It is strongly recommended that vitamin D (Calcifediol) blood levels are checked before administration of vitamin D injections. *Please be aware that blood testing that is non near patient testing (sent away to a laboratory for analysis), will require CQC or equivalent registration.*

Vitamin D2 (ergocalciferol) 300,000 IU solution

- Route of administration: IM injection
- Dosage: Adults & The Elderly Typically administered as a **single dose of 300,000 IU every 3-6 months.**
- Children 1-12 years 300,000 IU given in 2 divided doses.

Serum and urinary calcium concentrations, phosphate and BUN (Blood Urea Nitrogen), should be monitored at regular intervals, initially weekly, in order to achieve optimum clinical response and to avoid hypercalcaemia.

Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients

Hypercalcaemia, evidence of vitamin D toxicity, hypervitaminosis D, decreased renal function, metastatic calcification.

Warnings & Precautions

Vitamin D should be administered with caution to infants and patients who may have an increased sensitivity to its effects.

Use with care in patients with renal impairment, renal calculi or heart disease or arteriosclerosis who might be at increased risk of organ damage if hypercalcaemia were to occur. Because of the effect on serum calcium, Ergocalciferol should only be administered to patients with renal stones when potential benefits outweigh possible hazards.

Ergocalciferol is not recommended for use in hypoparathyroidism. In the event of hypoparathyroidism when Ergocalciferol is used, calcium, parathyroid hormone or Dihydrotachysterol may be required. Dihydrotachysterol (DHT) is **a synthetic vitamin D analog activated in the liver that does not require renal hydroxylation like vitamin D 2 (ergocalciferol) and vitamin D 3**

Dosage should be individualised. Frequent serum and urinary calcium, phosphate and urea nitrogen determinations should be carried out.

Adequate fluid intake should be maintained.

Should hyperglycaemia develop, Ergocalciferol should be discontinued immediately.

Pregnancy

There is no or limited amount of data from the use of ergocalciferol in pregnant women. Ergocalciferol Injection **should not** be used in pregnancy unless the potential benefit outweighs the potential hazards to the foetus.

Animal studies have shown foetal abnormalities associated with hypervitaminosis D.

Breast feeding

Ergocalciferol should not be administered to breast-feeding mothers as it is excreted in breast milk.

Interactions with other medicines and other forms of interactions

Ergocalciferol and:-

i) Magnesium-containing antacids: hypermagnesaemia may develop in patients on chronic renal dialysis.

ii) Digitalis glycosides: hypercalcaemia in patients on digitalis may precipitate cardiac arrhythmias.

iii) Verapamil atrial fibrillation has recurred when supplemental calcium and Ergocalciferol have induced hypercalcaemia.

iv) Anti-convulsants: vitamin D requirements may be increased in patients taking anti-convulsants,(e.g. carbamazepine, phenobarbital, phenytoin and primidone).

v) Thiazide diuretics: hypoparathyroid patients on Ergocalciferol may develop hypercalcaemia due to increased Ergocalciferol (although Ergocalciferol is not recommended for use in hypoparathyroidism).

Ergocalciferol may cause drowsiness and can affect the ability to drive and use machines. If affected, patients should not drive or operate machinery.

Pharmaceutical Particulars

Excipient Ethyl oleate

Shelf life 36 months

Special precautions for storage Store below 25°C.

Keep the ampoules in the outer carton in order to protect from light.

Nature and contents of container 1ml clear, one-point cut (OPC) glass Type 1 Ph Eur ampoules packed in cartons of 5 or 10 ampoules. Not all pack sizes may be marketed.
Special precautions for disposal and other handling

*The manufacturer states that plastic syringes should not be used to administer Ergocalciferol 3000,000 IU solution for injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements