Osteve®

Alendronate Sodium

DESCRIPTION :

Osteve (Alendronate Sodium) is a biophosphonate that acts as specific inhibitor of osteoclast-mediated bone resorption. Biophosphonates are synthetic analogs of pyrophosphate that bind to the hydroxypatite found in bone.

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each tablet of ***Osteve*** 35 contains alendronate sodium equivalent to 35mg of alendronic acid.

Each tablet of ***Osteve*** 70 contains alendronate sodium equivalent to 70mg of alendronic acid.

EXCIPIENTS:

See list of excipients.

THERAPEUTIC INDICATIONS:

- Treatment of postmenopausal osteoporosis.
- Prevention of postmenopausal osteoporosis.
- Treatment to increase bone mass in men with osteoporosis.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic Properties :

Alendronate is a biophosphonate that binds to bone hydroxyapatite and specifically inhibits the activity of osteoclasts, the bone-resorbing cells. Alendronate reduces bone resorption with no direct effect on bone formation, although the later process is ultimately reduced because bone resorption and formation are coupled during bone turnover.

Pharmacokinetic Properties :

Absorption :

In studies of treatment and prevention of osteoporosis, alendronate was effective when administered at least 30 minutes before breakfast. Concomitant administration of alendronate with coffee or orange juice reduced bioavailability by approximately 60 %.

Distribution:

Alendronate transiently distributes to soft tissues following administration but it is rapidly redistributed to bone or excreted in urine. Concentrations of drug in plasma following therapeutic oral dose are too low (less than 5 ng/mL).

Metabolism:

There is no evidence that alendronate is metabolised in animals or humans.

Excretion:

Alendronate is excreted unchanged in urine and little or no amount is recovered in faeces.

DOSAGE AND ADMINISTRATION:

- Treatment of postmenopausal osteoporosis, the usual dose is 70 mg once weekly.
- Prevention of postmenopausal osteoporosis, the usual dose is 35 mg once weekly.
- Treatment to increase bone mass in men with osteoporosis, the usual dose is 70 mg once weekly.

Swallow the whole tablet with a full glass of water on an empty stomach at least 30 minutes before breakfast (and any other oral medication); stand or sit upright for at least 30 minutes and do not lie down until after eating breakfast. Do not take the tablets at bedtime or before rising.

Patients should not chew the tablet or allow the tablet to dissolve in their mouths because of a potential for oropharyngeal ulceration.

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

Based on known pharmacokinetics of alendronate, no dosage adjustment is necessary for patients with liver function abnormalities.

CONTRA-INDICATIONS:

Hypersensitivity to any component of this product.

Abnormalities of esophagus and other factors which delay emptying (e.g. stricture or achalasia), hypocalcaemia, renal impairment, (creatinine clearance < 35 mL/min) inability to stand or sit upright for 30 minutes.

Use in children :

Osteve is not indicated for children.

PRECAUTIONS:

Correct disturbances of calcium and mineral metabolism (e.g. vitamin-D deficiency, hypocalcaemia), before initiating treatment with ***Osteve***.

Esophageal adverse experiences, such as esophagitis, esophageal ulcers and esophageal erosions have been reported in patients receiving treatment with ***Osteve***. In some cases these have been severe and required hospitalization. Physicians should therefore be alert to any signs or symptoms signaling a possible esophageal reaction and patients should be instructed to discontinue this drug and seek medical attention if they develop dysphagia, odynophagia, retrosternal pain or new or worsening heartburn.

The risk of severe esophageal adverse experiences appears to be greater in patients who fail to take Osteve properly. It is very important that the full dosing instructions are provided to, and understood by, the patient (see Dosage and Administration). Patient should be informed that failure to follow these instructions may increase their risk of esophageal problems.

Because of possible irritant effects of ***Osteve*** on the upper gastrointestinal mucosa and a potential for worsening of the underlying disease, caution should be used when this drug is given to patients with active upper gastrointestinal problems.

Missed dose :

Patient should be instructed that if they miss a dose of once weekly ***Osteve***, they should take one dose on the morning after they remember. They should not take two doses on the same day but should return to taking one dose once a week as originally scheduled on their choosen day.

PREGNANCY AND LACTATION:

Pregnancy category C.

Alendronate has not been studied in pregnant and breast-feeding women and is only indicated for the treatment of osteoporosis in postmenopausal women.

Effects on ability to drive and use machines

There is no evidence that ***Osteve*** affects the ability to drive or use machines.

DRUG INTERACTIONS:

- Antacids, calcium salts, and iron salts reduce gastrointestinal absorption of Osteve. Therefore, patients must wait at least one-half hour before taking any medications.

SIDE EFFECTS:

Esophageal reactions, abdominal pain and distention, diarrhoea or constipation, flatulence, musculoskeletal pain, headache; rarely rash, erythema, transient decrease in serum calcium and phosphate; nausea, vomiting, peptic ulceration and hypersensitivity reactions (including urticaria and angioedema) also reported.

Overdose:

Hypocalcemia, hypophosphatemia and upper gastrointestinal adverse events, such as upset stomach, heartburn, esophagitis, gastritis, or ulcer, may result from oral overdosage. No specific information is available on the treatment of overdosage with ***Osteve***.

Milk or antacids should be given to bind alendronate.

Due to the risk of esophageal irritation, vomiting should not be induced and the patient should remain fully upright.

PHARMACEUTICAL PARTICULARS:

Active ingredients :

Alendronate monosodium trihydrate.

List of Excipients :

Lactose anhydrous, Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate.

PRESENTATIONS:

Osteve is available in boxes of 4 tablets as 35mg and 70mg in Alu/Alu blister strips.

STORAGE:

Store below 25°C.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Manufactured by **SPIMACO**
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Saudi Pharmaceutical Industries &
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