CONTRAINDICATIONS
Ergocalciferol Capsules, USP are contraindicated in patients with hypercalcemia, hyperparathyroidism, systemic lupus erythematosus, hyperphosphatemia, hypercalciuria, and malignancy. Ergocalciferol treatment should not be used in patients with known vitamin D intoxication or hypercalcemia.

WARNINGS
It is advisable to discontinue use of ergocalciferol if symptoms of hypercalcemia occur. Patients with cancer should be observed carefully and withdrawn from the drug if toxicity develops.

PRECAUTIONS
General:
Vitamin D administration from fortified foods, dietary supplements, self-administered and prescription drug sources should be evaluated. Therapeutic dosage should be modified as soon as possible to minimize toxicity. Vitamin D is not to be administered suppositories as discussed with special individuals. In the case of hypervitaminosis D, vitamin D and calcium should be discontinued and all symptoms should be observed until they subside.

INDICATIONS AND USES
Ergocalciferol Capsules, USP are indicated for use in the treatment of hypocalcemia, rickets, osteomalacia, and hyperparathyroidism.

ADVERSE REACTIONS
Gastrointestinal:
Vomiting, diarrhea, constipation, dryness of mouth, nausea, and irritability.

Hypertension, edema, ankle swelling, and nephrocalcinosis.

Renal:
Polyuria, nocturia, White blood cells in urine, and hematuria.

Soft Tissue:
Osteoporosis, bone pain, soft tissue calcification, and increased skin malignancy.

CNS:
Dizziness, headache, insomnia, and confusion.

Metabolic:
Hypercalcemia, hyperphosphatemia, and hypercalciuria.

Hypervitaminosis D is characterized by effects on the following systems:

- Respiratory: Increased respiratory rate and depth
- Cardiovascular: Tachycardia, Hypertension, and Bradycardia
- Gastrointestinal: Nausea, Vomiting, Diarrhea, and Constipation
- Renal: Polyuria, Nitrogen retention, and Oliguria
- Soft Tissue: Osteoporosis, Pathologic fractures, and Bone pain
- Central Nervous System: Confusion, Dizziness, and Headache
- Endocrine: Hypercalcemia, Hyperphosphatemia, and Hypercalciuria

There are no known interactions between Ergocalciferol Capsules, USP and other medications.

DOSAGE AND ADMINISTRATION
The dosage of Ergocalciferol Capsules, USP should be individualized based on the patient's response and the presence of symptoms. The dosage ranges from 0.5 to 1.0 mcg daily, with the average dose being 2.5 mcg daily.

HOW SUPPLIED
Each capsule contains Vitamin D (Ergocalciferol) 1.25 mg equivalent to 50,000 USP Units. The USP strength is 5000 USP Units.

DOSAGE MUST BE INDIVIDUALIZED UNDER CLOSE MEDICAL SUPERVISION. Calcium intake should be adequate to prevent secondary hyperparathyroidism. Calcium may be given with the saline infusion to further increase urinary calcium, tubular, and renal events. A loop diuretic (furosemide, ethacrynic acid, or thiazide) may be given with the saline infusion to further increase urinary calcium. The treatment of hypervitaminosis D with hypercalcemia consists in immediate withdrawal of the vitamin, a low calcium diet, generous intake of fluids, along with symptomatic and supportive treatment. Hypervitaminosis D is treated by reducing the dose of vitamin D and monitoring the serum calcium concentration. In severe cases, the treatment may consist of intravenous calcium and alkaline diuresis. In patients with severe hypercalcemia, the treatment may include the use of calcitonin, estrogen, or vitamin D antagonist agents.

Geriatric Use
Clinical studies have shown no differences in the effectiveness of Ergocalciferol Capsules, USP in elderly and younger patients. However, the safety and efficacy of Ergocalciferol Capsules, USP in elderly patients have not been established.

Pediatric Use
Pediatric doses must be individualized (see DOSAGE AND ADMINISTRATION). Hypervitaminosis D is characterized by effects on the following systems:

- Respiratory: Increased respiratory rate and depth
- Cardiovascular: Tachycardia, Hypertension, and Bradycardia
- Gastrointestinal: Nausea, Vomiting, Diarrhea, and Constipation
- Renal: Polyuria, Nitrogen retention, and Oliguria
- Soft Tissue: Osteoporosis, Pathologic fractures, and Bone pain
- Central Nervous System: Confusion, Dizziness, and Headache
- Endocrine: Hypercalcemia, Hyperphosphatemia, and Hypercalciuria

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