OSTEONATE 70 mg

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE
OSTEONATE 70 mg, tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each OSTEONATE 70 mg tablet contains trihydrate monosodium alendronate which is equivalent to alendronic acid 70 mg.

OSTEONATE 70 mg tablets are sugar free and essentially 'sodium free'.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets.
OSTEONATE 70 mg tablets are white, oval, flat, with dimensions 14 x 8 mm, and marked on one face with "70".

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
OSTEONATE 70 mg is indicated for the treatment of:
Post-menopausal osteoporosis in women to reduce the risk of fractures, including those of the hip and spine (vertebral compression fractures).
Primary hypogonadal osteoporosis in men and to reduce the risk of vertebral fractures.

4.2 Posology and method of administration
Posology
Treatment of post-menopausal osteoporosis:
The recommended dosage is one 70 mg tablet once weekly.

Treatment of primary hypogonadal osteoporosis in men:
The recommended dosage is one 70 mg tablet once weekly.

OSTEONATE 70 mg must be taken at least 30 minutes before the first food, beverage or medication of the day with plain water only. Other beverages (including mineral water), food and some medicines are likely to reduce the absorption of OSTEONATE 70 mg (see section 4.5).

Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate (see section 4.4).

Special populations
Elderly patients:
No dosage adjustment is necessary for the elderly.

Renal impairment:
No dosage adjustment is necessary for patients with mild-to-moderate renal insufficiency.
OSTEONATE 70 mg is contraindicated in patients with creatinine clearance (35 - 60 mL/min) (see section 4.3).

Paediatric population
The safety and efficacy of OSTEONATE 70 mg in children less than 18 years of age has not been established.

Method of administration
For oral use.
To facilitate delivery to the stomach and thus reduce the potential for oesophageal irritation, OSTEONATE 70 mg should only be swallowed upon arising for the day with a full glass of water and patients should not lie down for at least 30 minutes and until after their first food of the day.
OSTEONATE 70 mg should not be taken at bedtime or before arising for the day.
Failure to follow these instructions may increase the risk of oesophageal adverse experiences (section 4.4).

Missed dose:
Medical practitioners should advise patients who forget to take OSTEONATE 70 mg to take the missed dose on the morning after they remember. They should not take two tablets on the same day. They should then return to take one tablet once a week on the same day of the week as originally scheduled.

4.3 Contraindications
- hypersensitivity to alendronate or to any of the components of OSTEONATE 70 mg
- severe renal function impairment when creatinine clearance is less than 35 mL/minute
- the risk factor should be considered when gastrointestinal problems such as duodenitis, dysphagia, gastritis, ulcers or symptomatic oesophageal diseases are present
- abnormalities of the oesophagus which delay oesophageal emptying, such as stricture or achalasia
- the inability to stand or sit upright for at least 30 minutes after taking the medicine
- paediatric age group: safety and efficacy have not been established
- pregnancy and lactation
- hypocalcaemia.

4.4 Special warnings and precautions for use
Osteonecrosis:
Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection with delayed healing, has been reported with oral bisphosphonates, such as OSTEONATE 70 mg. Most reported cases of bisphosphonate-associated osteonecrosis of the jaw have been in cancer patients treated with intravenous bisphosphonates.
A dental examination with appropriate preventive dentistry should be considered prior to treatment of bisphosphonates, including OSTEONATE 70 mg, in patients with concomitant risk factors (e.g. cancer, chemotherapy, radiotherapy, corticosteroids), poor oral hygiene, smoking, co-morbid disorders (e.g. pre-existing dental disease, anaemia, coagulopathy, infection, diabetes, obesity) and increasing age.
While on treatment, these patients should avoid invasive dental procedures if possible.
For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. Appropriate care by an oral surgeon and discontinuation of therapy should be considered. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw.
Clinical judgement of the treating medical practitioner should guide the management plan of each patient based on individual benefit/risk assessment.
During bisphosphonate treatment, all patients should be encouraged to maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain, or swelling.

Osteonecrosis of the external auditory canal:
Osteonecrosis of the external auditory canal has been reported with bisphosphonates (as in OSTEONATE 70 mg), mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms such as pain or discharge, or chronic ear infections.

Upper gastrointestinal disease:
OSTEONATE 70 mg is contraindicated in patients suffering from upper gastrointestinal diseases, such as dysphagia, duodenitis, gastritis, ulcers or symptomatic oesophageal conditions (including known Barrett's oesophagus), recent history (within the previous year) of major gastrointestinal disease such as peptic ulcer or active gastrointestinal bleeding, or surgery of the upper gastrointestinal tract other than pyloroplasty, because of possible irritant effects of OSTEONATE 70 mg on the upper gastrointestinal mucosa and a potential for worsening of the underlying disease (see section 4.3).
Oesophageal adverse experiences such as oesophagitis, oesophageal ulcers and oesophageal erosions, followed rarely by oesophageal stricture or perforation, have been reported in patients receiving treatment with OSTEONATE 70 mg. In some cases, these have been severe and required hospitalisation. Medical practitioners should therefore be alert to any signs or symptoms signalling a possible oesophageal reaction and patients should be instructed to discontinue OSTEONATE 70 mg and seek medical attention if they develop dysphagia, odynophagia, retrosternal pain or new or worsening heartburn.
The risk of severe oesophageal adverse experiences appears to be greater in patients who lie down after taking OSTEONATE 70 mg and/or who fail to swallow it with a full glass of water, and/or who continue to take OSTEONATE 70 mg after developing symptoms suggestive of oesophageal irritation. Therefore, it is very important that the full dosing instructions are provided to and understood by the patient (see section 4.2).
To facilitate delivery to the stomach and thus reduce the potential for oesophageal irritation, patients should be instructed to swallow OSTEONATE 70 mg with a full glass of water and not to lie down for at least 30 minutes and until after their first food of the day.
Patients should not chew or suck on the tablet because of a potential for oropharyngeal ulceration. Patients should be specifically instructed not to take OSTEONATE 70 mg at bedtime or before arising for the day. Patients should be informed that failure to follow these instructions may increase their risk of oesophageal problems. Causes of osteoporosis other than oestrogen deficiency, aging and glucocorticoid use should be considered.
While no increased risk was observed in extensive clinical trials, there have been rare (post-marketing) reports of gastric and duodenal ulcers, some severe and with complications (see section 4.8).

Hypocalcaemia:
Hypocalcaemia and other disorders affecting mineral metabolism (such as vitamin D deficiency) should be corrected before starting OSTEONATE 70 mg therapy, as OSTEONATE 70 mg may exacerbate these conditions. In patients with these conditions, serum calcium and symptoms of hypocalcaemia should be monitored during therapy with OSTEONATE 70 mg.
Due to positive effects of OSTEONATE 70 mg to increase bone mineral, small, asymptomatic decreases in serum calcium and phosphate may occur, especially in patients receiving glucocorticoids, in whom calcium absorption may be decreased.
Ensuring adequate calcium and vitamin D intake is especially important in patients receiving glucocorticoids.

Bone and mineral metabolism:
Causes of osteoporosis other than oestrogen deficiency, aging and glucocorticoid use should be investigated.

Musculoskeletal effects:
Bone, joint and/or muscle pain have been reported in patients taking bisphosphonates such as OSTEONATE 70 mg. These symptoms may be severe and/or incapacitating (see section 4.8). The time to onset of symptoms varies from one day to several months after starting treatment. Most patients had a relief of symptoms after stopping treatment. A subset had a recurrence of symptoms when re-challenged with the same medicine or another bisphosphonate.

Atypical fractures of the femur:
Low-energy fractures of the subtrochanteric and proximal femoral shaft have been reported in a small number of long-term (usually longer than 3 years) bisphosphonate-treated patients. Some were stress fractures (some of which were reported as insufficiency fractures) occurring in the absence of apparent trauma. Some patients experienced prodromal pain in the affected area, often associated with imaging features of stress fracture, weeks to months before a complete fracture occurred. Approximately one third of these fractures were bilateral; therefore, the contra-lateral femur should be examined in patients who have sustained a femoral shaft stress fracture. Stress fractures with similar clinical features also have occurred in patients not treated with bisphosphonates. Patients with suspected stress fractures should be evaluated, including evaluation for known causes and risk factors (e.g. vitamin D deficiency, malabsorption, glucocorticoid use, previous stress fracture, lower extremity arthritis or fracture, extreme or increased exercise, diabetes mellitus, chronic alcohol abuse), and receive appropriate orthopaedic care. Bisphosphonate therapy in patients with stress fractures should be discontinued.
During OSTEONATE 70 mg treatment, patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture.

Renal impairment:
OSTEONATE 70 mg is not recommended for patients with renal impairment where creatinine clearance is less than 35 mL/min, (see section 4.2 and 4.3).

Use in the elderly:
There is no age-related difference in the efficacy or safety profiles of OSTEONATE 70 mg.

Excipients with known effect
Sodium
OSTEONATE 70 mg contains less than 1 mmol sodium (0,023 g) per tablet, that is to say essentially 'sodium free'.

4.5 Interaction with other medicines and other forms of interaction
Other oral medications, such as mineral supplements and antacids, containing aluminium, calcium, iron or magnesium and some osmotic laxatives will interfere with the absorption of OSTEONATE 70 mg. Patients are advised to wait at least 30 minutes after OSTEONATE 70 mg before taking any other oral medication.

No other interactions of clinical significance are anticipated.

No adverse experiences attributable to the concomitant use of alendronate and oestrogen (intravaginal, transdermal or oral) in post-menopausal women have been identified.
There may be additive hypocalcaemic effects with aminoglycosides.
Patients should be advised to be cautious when using nonsteroidal anti-inflammatory drugs (NSAIDs) while taking OSTEONATE 70 mg, as these NSAIDs are associated with gastrointestinal irritation.

4.6 Fertility, pregnancy and lactation
Pregnancy
The safety of OSTEONATE 70 mg has not been established in pregnancy and therefore, should not be used during pregnancy (see section 4.3).

Breastfeeding
The safety of OSTEONATE 70 mg has not been established in lactation.
A risk to the newborn/infant cannot be excluded. OSTEONATE 70 mg should not be used during breastfeeding.

Fertility
Bisphosphonates are incorporated into the bone matrix, from which they are gradually released over a period of years. The amount of bisphosphonate incorporated into adult bone, and hence, the amount available for release back into the systemic circulation, is directly related to the dose and duration of bisphosphonate use (see section 5.2).
There are no data on foetal risk in humans. However, there is a theoretical risk of foetal harm, predominantly skeletal, if a woman becomes pregnant after completing a course of bisphosphonate therapy. The impact of variables such as time between cessation of bisphosphonate therapy to conception, the particular bisphosphonate used, and the route of administration (intravenous versus oral) on the risk has not been studied.

4.7 Effects on ability to drive and use machines
OSTEONATE 70 mg has no or negligible direct influence on the ability to drive and use machines.
There are no data to suggest that OSTEONATE 70 mg affects the ability to drive or use machines.
However, certain adverse reactions (for example blurred vision, dizziness and severe bone muscle or joint pain) that have been reported with OSTEONATE 70 mg may affect some patient's ability to drive and use machines. Individual responses to OSTEONATE 70 mg may vary (see section 4.8).

4.8 Undesirable effects
a. Summary of the safety profile
In a one-year study in postmenopausal women with osteoporosis, the overall safety profiles of a once weekly dose formulation of alendronate 70 mg and a daily formulation of alendronate 10 mg were similar. In two three-year studies of virtually identical design, in postmenopausal women (alendronate 10 mg: n=196, placebo: n=397) the overall safety profiles of alendronate 10 mg/day and placebo were similar.

b. Tabulated list of adverse effects
The frequencies of adverse events are ranked according to the following:
Frequent = Common ($\geq 1/100$ to $< 1/10$) and very common ($1>10$).
Less frequent = Infrequent ($\geq 1/1\ 000$ to $< 1/100$); Rare ($\geq 1/10\ 000$ to $< 1/1\ 000$); Very rare ($<1/10\ 000$).
Frequency not known = cannot be estimated from the available data.

System Organ Class	Frequency	Side effects
Neoplasms benign and malignant (including cysts and polyps)	*Less frequent*	Oesophageal cancer
	Frequency unknown	Barrett's oesophagus
Immune system disorders	*Less frequent*	Hypersensitivity reactions including urticaria and angioedema
Metabolism and nutrition disorders	*Less frequent*	Symptomatic hypocalcaemia, generally in association with predisposing conditions
Nervous system disorders	*Frequent*	Headache
	Less frequent	Dysgeusia, dizziness
Eye disorders	*Less frequent*	Uveitis, scleritis, episcleritis, non-specific conjunctivitis, abnormal or blurred vision, iritis, serious ocular reactions and optic neuritis, diplopia with conjunctival swelling, eyelid oedema
Ear and labyrinth disorders	*Frequent*	Vertigo
	Less frequent	Osteonecrosis of the external auditory canal (bisphosphonate class adverse reaction)
Cardiac disorders	*Less frequent*	Increased risk of arterial fibrillation
Gastrointestinal disorders	*Frequent*	Abdominal pain, dyspepsia, dysphagia, oesophageal ulcer, abdominal distention, oesophagitis, constipation, diarrhoea, flatulence, acid regurgitation
	Less frequent	Gastritis, nausea, melaena oesophageal erosions, oesophageal stricture, vomiting, oropharyngeal ulceration, oesophageal perforations, gastric and duodenal ulcers, ulcer bleeding
Hepatobiliary disorders	*Less frequent*	Hepatitis
Skin and subcutaneous tissue disorders	*Less frequent*	Rash, erythema, pruritus, photosensitivity, alopecia, Stevens-Johnson syndrome, toxic epidermal necrolysis
Musculoskeletal, connective tissue and bone disorders	*Frequent*	Musculoskeletal pain (severe and/or incapacitating bone, muscle or joint), muscle cramp
	Less frequent	Joint swelling, low-energy femoral shaft fracture, localised osteonecrosis of the jaw (generally associated with tooth extraction and/or local infection, with delayed healing)
	Frequency unknown	Transient acute symmetrical polyarthritis, synovitis (possibly causing carpal tunnel syndrome)*, low impact atypical fractures in the subtrochanteric region and prodromal symptoms (thigh pain, vague discomfort, subjective weakness)*
General disorders and administrative site conditions	*Less frequent*	Transient symptoms as in an acute-phase response (myalgia, arthralgia, bone pain, malaise, asthenia and fever, chills, fatigue), typically at the start of treatment, peripheral oedema
Investigations	*Frequency unknown*	Asymptomatic, mild and transient decreases in serum calcium and phosphate*

*Post marketing

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
Hypocalcaemia, hypophosphataemia and upper gastrointestinal adverse events, such as upset stomach, heartburn, oesophagitis, gastritis or ulcer, may result from oral overdosage.

Management of overdose:
The administration of milk and antacids may be of benefit. Because of the risk of oesophageal irritation, vomiting should not be induced. Keep the patient in an upright position.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Bisphosphonate, for the treatment of bone diseases
ATC code: M05BA04
Pharmacological classification: A.3.2 Connective tissue medicines, non-hormonal preparations.

Mechanism of action
Bisphosphonates are synthetic analogues of pyrophosphate that bind to the hydroxyapatite found in bone. Alendronate sodium is an aminobiphosphonate that acts as a specific inhibitor of osteoclast-mediated bone resorption.
Alendronate localises preferentially to sites of bone resorption, specifically under osteoclasts, and inhibits osteoclastic bone resorption with no direct effect on bone formation. Since bone formation and bone resorption are coupled, bone formation is also reduced, but less so than resorption, leading to progressive gains in bone mass.
During exposure to alendronate, normal bone is formed that incorporates alendronate into its matrix where it is pharmacologically inactive.

5.2 Pharmacokinetic properties
Absorption:
The mean oral bioavailability of alendronate in women is 0,57 % for the 70 mg tablet when administered after an overnight fast and two hours before a standardised breakfast. At 0,6 %, bioavailability in men is similar to that in women.
Bioavailability is decreased by 40 % when alendronate is given ½ - 1 hour before breakfast, when compared to taking the tablet two hours before eating.
Absorption is negligible when alendronate is administered up to two hours after a standardised breakfast. When alendronate is taken with coffee or citrus juice, bioavailability is reduced by 60 %.

Distribution:
Alendronate is transiently distributed to the soft tissue and then rapidly redistributed to bone or excreted in the urine. The volume of distribution is at least 28 L in humans.
Plasma concentrations of alendronate after oral dosing are lower than 5 ng/mL.
Protein binding is approximately 78 %.

Biotransformation:
There is no evidence that alendronate is metabolised by humans.

Elimination:
Following a single intravenous dose of 10 mg alendronate, the renal clearance was 71 mL/min. Systematic clearance does not exceed 200 mL/min. After 6 hours the plasma concentrations fell by more than 95 %.
The terminal half-life in humans is estimated to exceed 10 years, reflecting release of alendronate from the skeleton.

Pharmacokinetics in special patient groups
Renal impairment:
Alendronate that is not deposited in bone is rapidly excreted in the urine. No evidence of saturation of bone uptake was found after chronic dosing with cumulative intravenous doses up to 35 mg/kg in animals. Although no clinical information is available, it is likely that, as in animals, elimination of alendronate via the kidney will be reduced in patients with impaired renal function. Therefore, somewhat greater accumulation of alendronate in bone might be expected in patients with impaired renal function (see section 4.2).

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.
Studies in rats have shown that treatment with alendronate during pregnancy was associated with dystocia in dams during parturition which was related to hypocalcaemia.
In studies, rats given high doses showed an increased incidence of incomplete foetal ossification. The relevance to humans is unknown.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Cellulose microcrystalline
Crospovidone
Magnesium stearate

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from moisture and direct light.
Keep blisters in outer carton until required for use.

6.5 Nature and contents of container
OSTEONATE 70 mg tablets are packed in an OPA/Al/PVC/Al blister pack containing 4 tablets in an outer carton.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: + 27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBER
A42/3.2/0235

9. DATE OF FIRST AUTHORISATION
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25 July 2025

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NS2 11/3.2/0046

ZIMBABWE
P.P. 2025/31/6913

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

OSTEONATE 70 mg tablets
Alendronic acid
OSTEONATE 70 mg is sugar free and essentially 'sodium free'.

Read all of this leaflet carefully before you start taking OSTEONATE 70 mg
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- OSTEONATE 70 mg 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 70 mg is and what it is used for
2. What you need to know before you take OSTEONATE 70 mg
3. How to take OSTEONATE 70 mg
4. Possible side effects
5. How to store OSTEONATE 70 mg
6. Contents of the pack and other information

1. What OSTEONATE 70 mg is and what it is used for
OSTEONATE 70 mg contains alendronate, part of a group of medicines called non-hormonal medicines known as bisphosphonates.
It helps to rebuild bone and makes bone less likely to fracture.

OSTEONATE 70 mg is prescribed to treat osteoporosis (thinning of the bone) after menopause in women and also to treat osteoporosis in men. It also reduces the risk of spine and hip fractures.

2. What you need to know before you take OSTEONATE 70 mg
Do not take OSTEONATE 70 mg:
- if you are hypersensitive (allergic) to alendronate or any of the other ingredients of OSTEONATE 70 mg (see section 6)
- if you have severe kidney disease
- if you are suffering from any medical problems, especially a history of oesophageal (food pipe) and digestive disorders
- if you are not able to stay in an upright position for at least 30 minutes after taking OSTEONATE 70 mg
- if you are a child or adolescent
- if you are pregnant or breastfeeding your baby
- if your doctor has told you that you currently have low levels of calcium in your blood.

Warnings and precautions
Take special care with OSTEONATE 70 mg:
- if you have poor dental health, gum disease, a planned dental extraction or you do not receive routine dental care
- your doctor may require you to visit your dentist before starting treatment, especially if you have other medical conditions such as cancer, you are undergoing chemotherapy or radiotherapy, you are taking corticosteroids (such as prednisone or dexamethasone), you are or have been a smoker
- you should avoid dental procedures or surgery while taking OSTEONATE 70 mg
- if you develop chronic ear pain or ear infections
- if you have, or have recently had, 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), or you have recently had surgery on the gastrointestinal tract
- stop taking OSTEONATE 70 mg tablets immediately and consult your doctor if you develop the following symptoms of throat disease:
  - difficulty or pain swallowing
  - chest pain or new or worsening heartburn
- the risk of developing the above side effects can be reduced if you swallow OSTEONATE 70 mg with a full glass of water and/or if you do not lie down for at least 30 minutes. These side effects may worsen if you continue to take OSTEONATE 70 mg after developing these symptoms. Do not suck or chew the tablet as it may cause burning in the mouth and throat
- if you have been told by your doctor that you have low blood calcium or a vitamin D deficiency
- if you experience bone, joint or muscle pain whilst taking OSTEONATE 70 mg
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- if you experience thigh, hip or groin pain (an indication of possible atypical thigh bone fracture)
- if you suffer from kidney disease as you should not take OSTEONATE 70 mg (see Do not take OSTEONATE 70 mg).

Other medicines and OSTEONATE 70 mg
Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.
- do not take any mineral supplements or antacids, containing aluminium, magnesium, iron or calcium and certain laxatives with OSTEONATE 70 mg as it will decrease the absorption of the OSTEONATE 70 mg in the stomach. Make sure that your daily multivitamin supplement does not contain calcium, aluminium, magnesium or iron
- if you are taking a class of antibiotics called aminoglycosides
- certain medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, may interfere with how OSTEONATE 70 mg works and cause digestive problems. Caution should therefore be exercised if you take OTEONATE 70 mg and NSAIDs at the same time.

OSTEONATE 70 mg with food and drink
It is important to take OSTEONATE 70 mg with a full glass of water only (not mineral water) in the morning at least 30 minutes before taking any other food, beverages or any other medicines.
It is likely that food and beverages (including mineral water and milk) will make OSTEONATE 70 mg less effective if taken at the same time.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using OSTEONATE 70 mg.

Driving and using machines
OSTEONATE 70 mg has no or negligible direct influence on the ability to drive and use machines.
However, certain side effects (for example blurred vision, dizziness and severe bone muscle or joint pain) have been reported while taking OSTEONATE 70 mg.
It is not always possible to predict to what extent OSTEONATE 70 mg 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 70 mg affects them.

OSTEONATE 70 mg contains sodium
OSTEONATE 70 mg contains less than 1 mmol sodium (0,023 g) per tablet, that is to say essentially 'sodium free'.

3. How to take OSTEONATE 70 mg
Do not share medicines prescribed for you with any other person.
Always take OSTEONATE 70 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:
The usual dose is one OSTEONATE 70 mg tablet taken once a week.

Follow these instructions carefully to ensure you benefit from OSTEONATE 70 mg:
- choose one day of the week to take your tablet. Every week, take one OSTEONATE 70 mg tablet on that day
- OSTEONATE 70 mg should be swallowed with a full glass of plain water on an empty stomach. Do not take OSTEONATE 70 mg with bottled water, tea, coffee, milk or juice
- to help OSTEONATE 70 mg reach your stomach quickly and to reduce the chance of irritation when swallowing, OSTEONATE 70 mg must be taken at least 30 minutes before any food, beverage or any other medication
- swallow the tablet whole. Do not suck or chew the tablet
- do not take any milk, antacid or aluminium-, magnesium-, iron-, calcium products or certain types of laxatives with OSTEONATE 70 mg as it will decrease the absorption of the OSTEONATE 70 mg in the stomach
- do not lie down for at least 30 minutes after you have taken OSTEONATE 70 mg and do not lie down until you have eaten
- do not take OSTEONATE 70 mg at bedtime or before getting up in the morning.

It is important to follow the above instructions to reduce the risk of side effects related to the oesophagus (food pipe) e.g. irritation, inflammation or ulceration.

Your doctor may tell you to take calcium and/or vitamin D supplements whilst you are taking OSTEONATE 70 mg.

Children
The safety and effectiveness of OSTEONATE 70 mg in children have not been established.
Your doctor will tell you how long your treatment with OSTEONATE 70 mg will last. Do not stop treatment early.
If you have the impression that the effect of OSTEONATE 70 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more OSTEONATE 70 mg 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.

Symptoms of overdose may include:
- upset stomach, heartburn, throat or digestive problems, ulcers.

Taking milk or antacids may help relieve the symptoms.
Do not make yourself vomit, as it may cause irritation or pain on the oesophagus (food pipe).

If you forget to take OSTEONATE 70 mg
If you forget to take OSTEONATE 70 mg, take the missed dose on the morning after you remember. Do not take two tablets on the same day. You should then return to taking one tablet once a week on the same day as originally scheduled.

If you stop taking OSTEONATE 70 mg
It is important that you take OSTEONATE 70 mg for as long as your doctor prescribes the medicine. Since it is not known how long you should take OSTEONATE 70 mg, you should discuss the need to stay on this medicine with your doctor periodically to determine if OSTEONATE 70 mg is still right for you.

4. Possible side effects
OSTEONATE 70 mg can have side effects.
Not all side effects reported for OSTEONATE 70 mg are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using OSTEONATE 70 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using OSTEONATE 70 mg 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 allergic reaction to OSTEONATE 70 mg. 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:
- changes in the way your heart beats, for example, if you notice it is beating faster
- 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
- kidney failure: you may experience less urine than is normal for you, swelling of legs, ankles or feet, nausea or extreme tiredness
- 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 Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- 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
- bone, muscle and/or joint pain which is sometimes severe.

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
- abdominal pain, indigestion, bloated or swollen stomach, constipation, diarrhoea, wind, acid regurgitation from the stomach
- skin rash or redness
- muscle cramp, bone, muscle or joint pain
- vertigo (the feeling of moving or spinning while you aren't moving).

Less frequent side effects:
- cancer of the oesophagus
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- changes in your sense of taste, dizziness
- inflammation of the eye, redness or pain of the eye, abnormal or blurred vision, double vision, swelling around the eyes
- osteonecrosis of the external auditory canal (a rare medical condition in which a loss of blood flow to the tympanic bone causes bone tissue death, characterised by exposed bone)
- nausea, gastritis, vomiting, black or tar-like stools, oesophagus ulcers, holes in the oesophagus, stomach ulcers, bleeding ulcer
- liver problems, such as yellowing of skin and eyeballs (jaundice), pain in your upper right abdomen, abdominal swelling or generally feel unwell
- hair loss, itching of the skin, sensitivity to sunlight, skin rash
- joint swelling, swelling of your lower legs or hands
- temporary flu-like symptoms (muscle/joint pain, generally feeling unwell and in rare cases fever) usually at the start of treatment
- 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.

The following side effects have been reported but the frequency for them to occur is not known:
- low blood calcium levels.

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 ,pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of OSTEONATE 70 mg.
You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store OSTEONATE 70 mg
Store all medicines out of reach of children.
Store at or below 25 °C
Protect from moisture and direct light.
Keep blisters in outer carton until required for use.
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 70 mg contains:
The active substance is alendronic acid.
Each OSTEONATE 70 mg tablet contains trihydrate monosodium alendronate which is equivalent to alendronic acid 70 mg.

The other ingredients are:
Crospovidone, magnesium stearate and microcrystalline cellulose.

What OSTEONATE 70 mg looks like and contents of the pack
OSTEONATE 70 mg tablets are white, oval, flat, with dimensions of 14 x 8 mm, and marked on one face with "70".

OSTEONATE 70 mg tablets are available in an OPA/Al/PVC/Al blister pack containing 4 tablets in an outer carton.

Holder of Certificate of Registration

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NAMIBIA
NS2 11/3.2/0046

ZIMBABWE
P.P. 2025/31/6913

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

OSTEONATE 70 mg tablette
Alendroniese suur
OSTEONATE 70 mg is suikervry en wesenlik 'natrium vry'.

Lees hierdie hele inligtingsblad noukeurig deur, voordat u begin om OSTEONATE 70 mg te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- OSTEONATE 70 mg is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad

1. Wat OSTEONATE 70 mg is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u OSTEONATE 70 mg gebruik
3. Hoe om OSTEONATE 70 mg te gebruik
4. Moontlike newe-effekte
5. Hoe om OSTEONATE 70 mg te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat OSTEONATE 70 mg is en waarvoor dit gebruik word
OSTEONATE 70 mg bevat alendronaat, deel van 'n groep medisyne wat nie-hormonale medisyne genoem word, bekend as bisfosfonate.
Dit help met die heropbou van been en verminder die waarskynlikheid van 'n beenfraktuur.

OSTEONATE 70 mg word voorgeskryf om osteoporose (beenverdunning) na menopouse by vroue, te behandel en ook tydens osteoporose by mans. Dit verminder ook die risiko vir ruggraat- en heupfrakture.

2. Wat u nodig het om te weet, voordat u OSTEONATE 70 mg gebruik
Moet nie OSTEONATE 70 mg neem:
- indien u hipersensitief (allergies) is vir alendronaat, of vir enige van die ander bestanddele van OSTEONATE 70 mg nie (sien afdeling 6)
- indien u erge niersiekte het nie
- indien u aan enige mediese probleme ly nie, en veral 'n geskiedenis van esofageale (slukderm) en spysverteringsteurings, het nie
- indien u nie die vermoë het om in 'n regop posisie te bly vir ten minste 30 minute nadat OSTEONATE 70 mg geneem is nie
- indien u 'n kind of adolessent is nie
- indien u swanger is, of u baba borsvoed nie
- indien u deur u dokter vertel is dat u tans lae bloedkalsiumvlakke het nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met OSTEONATE 70 mg:
- indien u swak tandheelkundige gesondheid, of tandvleissiekte het, 'n tandekstraksie beplan, of u nie roetine tandheelkundige sorg ontvang nie
- u dokter mag aanbeveel dat u die tandarts besoek voordat u met behandeling begin, veral indien u ander mediese toestande soos kanker het, u chemoterapie of radioterapie ondergaan, u kortikosteroïede (soos prednisoon of deksametasoon) neem, of u 'n roker is, of was nie
- u moet tandheelkundige prosedures of chirurgie vermy terwyl OSTEONATE 70 mg geneem word
- indien u chroniese oorpyn of oorinfeksies ontwikkel
- indien u sluk- of spysverteringsprobleme het, of onlangs gehad het, u deur u dokter vertel is dat u Barrett se esofagus het ('n toestand geassosieer met veranderinge in die selle wat die onderste slukderm bedek), of u onlangs 'n operasie aan die gastro-intestinale kanaal ondergaan het
- staak die gebruik van OSTEONATE 70 mg tablette onmiddellik en raadpleeg u dokter indien u die volgende simptome of keelsiekte ontwikkel:
  - moeisame of pynlike sluk
  - borspyn of nuwe sooibrand, of bestaande sooibrand wat vererger
- die risiko vir die ontwikkeling van die bogenoemde newe-effekte mag afneem indien u OSTEONATE 70 mg saam met 'n vol glas water neem en/of u nie lê vir ten minste 30 minute nie. Hierdie newe-effekte mag vererger indien u aanhou om OSTEONATE 70 mg te neem, nadat hierdie simptome ontwikkel het. Moet nie die tablet suig of kou nie, aangesien dit die mond en keel mag brand
- indien u deur u dokter vertel is dat u lae bloedkalsium of 'n vitamien D tekort het
- indien u been-, spier- of gewrigspyn ervaar tydens die gebruik van OSTEONATE 70 mg
- indien daar aangedui is dat u sukkel om minerale in u maag of ingewande te absorbeer (wanabsorpsie sindroom)
- indien u dy-, heup- of liespyn ervaar ('n indikasie van moontlike atipiese dybeenfraktuur)
- indien u aan niersiekte ly, aangesien u nie OSTEONATE 70 mg moet neem nie (sien Moet nie OSTEONATE 70 mg neem).

Ander medisyne en OSTEONATE 70 mg
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem. Dit sluit aanvullende of tradisionele medisyne in.
- moet nie enige mineraalaanvullings of teensuurmiddels wat aluminium, magnesium, yster of kalsium bevat en sekere lakseermiddels, saam met OSTEONATE 70 mg neem nie, aangesien dit die absorpsie van OSTEONATE 70 mg vanuit die maag, verlaag. Maak seker dat 'n daaglikse multivitamien aanvulling nie kalsium, aluminium, magnesium of yster bevat nie
- indien u 'n klas antibiotika neem wat aminoglikosiede genoem word
- sekere medisyne soos ibuprofen, wat niesteroïedale anti-inflammatoriese medisynes (NSAIMs) genoem word, mag inmeng met die werking van OSTEONATE 70 mg en spysverteringsprobleme veroorsaak. Wees dus versigtig indien u OSTEONATE 70 mg en NSAIMs op dieselfde tyd neem.

OSTEONATE 70 mg saam met kos en drinkgoed
Dit is belangrik om OSTEONATE 70 mg slegs saam met 'n vol glas water (nie mineraalwater), in die oggend, ten minste 30 minute voordat enige ander kos, drankies of medikasie geneem word, te neem.
Dit is moontlik dat kos en drankies (insluitend mineraalwater en melk) OSTEONATE 70 mg minder doeltreffend maak indien dit op dieselfde tyd geneem word.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies, voordat u OSTEONATE 70 mg neem.

Bestuur en die hantering van masjiene
OSTEONATE 70 mg het geen, of 'n onbeduidende invloed op die vermoë om te bestuur of masjinerie te hanteer.
Sekere newe-effekte (byvoorbeeld versteurde visie, duiseligheid en erge been-, spier- of gewrigspyn), is egter aangemeld tydens die gebruik van OSTEONATE 70 mg.
Dit is nie altyd moontlik om te voorspel tot watter mate OSTEONATE 70 mg met die daaglikse aktiwiteite van 'n pasiënt mag inmeng nie. Pasiënte moet verseker dat hulle nie betrokke raak by bogenoemde aktiwiteite totdat hulle bewus is tot watter mate OSTEONATE 70 mg hulle beïnvloed nie.

OSTEONATE 70 mg bevat natrium
OSTEONATE 70 mg bevat minder as 1 mmol natrium (0,023 g) per filmbedekte tablet, so dit is wesenlik 'natriumvry'.

3. Hoe om OSTEONATE 70 mg te gebruik
Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Neem OSTEONATE 70 mg altyd presies soos deur u dokter aangedui word. U moet u dokter of apteker raadpleeg, indien u onseker is.

Volwassenes:
Die gewone dosis is een OSTEONATE 70 mg tablet wat een keer per week geneem word.

Volg hierdie instruksies noukeurig, om te verseker dat u voordeel trek uit die gebruik van OSTEONATE 70 mg:
- kies een dag van die week om u tablet te neem. Neem elke week, een OSTEONATE 70 mg tablet op die vasgestelde dag
- OSTEONATE 70 mg moet gesluk word met 'n vol glas, gewone water, op 'n leë maag. Moet nie OSTEONATE 70 mg saam met gebottelde water, tee, koffie, melk of sap neem nie
- om te help dat OSTEONATE 70 mg u maag vinnig bereik en om die kans vir irritasie te verminder wanneer u die tablet sluk, moet OSTEONATE 70 mg ten minste 30 minute voor enige kos, drankie of enige ander medikasie geneem word
- sluk die tablet heel. Moet dit nie suig of kou nie
- moet nie enige melk, teensuurmiddel, of aluminium-, magnesium-, yster-, of kalsiumprodukte, of sekere tipes lakseermiddels, saam met OSTEONATE 70 mg neem nie, aangesien dit die absorpsie van OSTEONATE 70 mg in die maag mag verminder
- moet nie lê vir ten minste 30 minute nadat u OSTEONATE 70 mg geneem het nie en moet nie lê totdat u geëet het nie
- moet nie OSTEONATE 70 mg teen slaaptyd, of voordat u opstaan in die oggend, neem nie.

Dit is belangrik om bogenoemde instruksies te volg, sodat die risiko vir newe-effekte wat verband hou met die esofagus (slukderm) bv. irritasie, inflammasie of ulserasie, verlaag word.

U dokter mag aanbeveel dat u kalsium en/of vitamien D aanvullings neem, terwyl u OSTEONATE 70 mg neem.

Kinders
Die veiligheid en doeltreffendheid van OSTEONATE 70 mg by kinders is nog nie vasgestel nie.
U dokter sal u vertel vir hoe lank u behandeling met OSTEONATE 70 mg sal duur. Moet nie die behandeling vroegtydig staak nie. Indien u onder die indruk is dat die uitwerking van OSTEONATE 70 mg té sterk of té swak is, vertel u dokter of apteker.

Indien u meer OSTEONATE 70 mg neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Simptome van oordosering mag die volgende insluit:
- omgekrapte maag, sooibrand, keel- of spysverteringsprobleme, ulkusse.

Die inname van melk of teensuurmiddels, mag help om simptome te verlig.
Moet nie uself laat braak nie, aangesien dit irritasie of pyn in die esofagus (slukderm) mag veroorsaak.

Indien u vergeet om 'n dosis OSTEONATE 70 mg te neem
Indien u vergeet om OSTEONATE 70 mg te neem, neem die vergete dosis die volgende oggend, nadat u onthou het. Moet nie twee tablette op dieselfde dag neem nie. U moet dan terugkeer na die inname van een tablet, een keer per week, op dieselfde dag as wat oorspronklik geskeduleer was.

Indien u die gebruik van OSTEONATE 70 mg staak
Dit is belangrik dat u OSTEONATE 70 mg neem vir solank as wat u dokter die medisyne voorskryf. Aangesien die tydsduur van OSTEONATE 70 mg gebruik nie bekend is nie, moet u die noodsaaklikheid van voortgesette behandeling met hierdie medisyne, met gereelde tussenposes, met u dokter bespreek om vas te stel of OSTEONATE 70 mg nog steeds geskik is vir u.

4. Moontlike newe-effekte
OSTEONATE 70 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir OSTEONATE 70 mg aangemeld is, word in hierdie inligtingsblad genoem nie. Sou u algemene gesondheid vererger, of indien u enige ongunstige effekte ervaar terwyl u OSTEONATE 70 mg neem, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van OSTEONATE 70 mg en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat asemhaling of sluk mag bemoeilik
- uitslag of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie teenoor OSTEONATE 70 mg ondervind het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- verandering in die manier hoe u hart klop, byvoorbeeld, indien u opmerk dat u hart vinniger klop
- sooibrand; vind dit moeilik om te sluk; pyn tydens die slukproses; ulserasie van die slukderm (esofagus – die buis wat u mond met u maag verbind) wat borspyn, sooibrand, moeisame of pynlike sluk, mag veroorsaak
- nierversaking: u mag vind dat u minder urineer as wat normaal is vir u, swelling van bene, enkels of voete, naarheid of uiterse moegheid
- toksiese epidermale nekrolise (TEN) ('n lewensbedreigende velversteuring met simptome soos 'n pynlike rooi oppervlakte wat vinnig versprei, velskilfering sonder blase, rou veloppervlaktes, of Stevens-Johnson-sindroom ('n lewensbedreigende velversteuring met simptome soos, 'n rooi-pers uitslag en blaasvorming)
- pyn in die mond, en/of kakebeen, swelling of sere in die mond, gevoelloosheid of 'n "swaar gevoel in die kaak", of 'n los tand. Hierdie mag tekens wees van skade aan die kakebeen (osteonekrose), algemeen geassosieer met stadige genesing en infeksie, veral na 'n tandekstraksie. Kontak u dokter en tandarts indien u sulke simptome ervaar
- been-, spier- en/of gewrigspyn, wat somtyds erg mag wees

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- hoofpyn
- buikpyn, indigestie, opgeblase of geswelde maag, hardlywigheid, diarree, winderigheid, suurbraking vanuit die maag
- uitslag of rooiheid van die vel
- spierkramp, been-, spier-, of gewrigspyn
- vertigo ('n gevoel dat u beweeg of draai, alhoewel u nie beweeg nie).

Minder algemene newe-effekte:
- kanker van die esofagus
- simptome van lae bloedkalsiumvlakke, insluitend spierkrampe, of spasmas en/of 'n prikkelende sensasie in die vingers en rondom die mond
- smaaksteurnis, duiseligheid
- inflammasie van die oog, rooiheid of oogpyn, abnormale, of versteurde visie, dubbelvisie, swelling rondom die oë
- osteonekrose van die uitwendige gehoorkanaal ('n skaars mediese toestand, waar 'n verlies van bloedvloei na die timpaniese been, afsterwe van beenweefsel veroorsaak, en gekenmerk word deur blootgestelde been)
- naarheid, gastritis, braking, swart of teer-agtige stoelgang, esofagus ulkusse, gate in die esofagus, maagsere, bloeiende ulkus
- lewerprobleme, soos vergeling van die vel en oogballe (geelsug), pyn in u boonste, regterkantste buik, abdominale swelling of 'n algemene gevoel van ongesteldheid
- haarverlies, gejeuk van die vel, sensitiwiteit vir sonlig, veluitslag
- gewrigswelling, swelling van u onderbene of hande
- tydelike griep-soortige simptome (spier/gewrigspyn, voel oor die algemeen ongesteld en in skaars gevalle, koors) gewoonlik met die aanvang van behandeling
- ongewone frakture van die dybeen, veral by pasiënte op langtermyn behandeling vir osteoporose, mag selde voorkom. Kontak u dokter indien u pyn, swakheid of ongemak in u dy, heup of lies ervaar, aangesien dit 'n vroeë indikasie van 'n moontlike fraktuur van die dybeen mag wees.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend:
- lae bloedkalsiumvlakke.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van OSTEONATE 70 mg in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om OSTEONATE 70 mg te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 25 °C.
Beskerm teen vogtigheid en direkte lig.
Hou stulpstroke in die buitenste kartonhouer, totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype, of rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat OSTEONATE 70 mg bevat:
Die aktiewe bestanddeel is alendroniese suur.
Elke OSTEONATE 70 mg tablet bevat alendronaatmononatriumtrihidraat, gelykstaande aan alendroniese suur 70 mg.

Die ander bestanddele is:
Kruisgekoppelde povidoon, magnesiumstearaat en mikrokristallyne sellulose.

Hoe OSTEONATE 70 mg lyk en die verpakkingsinhoud
OSTEONATE 70 mg tablette is wit, ovaal en plat, met afmetings van 14 x 8 mm, en gemerk aan die een kant met "70".

OSTEONATE 70 mg tablette is beskikbaar in 'n OPA/Al/PVC/Al stulpverpakking wat 4 tablette in 'n buitenste kartonhouer bevat.

Eienaar van die Registrasiesertifikaat

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