

Package leaflet: Information for the user

Alendronic Acid Bluefish once weekly 70 mg tablets (alendronic acid as 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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms 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 Alendronic Acid Bluefish Once weekly 70 mg Tablets are and what it is used for
2. What you need to know before you take Alendronic Acid Bluefish Once weekly 70 mg Tablets
3. How to take Alendronic Acid Bluefish Once weekly 70 mg Tablets
4. Possible side effects
5. How to store Alendronic Acid Bluefish Once weekly 70 mg Tablets
6. Contents of the pack and other information

1. What Alendronic Acid Bluefish once weekly 70 mg tablet is and what it is used for

The active ingredient, alendronate monosodium trihydrate, belongs to a group of non-hormonal medicines called “bisphosphonates”. It works by preventing the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. It reduces the risk of spine and hip fractures.

Alendronic Acid Bluefish Once weekly is used to treat the following condition:

- Postmenopausal osteoporosis.

Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At the menopause, the ovaries stop producing the female hormone, oestrogen, which helps to keep a woman’s skeleton healthy. As a result, bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Early on, osteoporosis usually has no symptoms. If left untreated, however, it can result in fractures (broken bones). Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures may occur during normal, everyday activity, such as lifting, or from injury that would not be sufficient to fracture normal bone. Fracture usually occurs at the hip, spine, or wrist and can lead not only to pain but also to considerable deformity and disability (such as stooped posture, or ‘dowager’s hump’ and loss of mobility).

Osteoporosis can be treated and it is never too late to begin treatment. Alendronic Acid Bluefish Once weekly 70 mg Tablets not only prevents the loss of bone but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

As well as your treatment with Alendronic Acid Bluefish Once weekly 70 mg Tablets, 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.

Exercise: Like 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 Alendronic Acid Bluefish once weekly 70 mg tablets

If any of the following applies to you, speak to your doctor or pharmacist before you start taking Alendronic Acid Bluefish Once weekly 70 mg Tablets as they may not be suitable for you.

Do not take Alendronic Acid Bluefish Once weekly 70 mg Tablets:

- if you are allergic to alendronate monosodium trihydrate or any of the other ingredients of this medicine (listed in section 6).
- if you have certain problems with your gullet (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing
- if you are unable to stand or sit upright for at least 30 minutes.
- if your doctor has told you that you have low blood calcium.

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Alendronate Acid Bluefish Once weekly 70mg Tablets:

- you suffer from kidney problems,
- you have any allergies,
- you have or recently had any swallowing or digestive problems,
- you have low blood calcium levels,
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome),
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus),

A dental examination should be considered before you start treatment with Alendronic Acid Bluefish Once weekly 70 mg Tablets if you have any of the conditions below.

- you have cancer,
- you are undergoing chemotherapy or radiotherapy,
- you are taking corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies,
- you have poor dental health, gum disease, a planned dental extraction or you don't receive routine dental care,
- you are or have been a smoker (as this may increase the risk of dental problems).

Appropriate preventive dental care, as recommended by the dentist, should be followed during treatment.

You may be advised to have a dental check-up before starting treatment with Alendronate Bluefish.

It is important to maintain good oral hygiene when being treated with Alendronate Bluefish. 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.

Irritation, inflammation or ulceration of the oesophagus (the tube that connects your mouth with your stomach) often with symptoms of chest pain, heartburn, or difficulty or pain upon swallowing may occur, especially if patients do not drink a full glass of water and/or if they lie down less than 30 minutes after taking Alendronic Acid Bluefish Once weekly 70 mg Tablets. These side effects may worsen if patients continue to take Alendronic Acid Bluefish Once weekly 70 mg Tablets after developing these symptoms

Children and adolescents

Alendronate should not be given to children and adolescents less than 18 years of age.

Other medicines and Alendronic Acid Bluefish once weekly 70 mg tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is likely that calcium supplements, antacids and some oral medicines will interfere with the absorption of Alendronic Acid Bluefish Once weekly 70 mg Tablets if taken at the same time. Therefore, it is important that you follow the advice given in section 3.

Certain drugs for rheumatism or long-term pain called NSAIDs (e.g. acetylsalicylic acid or ibuprofen) might cause digestive problems. Therefore, caution should be used when these drugs are taken at the same time as Alendronate Bluefish.

- After swallowing your tablet, wait at least 30 minutes before taking any other medication for the day. Alendronic Acid Bluefish Once weekly 70 mg Tablets are only effective if taken when your stomach is empty.

Alendronic Acid Bluefish Once weekly 70 mg Tablets with food and drink:

It is likely that food and beverages (including mineral water) will make Alendronic Acid Bluefish Once weekly 70 mg Tablets less effective if taken at the same time. Therefore, patients must wait at least 30 minutes after taking alendronate before taking any food or drink.

Pregnancy and breast-feeding:

Alendronic Acid Bluefish Once weekly 70 mg Tablets is only intended for use in postmenopausal women.

Alendronic Acid Bluefish Once weekly 70 mg Tablets can not be used during pregnancy and if you are breast-feeding.

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. Individual responses to Alendronate Bluefish may vary (See possible side effects, section 4.)

Alendronic Acid Bluefish Once weekly 70 mg Tablets contains sodium:

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

3. HOW TO TAKE ALENDRONIC ACID BLUEFISH ONCE WEEKLY 70 mg TABLETS

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

Your doctor has decided on the dose that is suited to you. The length of your course of treatment will depend on what condition you are suffering from. Always take Alendronic Acid Bluefish Once weekly 70 mg Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You may have previously been prescribed a 10 mg tablet of alendronate which is taken once a day. One Alendronic Acid Bluefish Once weekly 70 mg Tablets is taken once a week.

It is very important that you follow actions 2, 3, 4 and 5 described below. This will help the Alendronic Acid Bluefish Once weekly 70 mg Tablets reach your stomach quickly and help reduce the risk of irritating your oesophagus.

1. Choose the day of the week that best fits your schedule. Every week, take your Alendronic Acid Bluefish Once weekly 70 mg Tablets on your chosen day.
2. After getting up for the day and before taking your first food, drink or other medication, swallow your Alendronic Acid Bluefish Once weekly 70 mg Tablets whole with a full glass of plain water only (not mineral water)(not less than 200 ml or 7 fl. oz.), so that Alendronic Acid Bluefish Once weekly 70 mg Tablets is adequately absorbed.
 - 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 allow the tablet to dissolve in your mouth because of the possibility of mouth ulceration.

3. After swallowing your Alendronic Acid Bluefish Once weekly 70 mg Tablets do not lie down – stay fully upright (or sat upright) for at least 30 minutes and do not lie down until after your first food of the day.
4. Do not take Alendronic Acid Bluefish Once weekly 70 mg Tablets at bedtime or before getting up for the day.
5. If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Alendronic Acid Bluefish Once weekly 70 mg Tablets and contact your doctor.
6. After swallowing your Alendronic Acid Bluefish Once weekly 70 mg Tablets, wait at least 30 minutes before taking your first food, drink or other medication of the day, including antacids, calcium supplements and vitamins. Alendronic Acid Bluefish Once weekly 70 mg Tablets are only effective if taken when your stomach is empty.

If you take more Alendronic Acid Bluefish Once weekly 70 mg Tablets than you should:

If you (or someone else) accidentally take too many Alendronic Acid Bluefish Once weekly 70 mg Tablets, drink a full glass of milk and contact your doctor or pharmacist immediately. Do not make yourself vomit, and do not lie down.

If you forget to take Alendronic Acid Bluefish Once weekly 70 mg Tablets:

If you forget to take a dose, take one Alendronic Acid Bluefish Once weekly 70 mg Tablet on the morning after you remember. Do not take a double dose to make up for a forgotten dose. Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you stop taking Alendronic Acid Bluefish Once weekly 70 mg Tablets:

Always contact your doctor or pharmacist before you stop taking Alendronic Acid Bluefish Once weekly 70 mg Tablets. Alendronic Acid Bluefish Once weekly 70 mg Tablets can treat your osteoporosis only if you continue to take the tablets.

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.

See your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment:

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

- heartburn; difficulty swallowing; pain upon swallowing; ulceration of the gullet (oesophagus - the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing,

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, severe skin reactions,
- 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,

Other side effects include

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
- abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence;
- hair loss; itching
- headache ; dizziness
- tiredness; swelling in the hands or legs

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

- nausea; vomiting
- irritation or inflammation of the gullet (oesophagus – the tube that connects your mouth with your stomach) or stomach
- black or tar-like stools
- blurred vision;pain or redness in the eye,
- rash; redness of the skin
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment
- taste disturbance

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
- stomach or peptic ulcers (sometimes severe or with bleeding)
- narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach) rash made worse by sunlight,
- mouth ulcers when the tablets have been chewed or sucked

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.

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.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA 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 ALENDRONIC ACID BLUEFISH ONCE WEEKLY 70 mg TABLETS

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blisters and carton after EXP. The expiry date refers to the last day of the month.

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 Alendronic Acid Bluefish Once weekly 70 mg Tablets contain

- The active substance is alendronic acid. Each tablet contains 70 mg alendronic acid (equivalent to 91.37 mg sodium alendronate).
- The other ingredients are microcrystalline cellulose, crospovidone and magnesium stearate.

What Alendronic Acid Bluefish Once weekly 70 mg Tablets look like and contents of the pack

Each tablet is white, oval, flat and marked with a “70” on one side.

Alendronic Acid Bluefish Once weekly 70 mg Tablets are available in Al/Al blisters of 2, 4, 8 12, 40 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB, P.O.Box 49013, 10028 Stockholm, Sweden

Manufacturer

Bluefish Pharmaceuticals AB, Gavlegatan 22, 113 30, Stockholm, Sweden

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

Name of the Member State	Name of the medicinal product
Austria	Alendronsäure Bluefish 70 mg einmal wöchentlich Tabletten
Denmark	Alendronat Bluefish 70 mg tabletter
Germany	Alendronsäure Bluefish 70 mg Tabletten
Finland	Alendronat Bluefish 70 mg tabletti/tablette

Ireland	Alendronic Acid Bluefish Once weekly 70 mg Tablets
Iceland	Alendronat Bluefish 70 mg tafla
Norway	Alendronat Bluefish 70 mg tabletter
Poland	Alendronat Bluefish
Portugal	Ácido Alendrónico Bluefish 70 mg, comprimidos
Sweden	Alendronat Bluefish veckotablett 70 mg

This leaflet was last revised in April 2023