شركة الأصول الطبية التجارية
Alosool Medical Trading Co.

Direct Healthcare Practitioners Communication (DHPC) Letter

Date: 13-09-2026

Alfadiol 1 microgram soft capsules (Alfacalcidolum): Absence of Arabic and English labelling information on the outer packaging of Batch no. 010524.

Subject:

Dear healthcare providers,

Alosool Medical Trading Company in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

The availability of English package leaflet for Alfadiol 1 microgram soft capsules (Alfacalcidolum) and Important Safety Information

Summary:

Expiry date	Batch No.	Product Name
31/05/2027	010524	Alfadiol

As per the quality report received by the pharmaceutical sector regarding this product, the following details were included:

- **The issue (Packaging defect)**
  The outer packaging of the affected batch contains labelling information in a language other than Arabic or English, resulting in the absence of accessible product information for healthcare professionals and patients in Saudi Arabia.

- **The affected batch**
  The affected batch number is 010524 as per SFDA notification.

- **The corrective and preventive actions (CAPA's)**
  As a corrective action, An English Packaging leaflet for the affected batch (010524) is provided to ensure the appropriate product use until corrective labeling measured are completed.

Further safety information:

Healthcare professionals are advised to:

1- Review the enclosed package leaflet prior to dispensing the product.
2- Ensure the patient receive appropriate counseling regarding product use.
3- Exercise caution when dispensing the affected batch due to the lack of Arabic and English labelling information.

Call for Reporting Any Quality Defects or Side Effects:

Healthcare professionals are encouraged to report any suspected adverse reactions, medication errors, or quality defects associated with this product to National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA):

Website: https://ade.sfda.gov.sa/

E-mail: npc.drug@sfda.gov.sa
SFDA call center: 19999

Alosool Medical Trading company Contact point:
Name: Alhanouf Alabdulaziz In his capacity as: QPPV
E-mail: QPPV@omc-ksa.com
Mobile: 0535120254

For Medical Information enquiries, please contact:
Mobile: 0552040019
Email: Abdalkreem@omc-ksa.com

Annexes:
Alfadiol 1mcg soft capsule Leaflet

This document is approved by The Executive Directorate of Pharmacovigilance at SFDA.

Best regards
Alhanouf Alabdulaziz
QPPV

Package leaflet: Information for the patient

ALFADIOL, 0.25 micrograms, capsules, soft ALFADIOL, 1 microgram, capsules, soft

Alfacalcidolum

Read all of this leaflet carefully before you use this medicine as it contains important information for you.
- Please keep this leaflet so that you can read it again if necessary.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. It should not be passed on to others. The medicine may harm another person, even if their symptoms are the same.
- If you experience any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

Table of contents of the leaflet:

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

1. What Alfadiol is and what it is used for

Alfadiol contains the active substance alfacalcidol, which is a synthetic derivative of vitamin D. It facilitates the absorption of calcium from the gastrointestinal tract and its incorporation into bone tissue. Too little vitamin D in food and insufficient calcium supply can cause rickets in children, and in adults softening of the bones (osteomalacia) or increased susceptibility to fractures. Vitamin D and calcium deficiencies occur in women after menopause, in people in old age, as well as among people suffering from certain kidney diseases, consequently leading to osteoporosis.

In order to achieve full biological activity, vitamin D must undergo chemical transformations in the human body to alphacalcidol in the kidneys, and then in the liver to calcitriol.
In some kidney diseases, these transformations are difficult or even completely impossible, and therefore patients with these diseases suffer from calcium and phosphate metabolism disorders. Alfadiol is intended for use under medical supervision, especially in this group of patients.

Indications for the use of Alfadiol:

- postmenopausal osteoporosis and senile osteoporosis with a simultaneous deficiency of vitamin D or its active metabolites,
- low blood calcium levels (hypocalcaemia), especially in patients with conditions leading to impaired vitamin D hydroxylation in the kidneys,
- rickets and bone softening (osteomalacia) resistant to vitamin D,
- hypoparathyroidism,
- renal osteodystrophy (renal rickets causing bone disorders),
- calcium metabolism disorders in patients with chronic renal failure,
- nephrotic syndromes in children after long-term treatment with glucocorticoids.

2. What you need to know before you use Alfadiol Do

not take Alfadiol

Do not take this medicine if you have:
- if you are allergic to alfacalcidol or any of the other ingredients of this medicine (listed in section 6),
- allergy to peanuts or soy,
- high blood calcium levels (hypercalcemia), metastatic calcifications,
- high levels of phosphorus in the blood (hyperphosphatemia) – (except for hypoparathyroidism),
- high levels of magnesium in the blood (hypermagnesemia),
- spontaneous hypercalciuria (urinary excretion of calcium),
- softening of the bones after aluminum poisoning (osteomalacia),
- overdose and vitamin D poisoning,
- calcium nephrolithiasis (calcium deposition in the urinary tract),
- severe hepatic impairment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alfadiol.

- Your calcium levels may rise too much while you are using this medicine or phosphate in the serum, especially in patients with renal impairment. Therefore, the doctor will order a calcium level check – initially 1 to 2 times a week, and once a month after determining the dose of the drug.

- Caution should be exercised in patients with renal insufficiency and nephrolithiasis.

- The use of Alfadiol in the treatment of renal osteodystrophy requires systematic monitoring of the concentration of parathyroid hormone (PTH) in the blood – due to the risk of adynamic bone disease, consisting in disorders of bone metabolism.

- Patients with high plasma calcium levels may develop autonomic hyperparathyroidism in the course of renal osteodystrophy. These patients may not respond to this medicine.

- Patients with renal insufficiency, tertiary hyperparathyroidism or regular haemodialysis (potential phosphate decrease) are particularly susceptible to developing excessive calcium elevations. Early symptoms of excessive calcium levels include: polyuria, increased thirst, weakness, headaches,
  nausea, dry mouth, constipation, muscle pain, bone pain, and a metallic taste in the mouth.

- Depending on the patient's condition and risk factors, the doctor may order periodic (every 1-3 months) blood tests (determination of extraprotein nitrogen in plasma, creatinine, alkaline phosphatase, serum phosphate levels) and urine tests (daily excretion of calcium in the urine and calcium-creatinine ratio).

- In patients on a low-calcium diet, the response to Alfadiol may be reduced or may not occur at all.

- Caution should be exercised in patients treated with cardiac glycosides, e.g. digitalis, as hypercalcaemia may lead to cardiac arrhythmias in these patients.

- Elderly patients may need to take lower doses of Alfadiol.

Lek Alfadiol a inne leki

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not use the following medicines at the same time as Alfadiol:
- **cardiac glycosides** (medicines used to treat heart failure) – due to the risk of overdose,
- **Thiazide diuretics** (medicines that increase urine production, such as hydrochlorothiazide)
- **calcium-containing medicines** taken regularly at a daily dose of more than 1.5 g – due to the risk of increased blood calcium levels,
- **antacids in the stomach** – due to the risk of increased calcium levels in the blood,
- **medicines containing oestrogens**, as they may increase the effect of Alfadiol,
- **antacids containing magnesium salts**, as magnesium levels may increase,
- **antacids containing aluminium salts**, as they can lower magnesium levels in the blood,
- **hydantoin derivatives** (e.g. phenytoin), **barbiturates, primidone and other anticonvulsants** (used to treat epilepsy) as they may reduce the effect of Alfadiol,
- **glucocorticoids** (called steroids, used to treat m.in rheumatic disease) because they weaken the effect of Alfadiol,
- **salicylates**, as they may reduce the effect of Alfadiol,
- **colestiramine, colestipol** (medicines that lower blood cholesterol) and **paraffin oil**, as they inhibit the absorption of Alfadiol,
- medicines and dietary supplements containing **metal ions**.

Alfadiol with food and drink

Do not eat large amounts of dairy products (milk and milk products) while taking Alfadiol as they may cause an increase in the level of calcium in your blood.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Alfadiol should only be used during pregnancy if the doctor believes that the benefit to the mother outweighs the possible risk to the foetus.

Alfadiol should not be used if you are breastfeeding. Adverse effects of the drug on the nursing infant cannot be excluded.

Driving and using machines

There is no evidence that alfacalcidol adversely affects the ability to drive and use machines.

Alfadiol contains purified peanut oil, cochineal red, ethyl parahydroxybenzoate and sodium

- It contains peanut oil. Do not use if you are known to be hypersensitive to peanuts or soya (see section "Do not take Alfadiol").

– This medicine contains cochineal red (E124), a dye that may cause allergic reactions.
– It contains ethyl parahydroxybenzoate (E214), which may cause allergic reactions (possible late-type reactions).
– This medicine contains less than 1 mmol sodium (23 mg) in each capsule, i.e. the medicine is considered to be "sodium-free".

3. How to use Alfadiol

Always use this medication exactly as your doctor has told you. If you are not sure, ask your doctor.

The dosage and duration of treatment is determined by the doctor depending on the patient's age and condition.

Indication for use	**Children with a body weight of less than 20 kg**	**Children with a body weight of 20 to 40 kg**	**Adults (weighing more than 40 kg)**
	Dose of the drug		
– postmenopausal osteoporosis – senile osteoporosis	-	-	0.5 micrograms up to 1 microgram once a day
– nephrotic syndromes in children after long-term glucocorticoid treatment	0.25 micrograms 1 time daily	0.25 micrograms to 0.5 micrograms 1 time daily	-
– hypocalcemia – rickets and osteomalacia resistant to vitamin C. D – hypoparathyro idism – calcium disorders in patients with chronic renal failure, and renal osteodystrophy	0.25 micrograms 1 time daily	0.25 micrograms to 0.5 micrograms 1 time daily	0.5 micrograms up to 1 microgram once a day

Your doctor may determine the dosage based on the results of a blood test (a measure of calcium in the blood) or urine test (calcium excretion in the urine) and the amount of calcium you have daily intake.

If you take more Alfadiol than you should
If you take more medicine than you should, talk to your doctor or pharmacist immediately.

Symptoms of vitamin D overdose are:
– increased calcium levels in the blood (hypercalcaemia),
– anorexia, weakness,
– nausea, vomiting, diarrhoea,
– excretion of large amounts of urine (polyuria),
– Hyperhidrosis
– thirst

– headaches and dizziness.

After a significant overdose bordering on poisoning, bone pain, ectopic calcification (calcium deposition in unusual places), the presence of protein in the urine (proteinuria), hypertension, cardiac arrhythmias may occur.

In addition, a persistent overdose of vitamin D can cause generalized calcification of blood vessels and kidneys and rapid deterioration of kidney function.

If you forget to take Alfadiol
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose.
Take the next dose as directed by your doctor.
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Adverse reaction occurring with a frequency not known (frequency cannot be estimated from the available data):
- hypersensitivity reactions (e.g. hypersensitivity in patients with asthma, skin irritation, contact dermatitis, pruritus, rash, urticaria, eye irritation),
- increased calcium levels in the blood (hypercalcaemia),
- increased blood phosphorus levels – especially in patients with renal insufficiency,
- urinary excretion of calcium (hypercalciuria), polyuria,
- calcifications in the kidneys, ectopic calcifications (calcium deposition in unusual places),
- renal impairment (as a result of hypercalcemia),
- headache, dizziness, confusion,
- diarrhea, constipation, nausea, vomiting, dry mouth, increased thirst, irritation of the mucous membranes, including the gastric mucosa, metallic taste in the mouth (as a result of hypercalcemia),
- cardiac arrhythmias, muscle pain, bone pain, fatigue (associated with hypercalcaemia).

Reporting of adverse reactions
If you notice any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist. An adverse reaction can be reported directly to the Department of Monitoring of Adverse Reactions to Medicinal Products of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:
Al. Jerozolimskie 181C
02-222 Warsaw
Phone: + 48 22 49 21 301
Fax: + 48 22 49 21 309
Website: https://smz.ezdrowie.gov.pl
Adverse reactions can also be reported to the marketing authorisation holder.
By reporting side effects, it will be possible to gather more information about the safety of the medicine.

5. How to store Alfadiol

Keep this medicine out of the sight and reach of children. Store below 25°C.
Do not freeze.
Store in the original packaging in order to protect from light and moisture.
Do not use this medicine after the expiry date which is stated on the pack. The expiry date is the last day of the given month.
The notation on the packaging after the abbreviation EXP means the expiry date, and after the abbreviation Lot/LOT means the batch number.

Do not dispose of medication down the drain or household waste containers. Ask your pharmacist how to throw away medicines you no longer use. Doing so will help protect the environment.

6. Contents of the pack and other

information What Alfadiol contains
The active substance is alfacalcidol.
Each soft capsule contains 0.25 micrograms (μg) or 1 microgram (μg) of alfacalcidol.

Other excipients are: *all-rac-αlfa-tocopheryl* acetate, butylated hydroxytoluene (E321), purified peanut oil.
Alfadiol 0.25 μg shell: gelatin, glycerol, ethyl parahydroxybenzoate (E214), cochineal red (E124), titanium dioxide (E171), purified water.
Alfadiol 1 μg shell composition: gelatin, glycerol, ethyl parahydroxybenzoate (E214), cochineal red (E124), purified water.

What Alfadiol looks like and contents of the pack
Alfadiol 0.25 μg is a spherical soft capsule with an opaque gelatin red shell with a suture, completely filled with an oily solution.
Alfadiol 1 μg is a spherical soft capsule with a transparent gelatin red shell with a suture, completely filled with an oily solution. Packaging: 100 soft capsules – 2 PVC/PVDC/Aluminium blisters, 50 capsules each, in a cardboard box.

Marketing authorisation holder and

manufacturer Marketing authorisation

holder
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