Approved Patient Information Leaflet for Medicines for Human Use:
SOSKAIN

SCHEDULING STATUS: S3

SOSKAIN 50 000 IU soft gelatin capsule

Cholecalciferol (vitamin D_3)

Contains sugar: sorbitol 16,5 mg

Read all of this leaflet carefully before you start taking SOSKAIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your health care provider.
- SOSKAIN 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 SOSKAIN is and what it is used for
2. What you need to know before you take SOSKAIN
3. How to take SOSKAIN
4. Possible side effects
5. How to store SOSKAIN
6. Contents of the pack and other information

1. What SOSKAIN is and what it is used for

SOSKAIN contains cholecalciferol (vitamin D_3). Vitamin D_3 can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D_3 helps the kidneys and intestine absorb calcium and it helps build bones.

SOSKAIN is used: to treat vitamin D deficiency that has been confirmed by laboratory tests.

2. What you need to know before you take SOSKAIN

Do not take SOSKAIN

- if you are hypersensitive (allergic) to cholecalciferol (vitamin D_3) or any of the other ingredients of SOSKAIN (listed in section 6)
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you have kidney stones (renal calculi)
- if you have severe renal impairment
- if you have high levels of vitamin D_3 in your blood (hypervitaminosis D)
- if you have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
- if you are pregnant
- if you are under 18 years of age.

If any of the above applies to you, talk to your health care provider before taking SOSKAIN.

Warnings and precautions

Take special care with SOSKAIN

- if you are undergoing treatment with certain medicines used to treat heart disorders (e.g, cardiac glycosides, such as digoxin)
- if you have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D_3 in the body)
- if you are taking medicines containing vitamin D_3, or eating foods or milk enriched with vitamin D_3
- if you are likely to be exposed to a lot of sunshine whilst using

SOSKAIN

- if you take additional supplements containing calcium. Your health care provider will monitor your blood levels of calcium to make sure they are not too high whilst you are using SOSKAIN
- if you have kidney damage or disease. Your health care provider may want to measure the levels of calcium in your blood or urine.

Children

SOSKAIN is not suitable for use in children and adolescents under 18 years of age.

Other medicines and SOSKAIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.):

- medicines that act on the heart or kidneys, such as cardiac glycosides (e.g., digoxin) or diuretics ("water tablets" e.g. called thiazide diuretics). When used at the same time as vitamin D_3 these types of medicines may cause a large increase in the level of calcium in the blood and urine
- medicines containing vitamin D_3 or eating food rich in vitamin D_3, such as, some types of vitamin D_3-enriched milk
- actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g. clotrimazole and ketoconazole, medicines used to treat fungal disease).
  These medicines may interfere with the way your body process vitamin D_3
- the following medicines because they can interfere with the effect or the absorption of vitamin D_3:
  – antiepileptic medicines (anticonvulsants), barbiturates;
  – glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D_3;

– medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol);

– certain medicines for weight loss that reduce the amount of fat your body absorbs (e.g. orlistat);

- certain laxatives (such as liquid paraffin).

SOSKAIN with food and drink

The capsules should be swallowed whole with water.

You should take SOSKAIN preferably together with a large meal to help your body absorb the vitamin D.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or health care provider for advice before taking SOSKAIN.

SOSKAIN should not be taken by pregnant or breastfeeding women.

Driving and using machines

There is limited information on the possible effects of SOSKAIN on your ability to drive. However, it is not expected that it would affect your ability to drive or to operate machinery.

3. How to take SOSKAIN

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

Always take SOSKAIN exactly as your doctor or pharmacist has told you. Check with your health care provider if you are not sure.

The usual dose is 1 capsule (50 000 IU) once per week for 6 - 8 weeks, followed by maintenance therapy (such as 1 capsule once a month or as prescribed by your doctor). Your dosage may however be determined differently, depending on your individualised prescription.

Duration of administration

Your health care provider will tell you how long your treatment with SOSKAIN will last. Do not stop treatment early. If you have the impression that the effect of SOSKAIN is too strong or too weak, tell your health care provider.

Method of administration

The capsules should be swallowed whole with water.
You should take SOSKAIN preferably together with a large meal to help your body absorb the vitamin D.

If you take more SOSKAIN than you should

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

The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take SOSKAIN

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

If you stop taking SOSKAIN

If you have any further questions on the use of SOSKAIN, ask your health care provider.

4. Possible side effects

SOSKAIN can have side effects.

Not all side effects reported for SOSKAIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOSKAIN, please consult your health care provider for advice.

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

- Swelling of hands, feet, ankles, face lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Hives
- Fainting

These are all very serious side effects. If you have them you have had a serious reaction to SOSKAIN. You may need urgent medical attention or hospitalisation.

Tell you doctor if you notice any of the following:

Less frequent side effects:

- Too much calcium in your blood (hypercalcaemia)
- Too much calcium in your urine (hypercalciuria)

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. 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 SOSKAIN

5. How to store SOSKAIN

Store all medicines out of reach of children

- Do not use SOSKAIN after the expiry date which is stated on the carton after "Exp". The expiry date refers to the last day of that month.
- Do not store above 30 °C.
- Store in the original packaging until required for use.

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 SOSKAIN contains

- The active substance in SOSKAIN is cholecalciferol (also known as vitamin D_3). Each capsule contains 1,25 mg cholecalciferol equivalent to 50 000 IU vitamin D_3.

The other ingredients are:

Capsule content: vitamin E acetate (α-tocopheryl acetate), medium chain triglycerides.

Gelatin shell: gelatin, glycerol, sorbitol liquid, partially dehydrated quinoline yellow.

What SOSKAIN looks like and contents of the pack

SOSKAIN Yellow coloured, clear transparent round shaped gelatin capsule with a clear, colourless liquid fill.

Capsule dimensions: approximate length is 7,36 mm and approximate width is 6,27 mm.

SOSKAIN is supplied in white PVC/ PVDC aluminum blister strips of 10/12/20/50/100's pack sizes (10 or 12 capsules per blister strip packed in an outer carton).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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