PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

DENSATE 70 mg, Tablets

Sodium alendronate

Sugar free

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, pharmacist, nurse or other healthcare provider.
- 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 is in this leaflet

1. What DENSATE 70 mg is and what it is used for
2. What you need to know before you take DENSATE 70 mg
3. How to take DENSATE 70 mg
4. Possible side effects
5. How to store DENSATE 70 mg
6. Contents of the pack and other information

1. What DENSATE 70 mg is and what it 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).

2. What you need to know 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 (listed in section 6).
- 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 are unable to 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.

Warnings and precautions

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.
- Make sure to tell your doctor if you have ear symptoms such as pain, discharge or chronic ear infections.
- 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.
- If you have or have ever had any kidney problems.
- Bone, muscle and/or joint pain which is severe.
- If you have or have had a condition called hypoparathyroidism (a condition where your parathyroid gland does not work properly).

Children and adolescents

DENSATE 70 mg should not be given to children and adolescents less than 18 years of age.

Other medicines and DENSATE 70 mg

Always tell your healthcare provider if you are taking any other medicine. (This includes all 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.
- Iron, magnesium and certain laxatives will interfere with DENSATE 70 mg.
- 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.

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, 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 DENSATE 70 mg.

Driving and using machines

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

Patients may experience side effects such as blurred vision, dizziness and severe bone, muscle or joint pain that may affect your ability to drive or operate machinery (see section 4).

It is not always possible to predict to what extent DENSATE 70 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DENSATE 70 mg affects you.

DENSATE 70 mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. 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 told you. You should check with your doctor or pharmacist if you are not sure. 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.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DENSATE 70 mg can have side effects.

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 healthcare provider for advice.

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:

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

These are all very serious side effects. If you have them, you may have had a serious 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 (Stevens-Johnson syndrome and toxic epidermal necrolysis)

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;
- dizziness;
- spinning sensation;
- abdominal pain, heartburn;
- ulcers of the oesophagus, abdominal swelling (belly area);
- constipation, diarrhoea, excess amount of air/gas in the stomach;

- narrowing of the oesophagus, acid reflux;
- hair loss;
- itching;
- bone, muscle or joint pain;
- generally feeling unwell;
- swelling in the arms or legs.

Less frequent side effects

- oesophageal cancer;
- blood disorders (low white blood cell count, lack or dysfunctional of red blood cells, low platelet level);
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth;
- decreases in blood levels of phosphate;
- taste disturbance;
- blurred vision; pain or redness in the eye;
- double vision, swollen eyelid, eye inflammation;
- bone damage in the ear (symptoms such as ear pain, discharge from the ear, and/or an ear infection);
- an irregular, often rapid heart rate;
- nausea; vomiting;
- irritation or inflammation of the oesophagus;
- mouth sores (ulcers); stomach ulcers; ulcers in the duodenum (first part of the small intestine); inflammation of the stomach;
- significant bleeding from the gastrointestinal tract;
- increased liver enzymes, liver damage and inflammation of the liver;
- rash; redness of the skin;

- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur. 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.
- kidney failure;
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment.

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.

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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DENSATE 70 mg.

5. How to store 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).

6. Contents of the pack and other information

What DENSATE 70 mg contains:

The active substance is sodium alendronate equivalent to alendronic acid.

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

What DENSATE 70 mg looks like and contents of the pack

White to off-white, oval shaped, biconvex, uncoated tablets, debossed with ‘F’ on one side and ‘21’ on the other side.

DENSATE 70 mg:

Tablets are packed in printed aluminium foil with heat seal lacquer and clear PVC laminated with aclar. Each blister contains 4 tablets.

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

Holder of Certificate of Registration

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Access to the corresponding Professional Information

https://www.novagenpharma.co.za/products/ osteoporosis/