

PACKAGE LEAFLET

Package leaflet: Information for the user

Alendronate/Colecalciferol Teva 70 mg/2800 IU Tablets **Alendronate/Colecalciferol Teva 70 mg/5600 IU Tablets**

alendronic acid/colecalciferol

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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- It is particularly important to understand the information in section 3. How to Take Alendronate/Colecalciferol Teva, before taking this medicine.

What is in this leaflet

1. What Alendronate/Colecalciferol Teva is and what it is used for
2. What you need to know before you take Alendronate/Colecalciferol Teva
3. How to take Alendronate/Colecalciferol Teva
4. Possible side effects
5. How to store Alendronate/Colecalciferol Teva
6. Contents of the pack and other information

1. What Alendronate/Colecalciferol Teva is and what it is used for

What is Alendronate/Colecalciferol Teva?

Alendronate/Colecalciferol Teva is a tablet containing the two active substances, alendronic acid (as alendronate sodium monohydrate) and colecalciferol (known as vitamin D₃).

What is Alendronate/Colecalciferol Teva used for?

Your doctor has prescribed Alendronate/Colecalciferol Teva to treat your osteoporosis and because you are at risk of vitamin D insufficiency. Alendronate/Colecalciferol Teva reduces the risk of spine and hip fractures in women after menopause.

What is alendronic acid?

Alendronic acid belongs to a group of non-hormonal medicines called bisphosphonates.

Alendronic acid prevents bone loss (osteoporosis), and helps to rebuild bone. It reduces the risk of spine and hip fractures.

What is vitamin D?

Vitamin D is an essential nutrient, required for calcium absorption and healthy bones. The body can only absorb calcium properly from our food if it has enough vitamin D. Very few foods contain vitamin D. The main source is through exposure to summer sunlight, which makes vitamin D in our skin. As we get older our skin makes less vitamin D. Too little vitamin D may lead to bone loss and osteoporosis. Severe vitamin D deficiency may cause muscle weakness which can lead to falls and a greater risk of fractures.

What is osteoporosis?

Osteoporosis is a thinning and weakening of the bones. It is common in women after menopause. During 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 menopause, the greater the risk of osteoporosis.

Early on, osteoporosis usually has no symptoms. If left untreated, however, it can result in broken bones. Although these usually hurt, breaks in the bones of the spine may go unnoticed until they cause height loss. Broken bones can happen during normal, everyday activity, such as lifting, or from minor injury that would not generally break normal bone. Broken bones usually occur at the hip, spine, or wrist and can lead not only to pain but also to considerable problems like stooped posture ('dowager's hump') and loss of mobility.

How can osteoporosis be treated?

Osteoporosis can be treated and it is never too late to begin treatment.

As well as your treatment with Alendronate/Colecalciferol Teva, 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.

2. What you need to know before you take Alendronate/Colecalciferol Teva

Do NOT take Alendronate/Colecalciferol Teva:

- if you are allergic to alendronic acid, colecalciferol (vitamin D₃) 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 cannot 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/Colecalciferol Teva. It is important to tell your doctor before taking Alendronate/Colecalciferol Teva if:

- you suffer from kidney problems
- you have any swallowing or digestive problems
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- you have poor dental health, gum disease, a planned dental extraction or you don't receive routine dental care
- you have cancer
- you are undergoing chemotherapy or radiotherapy
- you are taking corticosteroids (such as prednisone or dexamethasone)
- you are or have been a smoker (as this may increase the risk of dental problems).

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

It is important to maintain good oral hygiene when being treated with Alendronate/Colecalciferol Teva. 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 gullet (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 Alendronate/Colecalciferol Teva. These side effects may worsen if patients continue to take Alendronate/Colecalciferol Teva after developing these symptoms (see section 4 “Possible side effects”).

Children and adolescents

Alendronate/Colecalciferol Teva should not be given to children less than 18 years of age.

Other medicines and Alendronate/Colecalciferol Teva

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

Calcium supplements, antacids, and some oral medicines may interfere with the absorption of Alendronate/Colecalciferol Teva if taken at the same time.

Therefore, it is important that you follow the advice given in section 3 “How to take Alendronate/Colecalciferol Teva”, and **wait at least 30 minutes** before taking any other oral medicines or supplements.

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 drugs are taken at the same time as Alendronate/Colecalciferol Teva.

Certain medicines or food additives may prevent the vitamin D in Alendronate/Colecalciferol Teva from getting into your body, including artificial fat substitutes, mineral oils, the weight loss medicine orlistat and cholesterol-lowering medicines; cholestyramine and colestipol. Medicines for fits (seizures) may decrease the effectiveness of vitamin D. In some cases, your doctor may prescribe additional vitamin D supplements.

Medicines containing colecalciferol (vitamin D₃) may interact with the following:

- thiazide diuretics (used to remove water from the body by increasing urine production)
- steroids such as hydrocortisone or prednisolone (used to treat inflammation)
- cardiac glycosides such as digitalis (used to treat heart disorders)
- actinomycin (a medicine used to treat some forms of cancer)
- imidazole antifungals (medicines such as clotrimazole and ketoconazole used to treat fungal diseases)

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

Alendronate/Colecalciferol Teva with food and drink

Food and beverages (including mineral water) can make Alendronate/Colecalciferol Teva less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3 “How to take Alendronate/Colecalciferol Teva”. You must wait at least 30 minutes before taking any food and beverages except water.

Pregnancy and breast-feeding

Alendronate/Colecalciferol Teva is only intended for use in postmenopausal women. You should not take Alendronate/Colecalciferol Teva if you are or think you may be pregnant, or if you are breast-feeding.

Driving and using machines

There have been side effects reported with Alendronate/Colecalciferol Teva (for example blurred vision, dizziness and severe bone, muscle or joint pain) that may affect your ability to drive or operate machinery (see section 4 “Possible side effects”). If you experience any of these side effects you should not drive or operate machinery until you feel better.

Alendronate/Colecalciferol Teva contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Alendronate/Colecalciferol Teva

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

Alendronate/Colecalciferol Teva is intended for use in osteoporotic postmenopausal women only.

Take one Alendronate/Colecalciferol Teva tablet ONCE A WEEK.

Follow these instructions carefully to make sure you will benefit from Alendronate/Colecalciferol Teva:

1. Choose the day of the week that best fits your schedule. Every week, take one Alendronate/Colecalciferol Teva tablet on your chosen day.
2. After getting up for the day and **before** taking any food, drink, or other medicine, swallow your Alendronate/Colecalciferol Teva tablet **whole** with a full glass of **tap water** only (not less than 200 ml or 7 fl . oz.).
 - **Do not** take with mineral water (still or sparkling), or with any other liquid including coffee, tea, juice or milk. **Only** take with tap water.
 - **Do not** crush or chew the tablet or allow it to dissolve in your mouth.
 - **Do not** take Alendronate/Colecalciferol Teva at bedtime or before getting up for the day.
3. **Do not** lie down — stay fully upright (sitting, standing or walking) — for **at least 30 minutes** after swallowing the tablet. Do not lie down until after your first food of the day.
4. After swallowing your Alendronate/Colecalciferol Teva tablet, **wait at least 30 minutes** before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Alendronate/Colecalciferol Teva is effective only if taken when your stomach is empty.

Use in children and adolescents

Alendronate/Colecalciferol Teva should not be given to children less than 18 years of age.

If you take more Alendronate/Colecalciferol Teva than you should

If you take too many tablets by mistake, drink a full glass of milk and contact your doctor **immediately**. Do not make yourself vomit, and do not lie down.

If you forget to take Alendronate/Colecalciferol Teva

If you miss a dose, just take one tablet on the morning after you remember. **Do not** take two tablets on the same day. Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you stop taking Alendronate/Colecalciferol Teva

It is important that you continue taking Alendronate/Colecalciferol Teva for as long as your doctor prescribes the medicine.

Alendronate/Colecalciferol Teva can only treat your osteoporosis 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:

- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing; severe skin reactions.

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):

- 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,
- 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 (feeling sick), vomiting (being sick)
- irritation or inflammation of the gullet (oesophagus – the tube that connects your mouth with your stomach) or stomach (see section 2 “What you need to know before you take Alendronate/Colecalciferol Teva”)
- 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, 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 (see section 2 “What you need to know before you take Alendronate/Colecalciferol Teva”). 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.
- mouth ulcers if 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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alendronate/Colecalciferol Teva

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 carton 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 protect the environment.

6. Contents of the pack and other information

What Alendronate/Colecalciferol Teva contains

- The active substances are alendronic acid and colecalciferol (vitamin D3).

Each 70 mg/2800 IU tablet contains 70 mg alendronic acid as alendronate sodium monohydrate and 70 micrograms (2800 IU) colecalciferol (vitamin D3).

Each 70 mg/5600 IU tablet contains 70 mg alendronic acid as alendronate sodium monohydrate and 140 micrograms (5600 IU) colecalciferol (vitamin D3).

- The other ingredients (excipients) are mannitol (E421), cellulose microcrystalline (E460), colloidal anhydrous silica (E551), magnesium stearate (E572), sucrose, copovidone (E1201), butylhydroxytoluene (BHT) (E321), medium-chain triglycerides, polyvinyl alcohol – part hydrolyzed, titanium dioxide (E171), macrogol 3350, talc (E553b).

What Alendronate/Colecalciferol Teva looks like and contents of the pack

Alendronate/Colecalciferol Teva 70 mg/2800 IU Tablets are white to off white, capsule shaped tablet, debossed with “A70” on one side and “2800” on the other side of the tablet.

Alendronate/Colecalciferol Teva 70 mg/5600 IU Tablets are white to off white, capsule shaped tablet, debossed with “A70” on one side and “5600” on the other side of the tablet.

The tablets are supplied in aluminium blisters in cartons in pack sizes of 4, 4 x 1, 4 (calendar pack), 12, 12 (calendar pack), 16, 24 or 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.

Swensweg 5
2031 GA Haarlem
The Netherlands

Manufacturer:

Teva Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary

Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands

Teva Czech Industries s.r.o., Ostravska 29, c.p. 305, 74770 Opava-Komarov, Czech Republic

Teva Operations Poland Sp. z.o.o, ul. Mogilska 80, 31-546 Krakow, Poland

Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren, Germany

Merckle GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany

Balkanpharma-Dupnitsa AD, Samokovsko Shosse Str. 3, Dupnitsa, 2600, Bulgaria

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

Austria	Alendronsäure comp. ratiopharm 70 mg/0.07 mg (2800 IU) & 70 mg/0.07 mg (5600 IU) Tabletten
Belgium	Alendronate Vitamin(e) D3 Teva 70 mg/2800 IU & 70 mg/5600 IU tabletten
Cyprus	Alendronate+Cholecalciferol /Teva 70 mg/0,07 mg (2800 IU) & 70 mg/0,14 mg (5600 IU) Δισκία
Czech Republic	ALENDRONIC ACID/ VITAMIN D3 Teva 70 mg/0,14 mg tablety
Estonia	Alendronic acid/Colecalciferol Teva
France	Acide alendronique Vitamine D3 70 mg/2800 UI, & 70 mg/5600 UI, comprimés
Germany	Alendronsäure-ratiopharm plus Colecalciferol 70 mg/2800 I.E. & 70 mg/5600 I.E. Tabletten
Greece	Alendronate+Cholecalciferol /Teva 70 mg/0,07 mg (2800 IU) & 70 mg/0,14 mg (5600 IU) Δισκία
Ireland	Alendronate/Colecalciferol Teva 70 mg/2800 IU & 70 mg/5600 IU Tablets
Italy	ALENDRONATO E COLECALCIFEROLO TEVA
Latvia	Alendronic acid/Colecalciferol Teva 70 mg/5600 SV tabletes
Luxembourg	Alendronsäure/Colecalciferol-ratiopharm 70 mg/2.800 I.E. & 70 mg/5.600 I.E Tabletten
Netherlands	alendroninezuur/cholecalciferol 70 mg/2800 IE & 70 mg/5600 IE Teva, tabletten
Portugal	Ácido alendrónico + Colecalciferol Teva
Romania	Da-Bone 70mg/2800UI & 70mg/5600UI comprimate
Slovenia	Alendor Combo 70 mg/0,14 mg tablete
Spain	Ácido alendrónico/Colecalciferol Tevagen 70mg/2.800 UI & 70mg/5.600 UI comprimidos

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