

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PLIVIT D3

4000 units/mL oral drops, solution

#### CHOLECALCIPHEROL

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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.*

*• 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 Plivit D3 is and what it is used for
2. Before you take Plivit D3
3. How to take Plivit D3
4. Possible side effects
5. How to store Plivit D3
6. Further information

#### *1. WHAT PLIVIT D3 IS AND WHAT IT IS USED FOR*

##### **Plivit D3 drops contain vitamin D and are used for:**

- The prevention of rickets in infants and young children, especially if the diet is not adequate (foods with too little vitamin D and reduced absorption of vitamin D in the digestive system) or when the child is prevented from exposure to the sun (winter months).
- Cases where there is the increased need for vitamin D (pregnant and lactating women).
- The prevention of osteoporosis.

Rickets is the name for a group of diseases that are caused by disorders of mineralization (investment of calcium in cartilage substance) of bones that are in the growth phase (rickets only Occur in children who are still growing).

Osteoporosis is a disorder of bone loss, and it is typical for postmenopausal women, and can cause fracture. A disease develops after the osteoclasts (bone cells type) attack and degrade the bone, and osteoblasts (bone cell types) are not able to fully restore the bone, as it is normally the case.

## 2. BEFORE YOU TAKE PLIVIT D3

### **Do not take PLIVIT D3 drops:**

- If you have increased levels of calcium in the blood (hypercalcaemia)
- If you are hypersensitive to any ingredient of the medicine

### **Be careful with PLIVIT D3 drops:**

- If you have impaired kidney function, or kidney stones.
- If you have heart problems.
- If you are taking PLIVIT D3 drops, you need to take into account the overall intake of vitamin D in the body due to the possibility of an overdose (Hypervitaminosis). Other sources of vitamin D can be different vitamin preparations, and food like milk enriched with vitamin D, fish oil, fish, eggs...)
- the total daily intake of vitamin D should not be higher than the 1000 IU both in children and in pregnant and breast-feeding women.
- Infants may be more sensitive to the effects of vitamin D and in this age group it should be administered with caution.

### **Taking other medicines with PLIVIT D3 drops**

Inform your doctor about all the medicines you are taking or have recently taken, including medicines obtained without a prescription, as well as other dietary preparations and food supplements, such as vitamins.

### **PLIVIT D3 drops can get in interaction (interaction) with the following medicines:**

- Cholestyramine, colestipol-medicines used in the treatment of high cholesterol.
- Neomycin-a medicine that is used in the treatment of bacterial infections (antibiotics).
- Phenytoin – medicine used in the treatment of epilepsy
- Barbiturates – a group of medications used in the treatment of epilepsy.
- Antacids – medications that neutralize stomach acid.

### **Pregnancy and breastfeeding**

PLIVIT D3 drops are indicated during pregnancy and breastfeeding, but the recommended dose must not be exceeded.

Vitamin D passes into breast milk and care must be taken when vitamin D is additionally given to infants.

## 3. HOW TO TAKE PLIVIT D3

Infants during the first year of life: 2-5 drops (400-1000 IU) per day, depending on the recommendation of the doctor.

Children older than one year, pregnant and lactating women: 2 drops (400 IU) per day.

For the prevention of osteoporosis: 2 – 5 drops (400 – 1000 IU) per day.

The drops are taken in a spoon of juice or milk.

One drop contains approximately 200 IU of cholecalciferol.

### **What if you take too many PLIVIT D3 DROPS?**

If you take too many PLIVIT D3 drops please contact your doctor or the nearest medical facility.

### **What if you forget to take PLIVIT D3 DROPS?**

If you forget to take PLIVIT D3 drops, continue with the next regular dose. Do not take a double dose to make up for the one you missed.

If you have any further questions on the use of PLIVIT D3 drops, talk to your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Side effects after taking the recommended dose of PLIVIT D3 drops generally do not occur.

If you notice any side effects talk to your doctor or pharmacist.

#### 5. HOW TO STORE PLIVIT D3

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Keep at a temperature of 2-8 ° c.

The shelf life of the medicinal product is 3 years from the date of manufacture.

The medicine should not be used after the expiry date marked on the package.

#### 6. FURTHER INFORMATION

As PLIVIT D3 drops contain

- the active substance in the D3 drops is cholecalciferol
- 1 mL (20 drops) of solution contains 4000 IU cholecalciferol.
- other ingredients: methyl parahydroxy benzoate; Butyl hydroxy toluene; glycerol MACROGOL hydroxy stearate; MACROGOL; propylene glycol; citric acid, anhydrous; sodium phosphate dibasic, anhydrous; water, purified.

#### ***The layout and contents of the Pack***

Colourless, clear to slightly opalescent solution.

10 mL of the solution in a brown glass vial with a plastic extension, in a box.

#### ***Regime of dispensing***

The medicine is issued on doctor`s prescription

#### ***Manufacturer***

Pliva Hrvatska d.o.o.

Prilaz baruna Filipovića 25, Zagreb, Croatia

#### ***Manufacturer of the medicinal product***

Pliva Hrvatska d.o.o.

Prilaz baruna Filipovića 25, Zagreb, Croatia