

Applicant: Aurogen South Africa (Pty) LTD
Product Name: **GENSOF** 10mg and 70mg.



Dosage form and strength: Each uncoated tablet contains sodium alendronate equivalent to alendronic acid 10mg and 70mg .

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking GENSOF .

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **GENSOF** 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.

S3

GENSOF (Tablet)

Sodium alendronate

1. WHAT GENSOF CONTAINS

The active substance is sodium alendronate.

GENSOF :

Each uncoated tablet contains sodium alendronate equivalent to alendronic acid 10 mg. Sugar free.

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

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.

2. WHAT GENSOF IS USED FOR

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

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- 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).

3. BEFORE YOU TAKE GENSOF

Do not take GENSOF :

- If you are hypersensitive (allergic) to alendronate, or any of the other ingredients of **GENSOF** .
- 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 **GENSOF** .
- If you are pregnant.
- If you are breast-feeding.
- In children. The safety of **GENSOF** 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 GENSOF :

- A dental examination should be considered before you start treatment with **GENSOF** 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 **GENSOF** , certain dental procedures should be avoided if possible. If you develop bone destruction in the jaw (called

osteonecrosis of the jaw) while taking **GENSOF** , having dental surgery may make this condition worse. Consult your dentist for more details.

- Before starting therapy with **GENSOF** , 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.
- **GENSOF 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 **GENSOF** or if you lie down in less than 30 minutes after taking **GENSOF** , or before your first food of the day.

Stop taking GENSOF 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 **GENSOF** tablet is chewed or sucked.
- Do **not** take **GENSOF** 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 GENSOF with food and drink:

- Take **GENSOF** you get up for the day and at least 30 minutes **before** taking your first food, drink, or other medicine.
- Swallow your **GENSOF** tablet with a full glass of **plain water** only.
- Do **not** take **GENSOF** with mineral water or other beverages.

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Pregnancy and Breast-feeding:

- The safe use of **GENSOF** during pregnancy and breast-feeding has not been determined.
- **GENSOF** is only intended for use in postmenopausal women.
- Do not take **GENSOF** if you are pregnant or if you are breast-feeding.

If you are pregnant or breast-feeding your baby while taking **GENSOF** , please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

- There is no information to show that **GENSOF** affects the ability to drive a car or operate machinery.

Taking other medicines with GENSOF :

- After swallowing your **GENSOF** 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 **GENSOF** if taken at the same time.
- Concomitant administration of nonsteroidal anti-inflammatory medicines (NSAIDs) such as indomethacin and ibuprofen with **GENSOF** may causes digestive problems.
- Low blood calcium levels occur with concurrent administration of **GENSOF** and aminoglycoside antibiotics, such as amikacin, gentamicin, netilmicin, streptomycin and tobramycin.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **GENSOF** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE GENSOF

Always take **GENSOF** 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 **GENSOF** is too strong or too weak, talk to your doctor or pharmacist.

- It is important to take **GENSOF** only as directed by your doctor.
- It is very important that you follow the following steps to help **GENSOF** reach your stomach quickly and help reduce possible irritation of your oesophagus (the tube that connects your mouth with your stomach):
 - Take **GENSOF** **after** you get up for the day and at least 30 minutes **before** taking your first food, drink, or other medicine.
 - Swallow your **GENSOF** tablet with a full glass of **plain water** only.
 - Do **not** take **GENSOF** 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 **GENSOF** . Do not lie down until after your first food of the day.
 - Do **not** take **GENSOF** at bedtime or before getting up for the day.
 - After swallowing **GENSOF** , 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 10 mg tablet once daily
 - For the treatment of osteoporosis in men, the usual dose is one 10 mg tablet once daily
 - 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.

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If you take more GENSOF 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, seek help at the nearest hospital or poison centre.

If you forget to take GENSOF :

If you miss a dose, take only one **GENSOF** on the morning after you remember. Do not take two tablets on the same day. Continue your usual schedule of one **GENSOF 70mg** tablet once a week for the on your chosen day or one tablet daily for the **GENSOF 10mg**

5. POSSIBLE SIDE-EFFECTS

GENSOF can have side-effects.

Get emergency medical help if you have any of these **signs of an allergic reaction**:

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

Call your doctor at once if you have any of these serious side-effects:

- 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

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,

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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 **GENSOF** .

Not all side-effects reported for **GENSOF** are included in this leaflet. Should your general health worsen while taking **GENSOF** , please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF GENSOFF

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.

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF GENSOFF

GENSOFF 10 mg:

Tablets are packed in printed aluminium foil with heat seal lacquer and clear PVC laminated with a clear. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

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Tablets are packed in 40 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad. Each container contains 30 tablets.

Pack size: 30's – One HDPE container contains 30 tablets.

GENSOF 70mg :

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.

8. IDENTIFICATION OF GENSOF

GENSOF 10 mg: White to off-white, round, biconvex, uncoated tablets, debossed with 'F' on one side and '18' on the other side.

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

9. REGISTRATION NUMBER/REFERENCE NUMBER

GENSOF 10 mg: 45/3.2/0584

GENSOF 70 mg: 45/3.2/0585

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1,
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

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11. DATE OF PUBLICATION

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