

## AD3 6000 IU/2000 IU in 1 ml oral drops, emulsion

VITAMIN A/CHOLECALCIFEROL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### What is in this leaflet?

1. What AD3 is and what it is used for
2. Before you use AD3
3. How to use AD3
4. Possible side effects
5. How to store AD3
6. Further information

#### 1. WHAT AD3 IS AND WHAT IT IS USED FOR

1 ml of AD3 6000 IU/2000 IU oral drops, emulsion, contains 6000 IU of vitamin A (retinol) and 2000 IU of vitamin D (cholecalciferol).

Vitamin A is essential for the regeneration of the visual pigment of the retina and for the normal structure of the upper layer of the skin and mucous membrane. Vitamin A deficiency leads to night blindness, excessive thickening of the skin and changes in the mucous membrane, which consequently becomes less resistant to infections.

Vitamin D regulates the metabolism of calcium and phosphorus, and prevents and treats rickets (a childhood bone disease).

AD3 is intended for the prevention of vitamin A and vitamin D deficiency in infants and small children.

#### 2. BEFORE YOU USE AD3

##### **Do not use AD3**

- If your child is allergic (hypersensitive) to retinol, cholecalciferol or any of the other ingredients of AD3.
- If your child has elevated blood calcium levels (hypercalcaemia).

##### **Take special care with AD3**

The amount of vitamins A and D should be properly regulated. All the sources from which the child receives the two vitamins should be kept in mind: breast milk, formula milk and other sources.

100 ml of human breast milk contains about 200 IU of vitamin A and 10 IU of vitamin D, and the same amount of cow's milk contains 80 IU of vitamin A and 10 IU of vitamin D.

The content of vitamins A and D varies in different types of formula milk and is stated in the enclosed instruction leaflet.

Do not exceed the prescribed dose of the drops without consulting the doctor.

If your child has kidney impairment, kidney stones or a heart disease, talk to the doctor before using AD3 drops. Plasma calcium and phosphate levels should be monitored regularly during treatment.

### ***Taking other medicines***

Please tell your doctor or pharmacist if your child is receiving or has recently received any other medicines, including medicines obtained without a prescription.

AD3 interacts with some other medicines, which may result in increased or decreased effects of AD3 or the other medicines. Talk to the doctor if your child is receiving the following medicines:

- water tablets (thiazide diuretics),
- medicines for the treatment of epilepsy (carbamazepine, phenobarbitone, phenytoin, primidone),
- medicines for the treatment of tuberculosis (rifampicin and isoniazid),
- medicines for the treatment of fungal infections (ketoconazole),
- anti-inflammatory medicines (corticosteroids),
- medicines for reducing blood lipids and cholesterol (cholestyramine),
- antibiotics (neomycin),
- medicines and preparations containing calcium or phosphates.

### ***Using AD3 with food and drink***

AD3 drops should be given to the child immediately before a meal, alone or in a teaspoon of milk.

### ***Pregnancy and breast-feeding***

Ask your doctor or pharmacist for advice before taking any medicine.

AD3 contains vitamins A and D in doses suitable for children. The medicine is not intended for use in pregnant women and breast-feeding mothers.

Vitamins A and D pass into breast milk.

### ***Driving and using machines***

AD3 has no influence on the ability to drive and use machines.

### ***Important information about some of the ingredients of AD3***

AD3 contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Macrogolglycerol hydroxystearate may cause stomach upset and diarrhoea.

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

## ***3. HOW TO USE AD3***

Always use AD3 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The drops should be administered immediately before a meal, alone or in a teaspoon of milk. Dosage is individual and depends on the child's age and diet (breast-feeding, formula milk, ready-made fruit and vegetable purees), the season of the year and the child's exposure to sunlight. Children who consume a lot of formula milk and eat ready-made purees with added vitamins may receive sufficient amounts of both vitamins. Nevertheless, doctors recommend that in winter time at least a minimal amount of AD3 drops (2 to 3 drops a day) should be administered also to these children.

AD3 drops are usually given to infants from 6 weeks to 1 year of age. The doctor can prescribe preventive intake of drops also after completed first year of age. The daily needs for vitamins A and D are the same as in a one-year-old child.

*Healthy infants under 6 months* require about 1500 IU of vitamin A and 300 IU of vitamin D daily.

The recommended daily dose for breast-fed and cow's milk-fed infants is 7 AD3 drops and for formula-fed infants up to 4 drops, depending on the vitamin content in the formula used.

*Children from 6 months to 3 years* require about 2000 IU of vitamin A and 400 IU of vitamin D daily.

The recommended daily dose for breast-fed and cow's milk-fed children is up to 10 AD3 drops and for formula-fed infants up to 8 AD3 drops.

Premature infants, children with digestive disorders (impaired or incomplete absorption of nutrients in the intestines – malabsorption syndrome) and children with chronic liver or kidney diseases require higher doses of vitamins. They are determined by the doctor according to the child's condition and diet.

### ***If you use more AD3 than you should***

One overdose is unlikely to result in dangerous side effects. Nevertheless, talk to the doctor.

Long-term use of doses above 10 times the daily need for vitamin A and 5 times the daily need for vitamin D may result in hypervitaminoses A and D. In the event of an overdose, stop giving the medicine immediately and talk to the doctor.

### ***If you forget to use AD3***

Do not give a double dose to your child to make up for a forgotten dose.

If you have forgotten to give a dose to your child at the scheduled time, give it as soon as you remember.

### ***If you stop using AD3***

Give AD3 to your child for as long as the doctor prescribed. If you stop giving the medicine too soon, the child may develop signs of vitamin A and vitamin D deficiency.

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

## ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, AD3 can cause side effects, although not everybody gets them.

Side effects are classified into the following groups in order of frequency:

- **Very common** Affects more than 1 user in 10
- **Common** Affects 1 to 10 users in 100
- **Uncommon** Affects 1 to 10 users in 1,000
- **Rare** Affects 1 to 10 users in 10,000
- **Very rare** Affects less than 1 user in 10,000
- **Not known** Frequency cannot be estimated from the available data

### ***Uncommon side effects***

- bloating

### ***Very rare side effects***

- diarrhoea
- hypersensitivity reactions (mainly skin reactions in the form of rashes)
- hypervitaminosis (the initial signs include nausea, lack of appetite, vomiting, diarrhoea, thirst, passing large amounts of urine, restlessness, bulging fontanelles, irritability, tiredness, dry skin, excessive peeling of the skin on the palms and soles or itching; in more severe cases, pain in the bones and joints, cramps and soft tissue calcification occur.)

If signs of hypervitaminosis or hypersensitivity occur, stop giving the drops and talk to the doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE AD3

Keep out of the reach and sight of children.

Do not use AD3 after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### **What AD3 contains**

- The active substances are retinol and cholecalciferol. 1 ml of oral drops, emulsion, (35 drops) contains 6000 IU of vitamin A (retinol) as retinyl palmitate and 2000 IU of vitamin D3 (cholecalciferol). One drop contains about 180 IU of vitamin A and 60 IU of vitamin D3.

- The other ingredients are: macrogolglycerol hydroxystearate, glycerol (E422), sodium benzoate (E211), propylene glycol (E1520), sucrose, saccharine sodium, orange flavour (ethanol) and purified water

### **What AD3 looks like and contents of the pack**

The oral drops, emulsion, are a clear to slightly opalescent, slightly yellow liquid.

AD3 is available in boxes with a bottle of 15 ml of oral drops, solution.

### **Marketing Authorisation Holder and Manufacturer**

KRKA, tovarna zdravil, d. d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

### **This leaflet was last approved on**

7 October 2011