PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

ALENDRONIC ACID TABLETS USP 70 MG TAJ PHARMA

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET:

1. WHAT SODIUM ALEDRONATE IS AND WHAT IT IS USED FOR

Sodium Aledronate contains the active substance Sodium Aledronate (as sodium alendronate trihydrate).

Your medicine is in the form of a tablet. Sodium Aledronate belongs to a group of non- hormonal medicines called bisphosphonates. Bisphosphonates can be used to help bone disease such as osteoporosis. Sodium Aledronate can treat and prevent osteoporosis in post-menopausal women, by stopping bones becoming thinner and weaker.

How can osteoporosis be treated?
As well as your treatment with Sodium Aledronate, your doctor may suggest you make changes to your lifestyle to help your condition, such as:

Stopping smoking Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of broken bones.

ExerciseLike muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise programme.

Eating a balanced diet your doctor can advise you about your diet or whether you should take any dietary supplements (especially calcium and Vitamin D).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SODIUM ALEDRONATE

DO NOT TAKE SODIUM ALEDRONATE:

- if you are allergic to Sodium Aledronate or any of the other ingredients of this medicine (listed in section 6)
- if you have problems with your gullet (oesophagus – the tube that connects your mouth with your stomach) causing difficulty swallowing or food to become stuck
- if you know you have very low blood levels of calcium (hypocalcaemia)
- If you are unable to stand or sit upright for at least 30 minutes.\

Warnings and precautions:
Talk to your doctor or pharmacist before taking Sodium Aledronate:

- if you suffer from kidney problems
- if you have any swallowing or digestive or gut problems or if in the last year you have had a stomach ulcer, bleed or surgery in the stomach, gullet or throat
- if you have pain on swallowing
- if you have been told you have low blood levels of calcium or you suffer from vitamin D deficiency or hypoparathyroidism (which can affect calcium levels). These need to be treated before you start taking Sodium Aledronate
- if your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)

Irritation, inflammation or ulceration of the gullet often with symptoms of chest pain, heartburn, or difficulty or pain upon

swallowing may occur, especially if the tablets are not taken with a full glass of water and/or if you lie down less than 30 minutes after taking the tablets. These side effects may worsen if you continue to take the tablets after developing these symptoms. See the 'How to take' instructions later on in this leaflet to see how you should take the tablets. If you have any questions, ask your doctor or pharmacist.

Dental and jaw problems
Sodium Aledronate can cause damage, including the death or loss of bone in the jaw. This risk is increased:

- if you have poor dental health, gum disease, poorly fitted dentures, a planned dental extraction or you do not receive routine dental care
- if you have cancer
- if you are undergoing chemotherapy or radiotherapy
- if you are taking corticosteroids (such as prednisone or dexamethasone)
- if you are taking angiogenesis inhibitors – medicines used in the treatment of cancer to prevent the growth of new blood vessels, such as bevacizumab or thalidomide
- if you are or have been a smoker

Therefore you may be advised to have a dental check-up before starting treatment with Sodium Aledronate.

It is important to maintain good oral hygiene when being treated with Sodium Aledronate**.** You should have routine dental check-ups throughout your treatment and you should contact your doctor or dentist if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling.

Children and adolescents:
Sodium Aledronate should not be given to children and adolescents less than 18 years of age.

Other medicines and Sodium Aledronate:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, or any of the following:\

- calcium supplements
- antacids for indigestion
- corticosteroid medicines, such as prednisone or dexamethasone, used to reduce inflammation; as it is important that you have a good dietary intake of calcium and vitamin D (a risk factor for dental problems – see 'Dental and jaw problems')
- certain medicines for rheumatism or long-term pain called NSAIDs (e.g. aspirin or ibuprofen) might cause digestive problems. Therefore, caution should be used when these medicines are taken at the same time as Sodium Aledronate.

Wait at least 30 minutes after taking Sodium Aledronate before taking any other medicines.

Sodium Aledronate with food and drink:
If taken at the same time it is likely that food and drink (including mineral water) will interfere with the absorption of Sodium Aledronate. Therefore you should take Sodium Aledronate with plain water at least 30 minutes before any food or drink.

Pregnancy and breast-feeding:
Sodium Aledronate is only intended for use in post-menopausal women. Do not take Sodium Aledronate if you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
There have been side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with Sodium Aledronate that may affect your ability to drive or operate machinery. Do not drive or operate machinery until you are sure you are not affected.

Sodium Aledronate contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sodium Aledronate contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. HOW TO TAKE SODIUM ALEDRONATE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one tablet once weekly.

Use in patients with kidney problems:
Sodium Aledronate is not recommended for patients with severe kidney problems.

Method of administration:

- Take on an empty stomach, as soon as you get out of bed in the morning, before you eat or drink anything.
- Swallow the tablet whole while staying in an upright position (sitting, standing or walking). Take with a full glass (not less than 200 ml) of plain water (not mineral water).
  - Do not take with mineral water (still or sparkling).
  - Do not take with coffee or tea.
  - Do not take with juice or milk.
  - Do not crush or chew or let the tablet dissolve in your mouth.
- Do not take at bedtime. You should not lie down after taking Sodium Aledronate until you have had something to eat.
- However, you must leave at least 30 minutes after swallowing the tablet before you eat, drink or take any other medicines.

Stop taking this medicine and tell your doctor if you notice:

- soreness, pain and difficulty swallowing
- pain in the centre of the chest
- heartburn, either new or worse than usual
- ulcers in your mouth and throat.

If you take more Sodium Aledronate than you should:
Drink a full glass of milk and contact your doctor or nearest hospital casualty department immediately. Take any remaining tablets and the container with you. Do not make yourself vomit, and do not lie down. In case of an overdose, you may experience an upset stomach, heartburn, stomach pain, nausea, vomiting, vomiting blood, blood in the bowel motions.

If you forget to take Sodium Aledronate:
Take the tablet in the morning after you remember. Do not take two tablets on the same day and return to taking one tablet once a week, on the day instructed by your doctor.

If you stop taking Sodium Aledronate:
Always talk to your doctor or pharmacist before you stop taking Sodium Aledronate.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor immediately if you experience any of the following symptoms:

Common (may affect up to 1 in 10 people):

- pain in the mouth, throat, chest or stomach which may be associated with eating. You may feel bloated, sick or be sick, have a loss of appetite or have a loss of weight. These may be signs of inflammation or ulceration in the digestive tract. If you are sick, you may also notice particles that looks like coffee grounds or you may pass black, tar-like stools
- new or worsening heartburn or indigestion, pain in the centre of chest or pain upon swallowing or difficulty swallowing. See your doctor as soon as possible if you have any of these effects

Uncommon (may affect up to 1 in 100 people):

- soreness or pain in one or both eyes. You may have redness, blurred vision, watery eyes, a sensitivity to light or floaters (shadows passing across your sight)

Rare (may affect up to 1 in 1,000 people):
allergic reactions such as hives, swelling of

the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing (angioedema)

- a skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome) or severe skin reactions which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)
- pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction
- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone

Very rare (may affect up to 1 in 10,000 people):

- talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

Contact your doctor or dentist if you experience such symptoms.

Other possible side effects:
Very common (may affect more than 1 in 10 people):

- bone, muscle and/or joint pain which is sometimes severe.

Common (may affect up to 1 in 10 people):

- joint swelling, swelling of the hands and legs
- abdominal pain, uncomfortable or full feeling in the stomach or belching after eating; constipation, diarrhoea, flatulence
- hair loss, itchy skin
- headache, dizziness, loss of balance or spinning sensation (vertigo), unusual weakness

Uncommon (may affect up to 1 in 100 people):

- nausea, vomiting
- rash, redness of the skin
- for a short time flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever. This is usually seen at the start of treatment
- changes in your taste.

Rare (may affect up to 1 in 1,000 people):

- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- narrowing of the gullet (oesophageal stricture)
- rash made worse by sunlight

Tell your doctor or pharmacist promptly about these or any other unusual symptoms.
It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effect
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. HOW TO STORE SODIUM ALEDRONATE

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label, carton and blister after "EXP". The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.\
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sodium Aledronate contains:
The active substance is Sodium Aledronate.
Each tablet contains:

Aldronate Sodium USP equivalent to Alendronic Acid	70mg

Excipients q.s.

What Sodium Aledronate looks like and contents of the pack:
PVC/PVDC/Al blisters.

Pack sizes: Blisters: 7, 14, 28, 30, 50, 90, 100 and 500mg modified-release tablets.

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

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