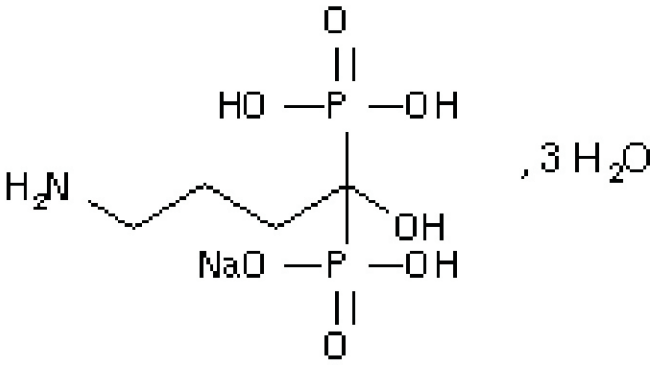
Taj Pharmaceuticals Ltd.

Alendronate sodium

CAS No. : 121268-17-5

Alendronate sodium Ph. Eur.
Specification: USP, Ph. Eur.

chemical name: (4-amino-1-hydroxybutylidene) bisphosphonic acid monosodium salt



Molecular formula: C4H12NNaO7P2, 3H2O

molecular weight: 325.1
CAS No: 121268-17-5

General requirements
Sodium alendronate is white or almost white crystalline powder, soluble in water, practically insoluble in methanol and methylene chloride.

TESTS	REQUIREMENTS	METHODS
Identification:		
A. IR spectrum	corresponds to sodium alendronate CRS	Ph. Eur.
B. chemical reaction	gives reaction of sodium	
Appearance of solution	clear and not more intensely coloured than reference solution B7 or BY7	Ph. Eur.
pH	4.0 to 5.0	Ph. Eur.
Related substances (HPLC):		
- impurity A	not more than 0.1	
- other single impurity	not more than 0.10%	Ph. Eur.
- total impurities	not more than 0.5%	
Phosphate and Phosphite (HPLC):		
- phosphate	not more than 0.5%	Ph. Eur.
- phosphite	not more than 0.5%	
Heavy metals	not more than 20 ppm	Ph. Eur.
Loss on drying	16.1% to 17.1%	Ph. Eur.

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Content of alendronate sodium calculated on the dried substance (HPLC)	98.0% - 102.0%	Ph. Eur.
Residual solvents:		
- methanol	not more than 500 ppm	

USES

Treatment of osteoporosis in postmenopausal women; prevention of osteoporosis in postmenopausal women at risk of developing osteoporosis; increase bone mass in men; treatment of glucocorticoid-induced osteoporosis in men and women; treatment of Paget disease of the bone.

prescribed for the prevention and treatment of osteoporosis, the brittle bone disease, in postmenopausal women. It is also used to increase bone mass in men with osteoporosis, and is prescribed for both men and women who have developed a form of osteoporosis sometimes caused by steroid medications such as prednisone. This drug can also be used to relieve Paget's disease of bone, a painful condition that weakens and deforms the bones.

HOW TO USE

Osteoporosis (Postmenopausal Women)
Adults (treatment)

PO 70 mg once weekly or 10 mg once daily.
Adults (prevention)

PO 35 mg once weekly or 5 mg once daily.
Osteoporosis (Men)
Adults

PO 70 mg once weekly or 10 mg once daily.
Glucocorticoid-Induced Osteoporosis
Adults

Alendronate Sodium,manufacturers,suppliers,exporters,products,factories,trade opportunities,trading agents
PO 5 mg once daily. For postmenopausal women not receiving estrogen, 10 mg once daily.
Paget Disease
Adults

PO 40 mg once daily for 6 mo. Re-treatment may be considered for patients who relapse after a 6-mo observation period.
General Advice

* Administer prescribed dose in the morning at least 30 min before the first food, beverage (other than water), or medication of the day.
* Have patient swallow tablet with a full glass (6 to 8 oz) of plain water and remain sitting or standing for at least 30 min.
* Have patient swallow oral solution directly from bottle, then drink at least 2 oz of plain water and remain standing or sitting for at least 30 min.

* Do not administer tablets or oral solution with any liquid other than plain water. Administration of alendronate with food, medication, juices, mineral water, coffee, or any other beverage will reduce alendronate absorption and efficacy.

SIDE EFFECTS

Side effects cannot be anticipated. If any develop or change in intensity, inform your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue using Fosamax.

* More common side effects may include:
Abdominal pain, Acid regurgitation, bone and joint pain, constipation, diarrhea, gas, indigestion, muscle pain, nausea

DRUG DESCRIPTION

A drug used to treat certain bone conditions, such as osteoporosis and Paget disease of the bone. It is also being studied in the treatment of hypercalcemia (high levels of calcium in the blood) and bone pain caused by cancer. Alendronate sodium slows the breakdown of bone and prevents the loss of calcium. It is a type of bisphosphonate.

alendronate sodium is a bisphosphonate that acts as a specific inhibitor of osteoclast-mediated bone resorption. Bisphosphonates are synthetic analogs of pyrophosphate that bind to the hydroxyapatite found in bone.

Alendronate sodium is chemically described as (4-amino-1-hydroxybutylidene) bisphosphonic acid monosodium salt trihydrate.

The empirical formula of alendronate sodium is C4H12NNaO7P2•3H2O and its formula weight is 325.12.

Alendronate sodium is a white, crystalline, nonhygroscopic powder. It is soluble in water, very slightly soluble in alcohol, and practically insoluble in chloroform.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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