

**Summary Public Assessment Report**  
**non-generics**

**Alfacalcidol Medreg 0,5 µg**  
**Alfacalcidol Medreg 1 µg**  
**alfacalcidol**

**SK/H/0305/001-002/DC**

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# Summary Public Assessment Report

## non-generics

### **Alfacalcidol Medreg 0,5 µg**

### **Alfacalcidol Medreg 1 µg**

alfacalcidol, soft capsule, 0,5 µg and 1 µg

This is a summary of the public assessment report (PAR) for **Alfacalcidol Medreg**. It explains how **Alfacalcidol Medreg** was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use **Alfacalcidol Medreg**.

For practical information about using **Alfacalcidol Medreg**, patients should read the package leaflet or contact their doctor or pharmacist.

### **What is Alfacalcidol Medreg and what is it used for?**

**Alfacalcidol Medreg** is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of **Alfacalcidol Medreg** is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

**Alfacalcidol Medreg** is used in adults, adolescents and children aged from 6 years to treat diseases where the amount of calcium in body needs changing.

It is used to treat:

- Changes in bone caused by kidney failure (osteodystrophy).
- Changes to the parathyroid glands. These are small glands found in the neck. They make a substance called the parathyroid hormone. This changes the amount of calcium in the body.
  - The glands may make the amount of calcium in the blood too high (hyperparathyroidism).
  - The glands may make the amount of calcium in the blood too low (hypoparathyroidism).
- Softening and deformity of the bones due to lack of calcium (rickets or osteomalacia).

### **How does Alfacalcidol Medreg work?**

**Alfacalcidol Medreg** contains active substance alfacalcidol, that belongs to a group of medicines called vitamin D analogues. It is a type of vitamin D.

Vitamin D controls the levels of two substances in human body. These substances are called calcium and phosphate. Human body needs both of these substances for healthy bones and teeth.

**Alfacalcidol Medreg** works by increasing the amount of vitamin D in human body. This means the levels of calcium and phosphate in human body will increase too.

## **How is Alfacalcidol Medreg used?**

The pharmaceutical form of **Alfacalcidol Medreg** is soft capsule and the route of administration is oral. The capsules should be swallowed whole after meal with sufficient amount of water. Physician will determine how many capsules should be taken, or given to a child. The usual starting dose is 1 microgram each day. For elderly, the starting dose is 0.5 microgram each day. For children from 6 years of age starting dose is 0.05 microgram per kilogram bodyweight each day. People usually take between 1 and 3 micrograms each day. If you have very low levels of calcium in your blood, your doctor may prescribe between 3 and 5 micrograms each day.

Patient taking this medicine may need blood tests to check the levels of calcium, some specific enzymes or parathyroid hormone in order to determine the right dose. Other tests such as X-rays can also be conducted.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

## **What benefits of Alfacalcidol Medreg have been shown in studies?**

As alfacalcidol is a well-known substance, and its use in the treatment of renal osteodystrophy, hyperparathyroidism (with bone disease) ,hypoparathyroidism, pseudo-deficiency (vitamin D-dependent) rickets and osteomalacia, hypophosphataemic vitamin D resistant rickets and osteomalacia is well established, the applicant presented data from the scientific literature.

The literature provided confirmed the efficacy and safety of alfacalcidol in the treatment of renal osteodystrophy, hyperparathyroidism (with bone disease) ,hypoparathyroidism, pseudo-deficiency (vitamin D-dependent) rickets and osteomalacia, hypophosphataemic vitamin D resistant rickets and osteomalacia.

## **What are the possible side effects from Alfacalcidol Medreg?**

The most common side effects with Alfacalcidol Medreg (which may affect up to 1 in 10 people) are abdominal/stomach pain or discomfort, rash, itching.

For the full list of all side effects reported with Alfacalcidol Medreg, see section 4 of the package leaflet.

## **Do not take Alfacalcidol Medreg**

- If you are allergic to alfacalcidol or any of the other ingredients of this medicine (listed in section 6).
- If you know you have a condition called hypercalcaemia. This means you have high levels of calcium in your blood.
- If you know that you have a condition called calcification. This means you have high levels of calcium in your body tissues.

For the full list of restrictions, see the package leaflet.

### **Why is Alfacalcidol Medreg approved?**

The State Institute for Drug Control decided that Alfacalcidol Medreg's benefits are greater than its risks and recommended that it be approved for use.

### **Other information about Alfacalcidol Medreg**

The marketing authorisation for Alfacalcidol Medreg was granted on 21.12.2024.

The full PAR for **Alfacalcidol Medreg** can be found on the website <http://www.sukl.sk>. For more information about treatment with **Alfacalcidol Medreg**, read the package leaflet (<http://www.sukl.sk>) or contact your doctor or pharmacist.

This summary was last updated in 02-2025.