Package leaflet: Information for the patient

Fostepor Once Weekly 70 mg tablets
sodium alendronate

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 Fostepor Once Weekly is and what it is used for

Fostepor Once Weekly contains the active substance sodium alendronate

Fostepor Once Weekly belongs to a group of medicines called bisphosphonates. Bisphosphonates can be used to help bone disease such as osteoporosis.
Osteoporosis is a thinning or weakening of the bones. Fostepor Once Weekly can treat osteoporosis in post-menopausal women. Fostepor Once Weekly can reduce the chance of fracturing your hip or your spine.

2. What you need to know before you take Fostepor Once Weekly

Do not take Fostepor Once Weekly:
- if you are allergic to alendronate sodium 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 are unable to stand or sit upright for at least 30 minutes
- if you know you have very low blood levels of calcium (hypocalcaemia).

Warnings and precautions:
Talk to your doctor or pharmacist before taking Fostepor Once Weekly**:**
- if you suffer from kidney problems
- if you have any swallowing or digestive or gut problems
  - 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 your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- 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 Fostepor Once Weekly.

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

Fostepor Once Weekly can cause damage (including 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.

You may be advised to have a dental check-up before starting treatment with Fostepor Once Weekly.

It is important to maintain good oral hygiene when being treated with Fostepor Once Weekly. 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.

Other medicines and Fostepor Once Weekly:
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 prednisolone 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 drugs for rheumatism or long-term pain called NSAIDs (e.g. aspirin or ibuprofen) might cause digestive problems. Therefore, caution should be used when these drugs are taken at the same time as Fostepor Once Weekly.

Wait at least 30 minutes after taking Fostepor Once Weekly before taking any other medicines.

Fostepor Once Weekly with food and drink:
Food and drinks may reduce the absorption of Fostepor Once Weekly into the blood. Therefore, you should take Fostepor Once Weekly with plain water at least 30 minutes before any food or drink

Pregnancy and breast-feeding:
Fostepor Once Weekly is only intended for use in post-menopausal women. Do not take Fostepor Once Weekly 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 alendronate that may affect your ability to drive or operate machinery. Do not drive or operate machinery until you are sure you are not affected.

Fostepor Once Weekly 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.

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

3. How to take Fostepor Once Weekly:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and Elderly:
The recommended dose is 70 mg once a week.

Use in patients with kidney problems:
Fostepor Once Weekly is not recommended for patients with severe kidney problems.

Use in children and adolescents:
Fostepor Once Weekly should not be given to children and adolescents less than 18 years of age.

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 200ml) 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 Fostepor Once Weekly 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 Fostepor Once Weekly than you should:
Drink a full glass of milk and contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. **Do not** make yourself sick, and **do not** lie down. In case of an overdose, you may experience an upset stomach, heartburn, inflammation of the food pipe, stomach pain, nausea, vomiting, vomiting blood, blood in the bowel motions (gastritis), ulcer. You may also have changes in your blood test results (such as low level of calcium and phosphate in your blood).

If you forget to take Fostepor Once Weekly:
Take the tablet on the morning after you remember. Do not take two tablets in the same day and return to taking one tablet once a week.

If you stop taking Fostepor Once Weekly:
Always talk to your doctor or pharmacist before stopping taking Fostepor Once Weekly.

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 center of chest or pain upon 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. Contact your doctor and dentist if you experience such symptoms.
- 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 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 in the hands or 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 effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fostepor Once Weekly

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 and blister after "EXP". The expiry date refers to the last day of that month.

This medicine 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 to protect the environment.

6. Contents of the pack and other information

What Fostepor Once Weekly contains:
The active substance is sodium alendronate equivalent to 70 mg of alendronic acid.
The other ingredients are lactose monohydrate; cellulose, microcrystalline; povidone; croscarmellose sodium and magnesium stearate.

What Fostepor Once Weekly looks like and contents of the pack:
Fostepor Once Weekly 70 mg tablets are white, with two curved sides and marked "AD 70" on one side and "G"on the reverse.

Fostepor Once Weekly is available in blister packs of 4, 8 or 12 tablets. Fostepor Once Weekly is also available in bottles of 4, 8 or 12 tablets and bottles of 100 tablets (dispensing pack).

The bottles may contain a plastic spacer at the top of the pack.

Not all pack sizes and types may be marketed.

Marketing Authorisation Holder:
Viatris Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer:
McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft.
Mylan utca 1.,
Komárom, 2900,
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Alendronsäure Viatris 70 mg - einmal wöchentlich – Tabletten
Belgium	Alendronate Viatris 70mg, tabletten
Czech Republic	Alendrogen 70mg, tablety
Denmark	Alendronat Viatris 70 mg tabletter
Finland	Alendronat Viatris 70 mg tabletti
Italy	Alendronato Mylan Generics
Ireland	Fostepor Once Weekly 70 mg Tablets
Norway	Alendronat Viatris tabletter 70 mg
Poland	Alendrogen tabletki, 70 mg
Portugal	Acido Alendronico Mylan
Slovenia	ALENAX 70 mg tablete
Sweden	Alendronat Viatris Veckotablett

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