

## APPROVED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

**ZODORAY 0,25 µg capsules, ZODORAY 0,5 µg capsules, ZODORAY 1 µg capsules**

**Alfacalcidol**

**Contains sugar: Sorbitol 10 mg**

### **Read all of this leaflet carefully before you start taking ZODORAY**

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

#### **1. What ZODORAY is and what it is used for**

Alfacalcidol belongs to a group of medicines called vitamin D analogues. It is a type of vitamin D.

Vitamin D controls the levels of calcium and phosphate in your body. Your body needs both of these substances for healthy bones and teeth. Alfacalcidol works by increasing the amount of vitamin D in your body. This means the levels of calcium and phosphate in your body will increase too.

**ZODORAY** is used to treat diseases where the amount of calcium in your body needs changing. It is used to treat:

- Changes in bone caused by kidney failure (renal bone disease).
- Changes to your parathyroid glands. These are small glands found in your neck. They make a substance called the parathyroid hormone. This changes the amount of calcium in your body.
  - The glands may make the amount of calcium in your blood too low (hypoparathyroidism).
  - The glands may make the amount of calcium in your blood too high (hyperparathyroidism).
- Softening and deformity of the bones due to lack of calcium, phosphorus or vitamin D (rickets or osteomalacia). This can be due to an inherited birth defect or due to lack of vitamin D absorption.

## **2. What you need to know before you take ZODORAY**

### **Do not take ZODORAY:**

- If you are hypersensitive (allergic) to alfacalcidol, arachis oil (peanut oil), soya or any of the other ingredients of ZODORAY (listed in section 6).
- If you know you have a condition called hypercalcaemia (high levels of calcium in your blood) or if you show signs of vitamin D intoxication.
- If you are pregnant or breastfeeding your baby.

### **Warnings and precautions**

Take special care with ZODORAY:

- If you have any problems with your kidneys. This includes kidney stones. Your doctor might give you medicine that binds minerals to reduce kidney stones.
- If you are taking medicine to treat convulsions or seizures such as barbiturates. These medicines may decrease the effect of ZODORAY (see **Other medicines and ZODORAY**).

You should only use ZODORAY during your pregnancy or when you are breastfeeding your baby if it is considered essential by your doctor.

### **Other medicines and ZODORAY**

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

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Thiazide diuretics, often called “water pills”: for increasing the amount of water (urine) that your body makes. You may get too much calcium in your blood.
- Calcium-containing medicines. You may get too much calcium in your blood.
- Other medicines that contain vitamin D. You may get too much calcium in your blood.
- Anticonvulsants (for example, barbiturates, phenytoin, carbamazepine or primidone): for epilepsy or fits. You may need a larger dose of ZODORAY.
- Antacids and laxatives containing magnesium: for heartburn or indigestion and constipation. You may get too much magnesium in your blood.
- Medicines containing aluminium. Too much aluminium is toxic.
- Bile acid sequestrants such as cholestyramine: for lowering your cholesterol level, or to help stop some types of diarrhoea or itching. Your ZODORAY may not enter your blood as usual.
- Digoxin (medicines used to treat heart problems).

While you are taking ZODORAY your doctor will take regular blood tests. This is very

important in children or patients with kidney problems. This is to check the level of calcium and phosphate in your blood while you take ZODORAY.

### **Pregnancy and, breastfeeding and fertility**

You should not use ZODORAY if you are pregnant or breastfeeding your baby or if you are in the first trimester of your pregnancy.

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

### **Driving and using machines**

It is not always possible to predict to what extent ZODORAY may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ZODORAY affects you.

### **ZODORAY contains arachis oil (peanut oil) and Lecithin (soya lecithin)**

ZODORAY contains arachis oil (peanut oil) and lecithin (soya lecithin). If you are allergic to peanut or soya, do not use this medicine.

Please ask your doctor if you are worried about any of the ingredients in ZODORAY.

ZODORAY contains a small amount of alcohol (ethanol). The small amount of alcohol in ZODORAY will not have any noticeable effects.

## **3. How to take ZODORAY**

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

Always take ZODORAY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

*Adults:* 1 µg daily  
*Children 20 kg body weight and above:* 1 µg daily  
*Children less than 20 kg body weight:* 0,05 µg/kg daily  
Elderly: The usual starting dose is 0,5 µg daily

Your doctor will tell you how long your treatment with ZODORAY will last. Do not stop treatment with ZODORAY unless your doctor tells you too.

If you have the impression that the effect of ZODORAY is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more ZODORAY than you should**

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

#### **If you forget to take use ZODORAY**

If you forget to take your medicine, take it as soon as you remember. Then take the next dose at the usual time. Do not take a double dose or extra capsule to make up for your forgotten dose.

#### **4. Possible side effects**

ZODORAY can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Skin rash or itching.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Less urine than is normal for you, swelling of hands, lower legs or feet, a fever with pain in your lower back. It may mean that you have serious kidney problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent*

- Stomach pain and discomfort,
- skin rash or itching.

*Less frequent*

- Feeling dizzy or confused, headache,
- loose stools, feeling sick, being sick (vomiting), being constipated,
- hives, swollen, pale red bumps on the skin,
- feeling weak, or pain in your muscles or bones,
- feeling tired.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. 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 ZODORAY.

## **5. How to store ZODORAY**

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- There are no special storage instructions for ZODORAY
- Do not store in a bathroom
- Do not use after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets), waste water or household waste. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What ZODORAY contains**

- The active substance is alfacalcidol.
- The other ingredients are: Anhydrous citric acid, all-rac-alpha-tocopherol (antioxidant), propyl gallate (antioxidant), anhydrous ethanol (1,0 % v/v), refined arachis oil (peanut oil).  
Soft gelatine capsule shell: Gelatine, glycerol, partially dehydrated sorbitol liquid (anidrisorb), purified water, medium chain triglyceride, Lecithin (soya lecithin).

Capsule colours:

For 1 µg capsules: Titanium dioxide (E171) and ferric oxide yellow (E172).

For 0,5 µg capsules: Titanium dioxide (E171) and ferric oxide red (E172).

For 0,25 µg capsules: Titanium dioxide (E171), ferric oxide red (E172) and ferric oxide black (E172).

**Warning(s):** Contains refined peanut oil, lecithin (soya lecithin), sorbitol and ethanol (1,0 % v/v).

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

ZODORAY 0,25 µg capsules: Reddish brown coloured, oval shaped soft gelatine capsules containing clear oily liquid.

ZODORAY 0,5 µg capsules: Light pink coloured, oval shaped soft gelatine capsules containing clear oily liquid.

ZODORAY 1 µg capsules: Pale yellow coloured, oval shaped soft gelatine capsules containing clear oily liquid.

White, opaque HDPE container with white opaque HDPE or polypropylene screw closure and induction sealing.

Pack sizes of 30's, 50's and 100's.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

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**Registration/Application number**

ZODORAY 1 µg                      53/22.1.4/0677

ZODORAY 0,5 µg                    53/22.1.4/0678

ZODORAY 0,25 µg                  53/22.1.4/0679

**Access to the corresponding Professional Information**