PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

VITAMIN D3 1000
Tablets

Active ingredient
Vitamin D3 1000IU
Inactive ingredients and allergens in the preparation - see section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
The medicine is not intended for children under 12 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Vitamin D3 supplement and adjunct treatment for osteoporosis.

Therapeutic group: Vitamin D

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you have a known sensitivity to any of the ingredients of the medicine.
- you suffer from hypercalcemia (excess calcium in the blood) and/or hypercalciuria (excess calcium in the urine).
- you suffer from systemic lupus (SLE).
- you suffer from pseudohypoparathyroidism.
- you suffer from hypervitaminosis D (a condition with excess vitamin D in the body, resulting from overconsumption).
- you suffer from severe kidney function impairment.
- you suffer from kidney stones.

Special warnings regarding use of the medicine

Before treatment with the medicine, inform the doctor
- if you have suffered in the past from kidney stones.
- if you suffer from impaired kidney function; sarcoidosis.
- if you are sensitive to any food or medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:
- orlistat (for weight loss) – lowers blood Vitamin D concentration.
- cholestyramine or laxatives such as paraffin oil – may reduce absorption of Vitamin D in the digestive system. Take Vitamin D3 1000 about one hour before or 4-6 hours after taking these preparations.
- actinomycin (a cytotoxic preparation) and imidazole (antifungal) – disrupt the activity of Vitamin D by inhibiting its metabolism.
- phenytoin (to treat epilepsy) and barbiturates (to treat epilepsy and sleep disturbances and as an anesthetic) – may reduce the effect of Vitamin D.
- thiazide diuretics – can reduce the secretion of calcium via the kidneys and cause hypercalcemia, excess calcium in the blood. Monitor blood and urine calcium levels during the course of prolonged treatment.
- glucocorticoids – may reduce the effect of Vitamin D.
- digitalis (for the heart) – the risk of heart rate disturbances may increase as a result of increased blood calcium levels when being treated with Vitamin D. This should be monitored.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, consult the doctor before using the medicine.

Important information regarding some of the ingredients of the medicine
The preparation contains approximately 53 mg lactose per tablet and approximately 1 mg sodium per tablet.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.
The usual dosage is generally: one tablet per day.
Do not exceed the recommended dose.
Swallow the medicine with water.

If you accidentally took a higher dosage, you may suffer from the side effects listed in section 4. If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of this preparation may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Stop use and refer to the doctor immediately if any of the following side effects occur, generally, as a result of overdose, such as: digestive system problems (nausea, vomiting, diarrhea or constipation), anorexia, weakness, apathy, lack of appetite, fatigue, headaches, muscle and joint aches, muscle weakness, drowsiness, increased thirst, frequent urination, later resulting in dehydration.

Uncommon side effects (effects that occur in 1-10 of 1,000 users):
Hypercalcemia (excess calcium in the blood) and hypercalciuria (excess calcium in the urine).

Rare side effects (effects occurring in 1-10 of 10,000 users):
Itching, rash and urticaria.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store conditions: Do not store at a temperature that exceeds 25°C.
- Use within one month of first opening.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains
  Lactose Monohydrate, Microcrystalline Cellulose, Starch 1500, Tri Sodium Citrate, Ascorbic Acid, Butylhydroxytoluene, Colloidal Silicon Dioxide, Stearic Acid, Indigo Blue Carmine, Sunset Yellow.
  Each tablet contains approximately 53 mg lactose and approximately 1 mg sodium.
- What the medicine looks like and the contents of the pack – a bottle with 30 beige tablets.
- License holder and address - Sam-On Ltd., 25 Haavoda St. Bat-Yam.
- This leaflet was checked and approved by the Ministry of Health in August 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1524533547