

**PATIENT INFORMATION LEAFLET
OSTEONATE 70 mg**

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OSTEONATE 70 mg tablets

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.
- **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.

1. WHAT OSTEONATE 70 mg CONTAINS:

The active substance is alendronic acid.

Each **OSTEONATE 70 mg** tablet contains trihydrate monosodium alendronate which is equivalent to 70 mg alendronic acid.

The other ingredients are cellulose microcrystalline, crospovidone and magnesium stearate.

OSTEONATE 70 mg is sugar free.

2. WHAT OSTEONATE 70 mg IS USED FOR:

OSTEONATE 70 mg is prescribed to treat osteoporosis (thinning of the bone) after menopause in women and also to treat osteoporosis in men.

3. BEFORE YOU TAKE OSTEONATE 70 mg:

Do not take OSTEONATE 70 mg:

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- if you are hypersensitive (allergic) to alendronate or any of the other ingredients of **OSTEONATE 70 mg** (see **WHAT OSTEONATE 70 mg CONTAINS**).
- if you are pregnant or breastfeeding.
- if you are suffering from any medical problems, especially a history of oesophageal (food pipe) and digestive disorders, and severe kidney problems.
- 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.

Take special care with OSTEONATE 70 mg:

- 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.
- if you have been told by your doctor that you have low blood calcium or a vitamin D deficiency (see **HOW TO TAKE OSTEONATE 70 mg**).
- 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.

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- You have poor dental health, gum disease, a planned dental extraction or you do not receive routine dental care.
- You should avoid dental procedures or surgery while taking **OSTEONATE 70 mg**.
- Do not suck or chew the tablet as it may cause burning in the mouth and throat.

Taking 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 and breastfeeding:

Do not use **OSTEONATE 70 mg** in pregnancy.

Do not use **OSTEONATE 70 mg** during breastfeeding as it enters breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **OSTEONATE 70 mg**.

Driving and using machinery:

OSTEONATE 70 mg will most likely not make you drowsy or impair your ability to drive and use machinery but take care if you feel dizzy, tired or drowsy while taking **OSTEONATE 70 mg**.

Taking other medicines with OSTEONATE 70 mg:

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

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- Do not take any mineral supplements or antacids, containing aluminium, magnesium, iron or calcium 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.
- Certain medicines called non-steroidal 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 **OSTEONATE 70 mg** and NSAIDs at the same time.

4. 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 instructed you. You should check with your doctor or pharmacist if you are unsure.

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- or calcium products with **OSTEONATE 70 mg** as it will decrease the absorption of the **OSTEONATE 70 mg** in the

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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**.

The safety and effectiveness of **OSTEONATE 70 mg** in children have not been established.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

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 overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The following side effects may occur if you take more **OSTEONATE 70 mg** than you should: 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 a dose of OSTEONATE 70 mg:

If you forget to take **OSTEONATE 70 mg**, take the missed dose on the morning after you

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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.

5. POSSIBLE SIDE EFFECTS:

OSTEONATE 70 mg may 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 taking

OSTEONATE 70 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **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
- skin 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
- throat problems, such as difficulty with swallowing, sore throat, bleeding in the mouth and throat, constant cough or changes in your voice. These side effects, if serious, may be a sign of throat cancer

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- kidney failure: you may experience less urine than is normal for you, swelling of legs, ankles or feet, nausea or extreme tiredness
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters).

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:

- headaches
- abdominal pain, indigestion, bloated or swollen stomach, nausea, vomiting, constipation, diarrhoea, wind, acid regurgitation from the stomach, black or tar-like stools
- bone, muscle and/or joint pain which is sometimes severe.

Less frequent side effects:

- you look pale and feel tired and breathless (you may have anaemia where you have less haemoglobin in your blood than is normal)
- bleeding from your gums, nose or mouth, any bleeding that will not stop, reddish or pink urine, unexpected bruising (you may have less platelets in your blood than is normal)
- signs of infections such as fever/chills or a sore throat (you may have less white blood cells than is normal)
- hallucinations (strange visions or sounds)
- vertigo (the feeling of moving or spinning while you aren't moving), changes in your sense of taste or dizziness
- inflammation of the eye, redness or pain of the eye, abnormal or blurred vision
- sore throat or difficulty swallowing, chest pain

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- liver problems, such as yellowing of skin and eyeballs (jaundice), pain in your upper right abdomen, abdominal swelling or generally feel unwell
- rash (occasionally due to sunlight), redness and itchiness of skin, hair loss
- joint swelling, redness or warmth, pain in the mouth or jaw, usually due to delayed healing and infection, often following tooth extraction, unusual fractures of the thigh bone or hip, thigh pain, vague discomfort, or weakness
- temporary flu-like symptoms (muscle/joint pain, generally feeling unwell and in rare cases fever) usually at the start of treatment
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- temporary decreases of phosphate levels in your blood which may be detected in a blood test.

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

6. STORING AND DISPOSING OF OSTEONATE 70 mg:

Store at or below 25 °C

Protect from light and moisture

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)

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.