopausal women

The recommended dose is 35 mg once weekly or 5 mg once daily. The safety of treatment and prevention of osteoporosis with Alendronic acid has been studied for up to 7 years.

Treatment of glucocorticoid-induced osteoporosis in men and women

The recommended dose is 5 mg once daily, except for post-menopausal women not receiving oestrogen, for whom the recommended dose is 10 mg once daily.

Paget's disease of bone in men and women

The recommended treatment regimen is 40 mg once a day for six months.

Contraindications

Hypocalcaemia; Renal impairment; Vitamin D deficiency; Active gastrointestinal problem such as dysphagia, oesophago-duodenitis or ulcer; and Hypersensitivity to any components of the tablet.

Drug Interactions

The incidence of upper gastrointestinal side effects are increased with the concomitant use of non-steroidal anti-inflammatory agents and aspirin. Absorption of Alendronate is reduced in the presence of antacids and calcium supplements.

Side Effects

The commonest symptomatic side effects are constipation, diarrhoea, oesophageal ulcer, flatulence, dysphagia, musculoskeletal pain, headache, rarely rash, erythema, transient decrease in serum calcium and phosphate, nausea, vomiting, peptic ulceration, hypersensitivity reactions including urticaria and angio-oedema.

Use in Special Populations

Pregnancy and lactation : Alendronate should not be given to pregnant women or nursing mother.

Elderly : No dosage adjustment is required for elderly patients. Because in clinical study there was no evidence of age related differences in the efficacy or safety profiles of Alendronic acid.

Children : It is not recommended for use.

Commercial Packs

Alendon[®] 70 Tablet : Box containing 30 tablets in 3 x 10's blister strips.
Each tablet contains Alendronate Sodium BP equivalent to 70 mg of Alendronic acid.

Alendon[®] 10 Tablet : Box containing 30 tablets in 3 x 10's blister strips.
Each tablet contains Alendronate Sodium BP equivalent to 10 mg of Alendronic acid.