

Package leaflet: Information for the user

Osteomel Once Weekly 70mg Tablets

Alendronic acid

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 Osteomel Once Weekly is and what it is used for
2. What you need to know before you take Osteomel Once Weekly
3. How to take Osteomel Once Weekly
4. Possible side effects
5. How to store Osteomel Once Weekly
6. Contents of the pack and other information

1. What Osteomel Once Weekly is and what it is used for

Alendronate belongs to a group of medicines called bisphosphonates. Alendronate prevents the loss of bone, and reduces the risk of spine and hip fractures.

Osteomel Once Weekly is used

- to treat **osteoporosis**. Osteomel Once Weekly has been shown to reduce the risk of spine and hip fractures in **women**.

Osteomel Once Weekly is a once weekly treatment.

Osteoporosis is a thinning and weakening of the bones. Early on, osteoporosis usually has no symptoms, but if left untreated it can cause fractured bones. Although these usually hurt, fractures in the spine may go unnoticed until they cause height loss. Fractures can happen during normal, everyday activity, such as lifting, or from minor injury that would not damage healthy bone. Fractures 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.

As well as your treatment with Osteomel Once Weekly, your doctor may suggest you make changes to your lifestyle (e.g. exercise and diet recommendations, stop smoking) to help your condition. Consult your doctor for more information on lifestyle changes.

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

DO NOT take Osteomel Once Weekly if you

- are **allergic** to alendronate, other bisphosphonates or any of the other ingredients of this medicine (listed in section 6)
- have **certain problems with your gullet** (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or your gullet does not work properly and therefore you have difficulties in swallowing (a condition called achalasia)
- cannot **stand or sit upright for at least 30 minutes**

- have **low calcium levels in your blood**

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given. (See also section 3 “How to take Osteomel Once Weekly”)

Warnings and precautions

Talk to your doctor or pharmacist before taking Osteomel Once Weekly

- if you have **kidney problems**
- if you have any allergies
- if you have any **swallowing problems** or **digestive problems** such as inflammation of the stomach lining or the duodenum (first section of the small intestine), or if you have had severe disease of the stomach or bowel such as ulcers, bleeding from the stomach or the bowel or surgery on your stomach or gullet in the last year
- 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 problems absorbing calcium or other disorders, which may lead to **low calcium levels in your blood** such as low vitamin D levels or the parathyroid gland does not work properly (a condition called hypoparathyroidism). Your doctor may prescribe you a calcium or vitamin D supplement to prevent low calcium levels in your blood
- if you have **cancer**
- if you are taking **corticosteroids** (medicines which may be used to treat inflammations)
- if you are undergoing **chemotherapy or radiotherapy**
 - if you are taking **angiogenesis inhibitors** (such as bevacizumab, or thalidomide)
- if you **smoke**
- if you have poor dental health, gum disease, a planned dental extraction

You may be advised to have a dental check-up before starting treatment with Osteomel Once Weekly. It is important to maintain good oral hygiene when being treated with Osteomel 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.

If you are **being treated by a dentist** or if you are going to have **dental surgery or dental extraction**, tell your dentist that you are taking Osteomel 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 you do not follow the dosage instructions or the instructions of your doctor correctly (see also section 3 “How to take Osteomel Once Weekly”). You should **stop taking** Osteomel Once Weekly and **see your doctor immediately** if you get any of these symptoms. Also see section 4 “Possible side effects”. If you ignore these symptoms and continue to take your tablet, it is likely that these gullet reactions may get worse.

Blood calcium and phosphate levels may be affected by these tablets. It is important that you tell your doctor that you are taking Osteomel Once Weekly if you have a **blood test**.

Children and adolescents

Osteomel Once Weekly should not be given to children and adolescents.

Other medicines and Osteomel Once Weekly

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

Please inform your doctor if you are taking **corticosteroids** (medicines which may be used to treat inflammations). It is possible that you need some examinations before starting treatment with Osteomel Once Weekly (e.g. dental examination).

You might get an irritated stomach if you are taking pain killers (e.g. acetylsalicylic acid, ibuprofen) together with Osteomel Once Weekly.

It is likely that the following medicines will interfere with the absorption of Osteomel Once Weekly if taken at the same time:

- **calcium supplements**
- **antacids** (medicines used to relieve heartburn),
- **some oral medicines**

Therefore you must wait **at least 30 minutes** after taking Osteomel Once Weekly before you take any other medicine (see also section 3 “How to take Osteomel Once Weekly”).

Osteomel Once Weekly with food and drink

It is likely that food and beverages (including mineral water) will make Osteomel Once Weekly less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3 “How to take Osteomel Once Weekly”.

Pregnancy and 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.

Pregnancy

You should not take Osteomel Once Weekly if you are or think you may be pregnant.

Breast-feeding

You should not take Osteomel Once Weekly if you are breast-feeding.

Driving and using machines

Osteomel Once Weekly can cause side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) that may affect your ability to drive or operate machinery. Individual responses to Osteomel Once Weekly may vary (see section 4 “Possible side effects”).

Osteomel 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.

Osteomel Once Weekly contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Osteomel Once Weekly

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

The recommended dose of Osteomel Once Weekly is **one tablet per week** (always choose the same day of the week).

It is very important that you follow instructions given below carefully so that you get the most benefit from your medicine and avoid problems with your gullet.

1. After getting up for the day and before taking any food, drink, or other medicine, swallow your Osteomel Once Weekly tablet whole **with a full glass of plain 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.
2. Do NOT chew or crush 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 food of the day.
 4. After swallowing your Osteomel Once Weekly, **wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins.** Osteomel Once Weekly is effective only if taken when your stomach is empty.
 5. Do NOT take Osteomel Once Weekly at bedtime or before getting up for the day.
 6. If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Osteomel Once Weekly and contact your doctor.
 7. It is important that you continue taking Osteomel Once Weekly for as long as your doctor prescribes the medicine. Osteomel Once Weekly can treat your osteoporosis only if you continue to take the tablets.

If you take more Osteomel Once Weekly than you should

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

Symptoms of an alendronate overdose may include

- low calcium level in the blood with symptoms such as skin sensations, e.g. numbness, burning, prickling, itching, or tingling (paraesthesia) or involuntary contraction of muscles
- low phosphate level in the blood with symptoms such as muscle dysfunction and weakness
- upset stomach and heartburn
- inflammation of the gullet or of the stomach lining and ulcers.

If you forget to take Osteomel Once Weekly

If you miss a dose, just take one tablet on the morning after you remember. Do not take a double dose to make up for a forgotten tablet. Do not take two tablets on the same day. Return to taking one tablet per week, as originally scheduled on your chosen day. If you are unsure, please ask your doctor.

If you stop taking Osteomel Once Weekly

Always ask your doctor, if you want to stop taking Osteomel Once Weekly or if you want to change the prescribed dosage schedule. Do not interrupt or discontinue the treatment without consulting your doctor.

If you have any further questions on the use of this product, 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 Osteomel Once Weekly and see your doctor immediately if you get any of the following symptoms:

- symptoms of a severe allergic reaction (angioedema; occurs rarely [may affect up to 1 in 1,000 people]) such as
 - swollen face, tongue or throat and/or
 - difficulty swallowing and difficulty breathing and/or
 - hives
- severe skin reactions (occurs very rarely [may affect up to 1 in 10,000 people]) such as a rash, blistering or other effects on the skin, eyes, mouth or genitals, itching or high temperature (symptoms of skin reactions called Stevens-Johnson syndrome or toxic epidermal necrolysis)
- chest pain, new or worsened heartburn, or difficulty or pain upon swallowing (this may reflect an irritation, inflammation or ulceration of the gullet; occurs commonly [may affect up to 1 in 10

people]). If you ignore these symptoms and continue to take your tablets it is likely that these gullet reactions may get worse.

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):

- headache
- dizziness
- abdominal pain, uncomfortable feeling in the stomach or belching after eating, constipation, full or bloated feeling in the stomach, diarrhoea, flatulence
- hair loss (alopecia)
- itching
- joint swelling
- tiredness
- swelling in the hands or legs
- vertigo

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

- feeling sick, vomiting
- irritation or inflammation of the gullet or stomach, damage of the gullet lining (oesophageal erosions) (see also section 3 “How to take Osteomel Once Weekly”)
- black or tarlike stools
- rash, redness of the skin
- taste disturbance
- blurred vision, pain or redness in the eye
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment

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

- narrowing of the gullet (see also section 3 “How to take Osteomel Once Weekly”)
- ulcers in the mouth or throat when the tablets have been chewed or sucked (see section 3 “How to take Osteomel Once Weekly”)
- ulcers in the stomach or bowel (sometimes severe or with bleeding)
- rash made worse by sunlight
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- 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. 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For Ireland: HPRA Pharmacovigilance

Website: www.hpra.ie

For Malta: ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Osteomel 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 blister and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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 Osteomel Once Weekly contains

The active substance is sodium alendronate trihydrate. Each tablet contains 70 mg alendronic acid as sodium alendronate trihydrate.

The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate.

What Osteomel Once Weekly looks like and contents of the pack

Osteomel Once Weekly tablets are available as white to off-white, oval tablet, length: 12.90 mm, width: 7.25 mm.

The tablets are supplied in triplex blister packs containing 2, 4, 8, 12, 14, 24 and 40 tablets or aluminium sachets containing 2, 4, 8, 12, 14, 24, 40 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland.

Manufacturer

Centrafarm Services B.V., Van de Reijtstraat 31-E, 4814 NE Breda, The Netherlands.

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Austria	Alendronstad 70 mg einmal wöchentlich - Tabletten
Belgium	Alendronat EG 70 mg tabletten
Denmark	Alendronat STADA
France	Alendronate EG 70 mg, comprimé
Germany	Alendronsäure AL 70 mg Tabletten
Ireland	Osteomel Once Weekly 70 mg tablets
Italy	Alendronato EG 70 mg compresse

Luxembourg	Alendronat EG 70 mg comprimés
Malta	Osteomel Once Weekly 70 mg tablets
Netherlands	Alendroninezuur CF 70 mg, tabletten
Portugal	Ácido Alendrónico Ciclum 70 mg comprimidos
Spain	Ácido Alendrónico Semanal STADA 70 mg comprimidos
Sweden	Alendronat STADA Veckotablett 70 mg tablett

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