

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

OSTEONATE PLUS 2800 ONCE A WEEK tablets.

70 mg alendronic acid and 70 mcg cholecalciferol (2800 IU vitamin D₃)

OSTEONATE PLUS 5600 ONCE A WEEK tablets.

70 mg alendronic acid and 140 mcg cholecalciferol (5600 IU vitamin D₃)

OSTEONATE PLUS ONCE A WEEK contains sugar (lactose and sucrose) in the following quantities, respectively:

OSTEONATE PLUS 2800 ONCE A WEEK: 87,140 mg; 13,745 mg

OSTEONATE PLUS 5600 ONCE A WEEK: 59,140 mg; 27,490 mg

Read all of this leaflet carefully before you start taking OSTEONATE PLUS ONCE A WEEK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- OSTEONATE PLUS ONCE A WEEK has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What OSTEONATE PLUS ONCE A WEEK is and what it is used for
2. What you need to know before you use OSTEONATE PLUS ONCE A WEEK
3. How to take OSTEONATE PLUS ONCE A WEEK
4. Possible side effects
5. How to store OSTEONATE PLUS ONCE A WEEK
6. Contents of the pack and other information

1. What OSTEONATE PLUS ONCE A WEEK is and what it is used for

OSTEONATE PLUS ONCE A WEEK is a tablet containing the two active substances, alendronic acid (commonly called alendronate) and cholecalciferol known as vitamin D₃.

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

Alendronate prevents the loss of bone that occurs in women after they have been through menopause and helps to rebuild bone. It reduces the risk of spine and hip fractures.

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.

OSTEONATE PLUS ONCE A WEEK is used to treat your osteoporosis (a thinning and weakening of the bones). OSTEONATE PLUS ONCE A WEEK may reduce your risk of developing bone fractures, including those of the hip and spine and to help ensure vitamin D adequacy.

2. What you need to know before you take OSTEONATE PLUS ONCE A WEEK

Do not take OSTEONATE PLUS ONCE A WEEK:

- if you are hypersensitive (allergic) to alendronate, cholecalciferol, or to any of the ingredients of OSTEONATE PLUS ONCE A WEEK (see section 6)
- if you have certain problems with your oesophagus (the tube that connects your mouth to 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 calcium levels in your blood
- if you have severe kidney problems
- if you are pregnant or breastfeeding your baby
- children under 18 years of age.

Warnings and precautions

Tell your doctor before taking OSTEONATE PLUS ONCE A WEEK

if:

- you have any upper gastro-intestinal problems, such as difficulty or pain when swallowing, diseases of the tube connecting your throat to your stomach (oesophagus) (including Barrett's oesophagus, where the lower portion of your oesophagus is damaged from repeated exposure to stomach acid), inflammation of your stomach lining (gastritis), inflammation of the first part of your small intestine (duodenitis), or ulcers, or if you have had a stomach ulcer within the previous year, active gastrointestinal bleeding, or surgery of your upper gastrointestinal tract.

These conditions may worsen if you continue to take OSTEONATE PLUS ONCE A WEEK after developing these symptoms:

- you are taking a nonsteroidal anti-inflammatory medicine (NSAID) for rheumatism or long-term pain. Both medicines can cause irritation to the lining of the stomach and intestine
- you have low blood levels of calcium (hypocalcaemia), vitamin D, or parathyroid hormone (hypoparathyroidism). Your doctor may need to monitor your blood levels closely
- you have cancer. This may increase your risk of developing damage in the jaw (osteonecrosis) generally associated with delayed healing and infection
- you have blood cancer (leukaemia), cancer of the body's disease-fighting network (lymphoma) or a disease that causes the growth of inflammatory cell collections most often in the lungs and lymph nodes (sarcoidosis). Your doctor may need to monitor your blood levels closely

- you suffer from having trouble absorbing minerals in your stomach or intestines (malabsorption syndrome). Vitamin D₃ absorption may be impacted
- you are undergoing chemotherapy, radiotherapy or you are taking a medicine that blocks blood flow to and growth of cancer cells (angiogenesis inhibitors) or taking any steroid medicine. This may increase your risk of developing jaw osteonecrosis
- you have poor dental health, gum disease, other dental disease, poorly fitting dentures, you have a planned tooth extraction or other invasive dental procedure, or you do not receive routine dental care. This may increase your risk of developing jaw osteonecrosis
- you have a condition that reduces blood and oxygen flow to organs of the body (anaemia), have a condition that causes excessive bleeding or excessive clotting (coagulopathy), have an infection or you are or have been a smoker. This may increase your risk of dental problems and developing jaw osteonecrosis.

You may be advised to have a dental check-up before starting treatment with OSTEONATE PLUS ONCE A WEEK.

It is important to maintain good oral hygiene when being treated with OSTEONATE PLUS ONCE A WEEK. 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 get any of these symptoms or diseases, during your treatment with OSTEONATE PLUS ONCE A WEEK, tell your doctor straight away because it could be serious:

- difficulty or pain when swallowing, chest pain or new or worsening heartburn. These symptoms are more likely to occur if you lie down within 30 minutes after taking OSTEONATE PLUS ONCE A WEEK and/or you do not swallow the tablets with a full glass of water. These symptoms can become severe and could lead to hospitalisation. Discontinue OSTEONATE PLUS ONCE A WEEK and contact your doctor
- you experience bone, joint or muscle pain
- you experience pain, swelling, tenderness and/or bruising in your thigh, hip or groin. This could be an indication of stress fractures in your leg bone. Your doctor will indicate the correct treatment for this
- you experience ear problems such as pain, discharge or ear infection

Other medicines and OSTEONATE PLUS ONCE A WEEK

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is likely that calcium supplements, antacids and some oral medicines may interfere with the absorption of alendronate, if taken at the same time as OSTEONATE PLUS ONCE A WEEK. It is therefore important that you wait at least 30 minutes after taking OSTEONATE PLUS ONCE A WEEK before taking any of these other oral medicines or supplements.

Certain medicines for rheumatism or long-term pain, called nonsteroidal anti-inflammatory medicine (NSAIDs) (e.g. aspirin and ibuprofen) may cause digestive problems.

Caution should be used when taking these medicines with OSTEONATE PLUS ONCE A WEEK.

It is likely that some food additives or medicines (including artificial fat substitutes, mineral oils, the weight loss medicine orlistat, and the cholesterol-lowering medicines cholestyramine and colestipol) may prevent the vitamin D, as contained in OSTEONATE PLUS ONCE A WEEK from being absorbed into your body.

Medicines used to treat seizures, cimetidine used as treatment for stomach ulcers, and thiazides (water tablets) used to lower blood pressure, may decrease the effectiveness of vitamin D. Your doctor may advise you to take additional vitamin D supplements if you are taking any of these medicines with OSTEONATE PLUS ONCE A WEEK.

OSTEONATE PLUS ONCE A WEEK with food and drink

It is likely that food and drinks (including bottled mineral water), taken at the same time as OSTEONATE PLUS ONCE A WEEK, will decrease the absorption of alendronate and reduce the effectiveness of OSTEONATE PLUS ONCE A WEEK. It is therefore important that you wait at least 30 minutes after taking OSTEONATE PLUS ONCE A WEEK before you eat or drink anything (except water).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking OSTEONATE PLUS ONCE A WEEK.

OSTEONATE PLUS ONCE A WEEK is only intended for use in postmenopausal women. Do not take OSTEONATE PLUS ONCE A WEEK if you are pregnant or breastfeeding your baby.

Driving and using machines

OSTEONATE PLUS ONCE A WEEK may cause side effects such as blurred vision, dizziness and severe bone muscle or joint pain, which could affect your ability to drive and use machines.

It is not always possible to predict to what extent OSTEONATE PLUS ONCE A WEEK may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which OSTEONATE PLUS ONCE A WEEK affects them.

OSTEONATE PLUS ONCE A WEEK contains lactose and sucrose

OSTEONATE PLUS ONCE A WEEK contains lactose and 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 OSTEONATE PLUS ONCE A WEEK

Do not share medicines prescribed for you with any other person. Always use OSTEONATE PLUS ONCE A WEEK exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet of OSTEONATE PLUS ONCE A WEEK taken once a week.

Follow these instructions carefully to ensure you benefit from OSTEONATE PLUS ONCE A WEEK:

- choose a day of the week to take your tablet. Every week, take one OSTEONATE PLUS ONCE A WEEK tablet on that day

- to help OSTEONATE PLUS ONCE A WEEK reach your stomach quickly and to reduce the chance of irritation when swallowing, OSTEONATE PLUS ONCE A WEEK must be taken at least 30 minutes before the first food, drink or other medication of the day
- OSTEONATE PLUS ONCE A WEEK should be swallowed with a full glass of water only. Do not take OSTEONATE PLUS ONCE A WEEK with bottled water, tea, coffee, milk or juice
- swallow the tablet whole. Do not crush, chew or suck the tablet
- you should not lie down for at least 30 minutes after taking OSTEONATE PLUS ONCE A WEEK, and do not lie down until you have eaten
- do not take OSTEONATE PLUS ONCE A WEEK at bedtime or before getting up in the morning
- if you develop difficulty or pain in swallowing, chest pain, or new or worsening heartburn, stop taking OSTEONATE PLUS ONCE A WEEK and contact your doctor.

Your doctor may tell you to take calcium and/or vitamin D supplements whilst you are taking OSTEONATE PLUS ONCE A WEEK.

Children:

Children under 18 years of age should not take OSTEONATE PLUS ONCE A WEEK (see Do not take OSTEONATE PLUS ONCE A WEEK).

Your doctor will tell you how long your treatment with OSTEONATE PLUS ONCE A WEEK will last. Do not stop treatment early because your symptoms may return.

If you have the impression that the effect of OSTEONATE PLUS ONCE A WEEK is too strong or too weak, tell your doctor or pharmacist.

If you take more OSTEONATE PLUS ONCE A WEEK than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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.

Symptoms of overdose may include:

- reduced levels of calcium and phosphates in your blood, upset stomach, heartburn, inflammation of the oesophagus, stomach pain with nausea or vomiting, ulcer.

If you forget to take OSTEONATE PLUS ONCE A WEEK

If you forget to take OSTEONATE PLUS ONCE A WEEK, take in the morning after you remember. Return to taking one tablet once a week on the original chosen day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking OSTEONATE PLUS ONCE A WEEK

It is important that you take OSTEONATE PLUS ONCE A WEEK for as long as your doctor prescribes the medicine. Since it is not known how long you should take OSTEONATE PLUS ONCE A WEEK, you should discuss the need to stay on this medicine with your doctor periodically to determine if OSTEONATE PLUS ONCE A WEEK is still right for you.

4. Possible side effects

OSTEONATE PLUS ONCE A WEEK can have side effects.

Not all side effects reported for OSTEONATE PLUS ONCE A WEEK are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using OSTEONATE PLUS ONCE A WEEK, please consult your healthcare provider for advice.

If any of the following happens, stop using OSTEONATE PLUS ONCE A WEEK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to OSTEONATE PLUS ONCE A WEEK. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- irritation or ulceration of the oesophagus, difficulty or pain when swallowing, chest pain or worsening heartburn. These reactions are more likely to occur if you lie down within 30 minutes after taking OSTEONATE PLUS ONCE A WEEK and/or you do not swallow the tablets with a full glass of water
- Stevens-Johnson syndrome (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin) or other serious skin disorders.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- stomach pain, indigestion or belching, constipation, diarrhoea, flatulence, sore throat with ulcers, difficulty or discomfort in swallowing (dysphagia), full or bloated stomach, acid reflux
- bone, muscle or joint pain
- dizziness, feeling dizzy when standing still (vertigo)
- pruritus (itching)
- hair loss (alopecia).

Less frequent side effects:

- irritation or inflammation of the gullet (oesophagus – the tube that connects your mouth with your stomach) or stomach, heartburn, ulcer (painful sore) located in the lining of the lower part of the oesophagus, swelling of the throat, hole in the oesophagus, stomach or peptic ulcers (sometimes severe or with bleeding)
- nausea, vomiting, black and/or tar-like stools
- severe bone joint or muscle pain that hinders movement, joint swelling, unusual fracture of the thigh bone
- 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
- inflammation, pain or redness of the eye, blurred vision or loss of vision
- temporary flu-like symptoms, such as aching muscles, generally feeling unwell and weak; sometimes with fever, usually at the start of treatment, swelling of the legs or ankles
- rash, superficial reddening of the skin, usually in patches
- severe itching of the skin (pruritis), skin rash, sensitivity to sunlight
- changes in mineral levels in the blood
- decreased taste sensitivity
- symptoms of low blood calcium levels including muscle cramps or spasms and/or

tingling sensation in the fingers or around the mouth

- ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

The following side effects have been reported but the frequency for them to occur is not known:

- severe bone, joint or muscle pain that hinders movement, joint swelling
- unusual thighbone fracture
- brief occurrence of muscle pain and fever
- laboratory test results indicating decreased calcium and phosphate in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of OSTEONATE PLUS ONCE A WEEK. You can also send an email directly to the company, pharmacovigilnce@pharmadynamics.co.za to ensure safety of the product.

5. How to store OSTEONATE PLUS ONCE A WEEK

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original blister in order to protect from moisture and light.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OSTEONATE PLUS ONCE A WEEK contains

OSTEONATE PLUS 2800 ONCE A WEEK: The active ingredients are sodium alendronate trihydrate equivalent to 70 mg alendronic acid and cholecalciferol concentrate (powder form) equivalent to 70 mcg cholecalciferol (2800 IU Vitamin D₃).

OSTEONATE PLUS 5600 ONCE A WEEK: The active ingredients are sodium alendronate trihydrate equivalent to 70 mg alendronic acid and cholecalciferol concentrate (powder form) equivalent to 140 mcg cholecalciferol (5600 IU Vitamin D₃).

The other ingredients are:

Aluminium magnesium silicate, butylhydroxytoluene (BHT) E321, croscarmellose sodium, gelatin (100 Bloom), lactose, magnesium stearate, maize starch, microcrystalline cellulose, sunflower oil (refined) and sucrose.

What OSTEONATE PLUS ONCE A WEEK looks like and contents of the pack

OSTEONATE PLUS 2800 ONCE A WEEK: White to off-white oblong, biconvex tablets, mottled, engraved with 2800 on one side with dimensions 12,3 mm $\pm$ 0,2 mm in length and 6,5 $\pm$ 0,2 mm in width.

OSTEONATE PLUS 5600 ONCE A WEEK: White to off-white , modified rectangle-shaped tablets, mottled, engraved with 5600 on one side with dimensions 11,4 mm $\pm$ 0,2 mm in length and 7,2 $\pm$ 0,2 mm in width.

OSTEONATE PLUS ONCE A WEEK tablets are packed in PA/ALL/PVC - aluminium foil (Alu – Alu) blister strips, inside a carton. Each carton contains 4 tablets.

Holder of Certificate of Registration

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Osteonate Plus 2800 Once a week
Osteonate Plus 5600 Once a week
Pharma Dynamics (Pty) Ltd

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OSTEONATE PLUS 2800 ONCE A WEEK: A50/3.2/0636*

OSTEONATE PLUS 5600 ONCE A WEEK: A50/3.2/0637

**Not all strengths may be marketed.*

www.pharmadynamics.co.za