

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Arthroplus<sup>®</sup>**, 70 mg tablets,  
alendronic acid

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, please talk to your doctor or pharmacist or other healthcare professional or directly to the National Medicines Agency (Mesogion 284, 15562, Chologos, [www.eof.gr](http://www.eof.gr))
- It is particularly important to understand the information in section “3. HOW TO TAKE ARTHROPLUS<sup>®</sup>” before taking this medicine.

**In this leaflet:**

1. What **Arthroplus<sup>®</sup>** is and what it is used for.
2. Before you take **Arthroplus<sup>®</sup>**.
3. How to take **Arthroplus<sup>®</sup>**.
4. Possible side effects.
5. How to store **Arthroplus<sup>®</sup>**.
6. Other information.

**1. WHAT ARTHROPLUS<sup>®</sup> IS AND WHAT IS USED FOR****What is Arthroplus<sup>®</sup>?**

**Arthroplus<sup>®</sup>** belongs to a group of non-hormonal medicines known as bisphosphonates.

**Arthroplus<sup>®</sup>** prevents loss of bone mass that occurs in women after they have been through the menopause.

It has also been shown to help rebuild bone and reduce the risk of spine and hip fractures (broken bones) in women (after their menopause).

**What is Arthroplus<sup>®</sup> used for?**

Your doctor has prescribed **Arthroplus<sup>®</sup>** for the treatment of osteoporosis. **Arthroplus<sup>®</sup>** reduces the risk of spine and hip fractures.

**Arthroplus<sup>®</sup> must be taken once a week.**

**What is osteoporosis?**

Osteoporosis is thinning and weakening of your bones. It is common in women after the menopause. At the menopause, the ovaries stop producing the female hormone, estrogen, 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 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 injuries that would not fracture normal bone. Broken bones usually occur at the hip, spine or wrist and can lead not only to pain but also considerable problems like stooped posture (dowager's hump) and loss of mobility.

**How can osteoporosis be prevented?**

It is important to remember that if you already have osteoporosis it can be treated and that is never too late to begin. **Arthroplus**<sup>®</sup> not only prevents the loss of bone mass but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

In addition to your treatment with **Arthroplus**<sup>®</sup>, your doctor may recommend that you may make some changes to your lifestyle which may help your condition. These are:

<i>Stopping of smoking</i>	Smoking appears to increase the rate at which you lose bone and therefore, may increase your risk of broken bones.
<i>Exercise</i>	Like muscles, bones need exercise to stay strong and healthy. Talk to your doctor before you begin any exercise program.
<i>Eating a balanced diet</i>	Your doctor can advise you about your diet or whether you should take any dietary supplements (especially calcium and vitamin <i>D</i> ).

**2. BEFORE YOU TAKE ARTHROPLUS<sup>®</sup>****Do not take Arthroplus<sup>®</sup> if you:**

1. are allergic (hypersensitive) to alendronate sodium trihydrate or of any other ingredients.
2. have certain problems with your gullet (esophagus – the tube that connects your mouth to your stomach) such as narrowing or difficulty swallowing.
3. cannot stand or sit upright for at least 30 minutes.
4. were informed by your doctor that you have low blood calcium.

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

**Take special care with Arthroplus<sup>®</sup>**

It is important to tell your doctor before taking **Arthroplus**<sup>®</sup> if you:

- suffer from kidney problems
- have any allergies
- have any swallowing or digestive problems
- have been told that you have low blood calcium
- have gum disease
- have planned tooth extraction

Tooth extraction should be considered before you start treatment with **Arthroplus**<sup>®</sup> if you have any of the following:

- have cancer
- are undergoing chemotherapy or radiotherapy
- are taking corticosteroids
- don't receive routine dental care
- dental disease

It is important to maintain food oral hygiene when being treated with **Arthroplus**<sup>®</sup>.

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 **Arthroplus**<sup>®</sup>. These side effects may worsen if patients continue to take **Arthroplus**<sup>®</sup> after developing these symptoms.

**Taking other medicines**

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of **Arthroplus**<sup>®</sup>, if taken at the same time. Therefore, it is important that you follow the advice given in section “**3. HOW TO TAKE ARTHROPLUS**”.

Please tell your doctor about all medicines you are taking or plan to take, including any obtained without a prescription.

**Taking Arthroplus<sup>®</sup> with food and drink**

It is likely that food and drinks (including mineral water) will make **Arthroplus**<sup>®</sup> less effective if taken at the same time.

Therefore it is important that you follow the advice given in section “**3. HOW TO TAKE ARTHROPLUS**”.

**Children and adolescents**

**Arthroplus**<sup>®</sup> is not indicated for use in children and adolescents.

**Pregnancy and breast-feeding**

**Arthroplus**<sup>®</sup> is only intended for use in postmenopausal women. Do not take **Arthroplus**<sup>®</sup> if you are or think you may be pregnant, or if you are breast-feeding.

**Driving and using machines**

**Arthroplus**<sup>®</sup> is not expected to have any effects on your ability to drive and use machines.

**3. HOW TO TAKE ARTHROPLUS****Take one tablet Arthroplus<sup>®</sup> once a week.**

Follow these instructions carefully to make sure you will benefit from **Arthroplus**<sup>®</sup>.

- 1) Choose the day of the week that best fits your schedule. Every week, take one tablet **Arthroplus**<sup>®</sup> on the day of your choice.

*It is very important to follow instructions 2), 3), 4) and 5) to help **Arthroplus**<sup>®</sup> tablet reach your stomach quickly and help reduce the chance of irritating your gullet (esophagus – the tube that connects your mouth to your stomach).*

- 2) After getting up for the day and before taking any food, drink or other medicine, swallow your **Arthroplus**<sup>®</sup> tablet in whole with a full glass of water only (not mineral water) (not less than 200 ml or 7 fl. oz.).
  - 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 the tablet or allow it to dissolve in your mouth.

- 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 meal of the day.
- 4) Do not take **Arthroplus**<sup>®</sup> at bedtime or before getting up for the day.
- 5) If you experience difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking **Arthroplus**<sup>®</sup> and contact your doctor.
- 6) After swallowing **Arthroplus**<sup>®</sup> tablet, wait at least 30 minutes before taking your first meal, drink or other medicine of the day, including antacids, calcium supplements and vitamins. **Arthroplus**<sup>®</sup> is effective only if taken when your stomach is empty.

**If you take more Arthroplus® 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 Arthroplus®**

If you miss a dose, just take one **Arthroplus®** 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 Arthroplus®**

It is important that you continue taking **Arthroplus®** for as long as your doctor prescribes the medicine. **Arthroplus®** can treat your osteoporosis only if you continue to take the tablets..

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines **Arthroplus®** can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported.

Very common (occurring in at least 1 of 10 patients treated).

Common (occurring in at least 1 of 100 and less than 1 of 10 patients treated).

Uncommon (occurring in at least 1 of 1,000 and less than 1 of 100 patients treated).

Rare (occurring in at least 1 of 10,000 and less than 1 of 1,000 patients treated).

Very uncommon (occurring in at least 1 of 10,000 patient treated).

***Immune system disorders:***

*Rare:*

hypersensitivity reactions including urticaria, swelling of the face, lips, tongue and/ or throat, possibly causing difficulty breathing or swallowing.

***Metabolism and nutrition disorders:***

*Rare:*

*Symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth.*

***Nervous system disorders:***

*Rare:*

Headache.

***Eye disorders:***

*Uncommon:*

Blurred vision, pain or redness in the eye.

***Gastrointestinal disorders:***

*Common:*

Abdominal pain, uncomfortable feeling in the stomach or belching after eating, constipation, full or bloated feeling in the stomach, diarrhea, flatulence, heartburn, difficulty swallowing, pain upon swallowing, ulceration of the gullet (esophagus) which can cause chest pain, heartburn or difficulty or pain upon swallowing.

*Uncommon:*

Nausea, vomiting, irritation or inflammation of the gullet (esophagus) or stomach, black or tar-like stools.

*Rare:*

Narrowing of the gullet (esophagus), mouth ulcers when the tablets have been chewed or sucked, stomach or peptic ulcers (sometimes severe or with bleeding).

**Skin:***Uncommon:*

Rash, itching, redness of the skin.

*Rare:*

Rash made worse by sunlight

*Very rare:*

Severe skin reactions.

**Musculoskeletal disorders:***Common:*

Bone, muscle and/or joint pain.

*Rare:*

Pain in the jaw, generally associated with delayed healing and infection, often following tooth extraction.

Severe pain in bone, muscle or joints.

**General disorders:***Rare:*

Transient symptoms as in an acute-phase response, myalgia, malaise and rarely fever, typically in association with initiation of treatment.

The following adverse reactions were identified through post-marketing surveillance (frequency not known):

**Nervous system disorders:**

Dizziness.

**Musculoskeletal disorders:**

Joint swelling.

Fracture of the thigh bone particularly in patients on long-term treatment with alendronic acid. Pain in the thigh, leg weakness or local irritation must be considered as indications of a possible fracture of the thigh bone.

**General disorders:**

Fatigue, swelling in the hands and legs.

**Laboratory evidence:***Very common:*

Moderate to transient decrease in blood calcium and phosphates levels, generally within the normal limits.

Inform your doctor or pharmacist promptly about any of the above or any other unusual symptom that you may experience. You may be asked on the nature of the symptom, when it started and how long it lasted.

If you get any side effects, please talk to your doctor or pharmacist or other health care professional or directly to the National Medicines Agency (Mesogion 284, 15562, Cholongos, [www.eof.gr](http://www.eof.gr)).

**5. HOW TO STORE ARTHROPLUS®**

Keep out of reach and sight of children.

Do not use **Arthroplus®** after the expiration date which is stated on the carton and blister after EXP. The expiration date refers to the last day of the month mentioned.

This medicinal product does not require any special storage conditions. Do not remove the tablets from the blister pack until you are ready to take the medicine.

Medicines should not be disposed via wastewater or household water. Ask your pharmacist how to dispose the medicines that you no longer use. These measures will help to protect the environment.

**6. OTHER INFORMATION**

## **What Arthroplus® contain**

### ***Active substance:***

The active substance is alendronate sodium trihydrate.

Each tablet contains 70 mg alendronic acid as alendronate sodium trihydrate.

***Other excipients:*** Sorbitol, Starch maize, Sodium starch glycolate, Stearic acid, Magnesium stearate.

### **What Arthroplus® looks like and contents of the pack**

Tablets are enclosed in ALU/ALU blisters and in cartons in the following pack sizes:

- 4 tablets (1 ALU/ALU blister containing 4 tablets).
- 8 tablets (2 ALU/ALU blister each containing 4 tablets).
- 12 tablets (3 ALU/ALU blister each containing 4 tablets).

Not all pack sizes may be marketed.

### **MARKETING AUTHORIZATION HOLDER:**

TARGET PHARMA LTD.,

54 Menandrou str., 104 31 Athens Greece,

Tel.: +30 210 5224830, Fax: +30 210 5224838,

E-mail: [info@targetpharma.gr](mailto:info@targetpharma.gr), <http://www.targetpharma.gr>.

### **MANUFACTURER:**

RAFARM SA,

12 Korinthou str., 15451 New Psychico, Athens Greece.

**This leaflet was last approved on: 23-01-2014**

**ADMINISTRATION: This medicine is administered by medicinal prescription only.**