

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DENSATE 70 mg (Tablet)

Sodium alendronate

Read all of this leaflet carefully before you start taking **DENSATE 70 mg**

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist.

DENSATE 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 **DENSATE 70 mg** CONTAINS

The active substance is sodium alendronate.

DENSATE 70 mg:

Each uncoated tablet contains sodium alendronate equivalent to alendronic acid 70 mg. Sugar free.

The other ingredients are cellulose microcrystalline, magnesium stearate, maize starch, povidone and sodium starch glycolate.

WHAT **DENSATE 70 mg** IS USED FOR

DENSATE 70 mg belongs to a class of medicines called bisphosphonates. **DENSATE 70 mg** works by preventing bone breakdown and increasing bone density.

The treatment of osteoporosis (thinning of bone) in women after menopause. It reduces the chance of having a hip or spinal fracture (break).

The treatment of osteoporosis in men. It reduces the chance of having a spinal fracture (break).

BEFORE YOU TAKE DENSATE 70 mg

Do not take DENSATE 70 mg:

If you are hypersensitive (allergic) to alendronate, or any of the other ingredients of **DENSATE 70 mg**.

If you have severe kidney problems.

If you have disorders of the oesophagus e.g. narrowing or achalasia (a condition causing difficulty in swallowing, regurgitation and sometimes chest pain).

If you have low blood calcium levels.

If you have a vitamin D deficiency.

If you cannot stand or sit upright for 30 minutes after taking **DENSATE 70 mg**.

If you are pregnant.

If you are breastfeeding.

In children. The safety of **DENSATE 70 mg** in children has not been determined.

If you have stomach or intestine problems such as inflammation of the small intestine, difficulty in swallowing, inflammation of the stomach, ulcers or a disease of the oesophagus.

Take special care with DENSATE 70 mg:

A dental examination should be considered before you start treatment with **DENSATE 70 mg** if you have cancer, are undergoing chemotherapy, are taking corticosteroids or have poor oral hygiene. If you have any of these conditions and are taking **DENSATE 70 mg**, certain dental procedures should be avoided if possible. If you develop bone destruction in the jaw (called osteonecrosis of the jaw) while taking **DENSATE 70 mg**, having dental surgery may make this condition worse. Consult your dentist for more details.

Before starting therapy with **DENSATE 70 mg**, low blood calcium levels and vitamin D deficiency should be corrected.

Tell your doctor if you have stomach or intestine problems such as inflammation of the small intestine, difficulty in swallowing, inflammation of the stomach, ulcers or a disease of the oesophagus.

DENSATE 70 mg may cause problems in your oesophagus (the tube that connects the mouth and stomach). These problems include inflammation, or ulcers of the oesophagus, which may sometimes bleed and cause narrowing of the oesophagus.

This may occur especially if you do not drink a full glass of water with **DENSATE 70 mg** or if you lie down in less than 30 minutes after taking **DENSATE 70 mg**, or before your first food of the day.

Stop taking DENSATE 70 mg and call your doctor right away if you get any of these signs of possible serious problems of the oesophagus: Chest pain, new or worsening heartburn, trouble or pain when swallowing.

Mouth sores (ulcers) may occur if the **DENSATE 70 mg** tablet is chewed or sucked.

Do **not** take **DENSATE 70 mg** at bedtime or before getting up for the day.

Small decreases in blood levels of calcium and phosphate may occur, especially in patients taking glucocorticoid medicines.

Make sure that you are taking in adequate calcium and vitamin D, especially if you are receiving glucocorticoid medicines.

Taking DENSATE 70 mg with food and drink:

Take **DENSATE 70 mg** **after** you get up for the day and at least 30 minutes **before** taking your first food, drink, or other medicine.

Swallow your **DENSATE 70 mg** tablet with a full glass of **plain water** only.

Do **not** take **DENSATE 70 mg** with mineral water or other beverages.

Pregnancy and Breastfeeding:

The safe use of **DENSATE 70 mg** during pregnancy and breastfeeding has not been determined.

DENSATE 70 mg is only intended for use in postmenopausal women.

Do not take **DENSATE 70 mg** if you are pregnant or if you are breastfeeding.

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

Driving and using machinery:

There is no information to show that **DENSATE 70 mg** affects the ability to drive a car or operate machinery.

Important information about some of the ingredients of DENSATE 70 mg

DENSATE 70 mg tablets are sugar free.

Taking other medicines with DENSATE 70 mg:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines)

After swallowing your **DENSATE 70 mg** tablet, wait at least 30 minutes before you take other oral medicines, including antacids and calcium supplements. Calcium supplements, antacids and other oral medicines will interfere with the absorption of **DENSATE 70 mg** if taken at the same time.

Concomitant administration of nonsteroidal anti-inflammatory medicines (NSAIDs) such as indomethacin and ibuprofen with **DENSATE 70 mg** may cause digestive problems.

Low blood calcium levels occur with concurrent administration of **DENSATE 70 mg** and aminoglycoside antibiotics, such as amikacin, gentamicin, netilmicin, streptomycin and tobramycin.

HOW TO TAKE DENSATE 70 mg

Do not share medicines prescribed for you with any other person.

Always take **DENSATE 70 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **DENSATE 70 mg** is too strong or too weak, talk to your doctor or pharmacist.

It is important to take **DENSATE 70 mg** only as directed by your doctor.

It is very important that you follow the following steps to help **DENSATE 70 mg** reach your stomach quickly and help reduce possible irritation of your oesophagus (the tube that connects your mouth with your stomach):

Take **DENSATE 70 mg** **after** you get up for the day and at least 30 minutes **before** taking your first food, drink, or other medicine.

Swallow your **DENSATE 70 mg** tablet with a full glass of **plain water** only.

Do **not** take **DENSATE 70 mg** with mineral water or other beverages.

Do **not** crush, chew or suck the tablet. Swallow the tablet whole.

Do not lie down, stay fully upright (sitting, standing or walking) for at least 30 minutes after swallowing **DENSATE 70 mg**. Do not lie down until after your first food of the day.

Do **not** take **DENSATE 70 mg** at bedtime or before getting up for the day.

After swallowing **DENSATE 70 mg**, wait at least 30 minutes before taking calcium and vitamin D supplements. Calcium and vitamin D supplements should be taken if your diet is inadequate.

Dosage:

For the treatment of osteoporosis (thinning of bone) in women after menopause, the usual dose is one 70 mg tablet once weekly.

For the treatment of osteoporosis in men, the usual dose is one 70 mg tablet once weekly.

If you take more DENSATE 70 mg than you should:

Do not make yourself vomit and do not lie down.

Taking milk and antacids is recommended.

Overdose symptoms may include low levels of calcium in the blood, low levels of phosphate in the blood, upset stomach, heartburn, inflammation of the oesophagus, inflammation of the stomach or ulcer.

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

If you forget to take DENSATE 70 mg:

If you miss a dose, take only one **DENSATE 70 mg** on the morning after you remember. Do not take two tablets on the same day. Continue your usual schedule of one **DENSATE 70 mg** tablet once a week on your chosen day.

POSSIBLE SIDE EFFECTS

DENSATE 70 mg can have side effects.

If any of the following happens, stop taking **DENSATE 70 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DENSATE 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:

chest pain

new or worsening heartburn

trouble or pain when swallowing.

black or tar-like stools, vomiting blood

severe joint, bone or muscle pain

jaw pain, numbness or swelling

severe skin reactions

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

Tell your doctor if you notice any of the following:

Other side effects include: symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth; headache; blurred vision, pain or redness in the eye; abdominal (stomach area) pain; heartburn; abdominal swelling; ulcers of the oesophagus; irritation or inflammation of the oesophagus; narrowing of the oesophagus; mouth sores (ulcers); stomach ulcers; ulcers in the duodenum (first part of the small intestine); inflammation of the stomach; excess amount of air/gas in the stomach; nausea; vomiting; constipation; diarrhoea; rash; redness of the skin; itching; transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment; decreases in blood levels of calcium and phosphate.

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **DENSATE 70 mg**.

Not all side effects reported for **DENSATE 70 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DENSATE 70 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

STORING AND DISPOSING OF DENSATE 70 mg

Store in a dry place at or below 25 °C (room temperature).

Do not remove blisters from carton until required for use.

Keep original containers well closed.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF DENSATE 70 mg

DENSATE 70 mg:

Tablets are packed in printed aluminium foil with heat seal lacquer and clear PVC laminated with a clear.

Each blister contains 4 tablets.

Pack size: 4's – Each carton contains 1 blister of 4 tablets each.

IDENTIFICATION OF DENSATE 70 mg

DENSATE 70 mg: White to off-white, oval shaped, biconvex, uncoated tablets, debossed with 'F' on one side and '21' on the other side.

REGISTRATION NUMBER/REFERENCE NUMBER

DENSATE 70 mg: 45/3.2/0581

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