**Domnisol** (Calcifediol monohydrate) **soft capsules 266 micrograms**

**PRESCRIBING INFORMATION:** Please refer to Summary of Product Characteristics (SmPC) before prescribing.

**ACTIVE INGREDIENT:** Calcifediol monohydrate 266 micrograms.

**INDICATIONS:**
Treatment of vitamin D deficiency in adults.
Prevention of vitamin D deficiency in adults with identified risks.
As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

**DOSAGE AND ADMINISTRATION:**
**Dose titration:** Dose, frequency and duration determined by the prescriber considering the plasma levels of 25(OH)D, type and condition of the patient and other comorbidities such as obesity, malabsorption syndrome, treatment with corticosteroids.

The general posology for the treatment and maintenance of vitamin D deficiency is one capsule/month orally, although higher doses may be required in certain cases.

**Treatment of vitamin D deficiency in adults**: one capsule/month. Higher doses may be required, maximum dose should not exceed one capsule per week.
**Maintenance therapy following treatment for deficiency in adults**: one capsule/month. 25(OH)D should be measured approximately 3 to 4 months after beginning maintenance therapy to confirm that target level has been reached. Thereafter, the levels should be measured at 6 monthly intervals to ensure that effective therapeutic levels are maintained.
**Prevention of deficiency in adults:** one capsule/month
**Adjunct to specific therapy for osteoporosis:** one capsule (266 micrograms of Calcifediol) once a month.
Paediatric population: not recommended
Hepatic impairment: no dose adjustment required
Renal impairment: no dose adjustment required if mild to moderate, not recommended if severe
Obese patients, patients with malabsorption syndromes and patients taking medications affecting vitamin D metabolism: higher doses may be required

**CONTRAINDICATIONS:** Hypersensitivity to the active ingredient or to any of the excipients, hypercalcemia (serum calcium > 10.5 mg/dl), hypercalciuria, calcium lithiasis, hypervitaminosis D.

**SPECIAL WARNINGS AND PRECAUTIONS:**
Once patient is stabilised, regularly monitor: 25(OH)D, serum calcium, phosphorus, alkaline phosphatase, urinary calcium and phosphorus in 24 hours. Use with caution in patients with renal impairment. Vitamin D must not be used in severe renal impairment. Perform serum calcium and phosphorus monitoring and hypercalcemia prevention in patients with chronic kidney disease. In severe renal failure (creatinine clearance <30ml/min) a very significant reduction in the pharmacological effects may occur.
Heart failure: use with caution, monitor serum calcium constantly, especially in patients on digitalis.
Hypoparathyroidism: activity of calcifediol may decrease. Kidney stones: Calcaemia should be monitored, and vitamin D supplements administered only if benefits outweigh risks. Patients with prolonged immobilisation: dose reduction may be necessary. Administer with caution in sarcoidosis, tuberculosis, or other granulomatous disease and monitor serum and urinary calcium concentrations. Prevention of overdose: provide information to patients and families / caregivers regarding prescribed dosage and recommendations about concomitant intake of calcium supplements and diet. Laboratory test results may be altered, including the Zlatkis-Zak method for measuring serum cholesterol. Each capsule contains

4.98 mg ethanol and 22mg sorbitol. Sorbitol may affect the bioavailability of other medicinal products for oral use.

**INTERACTIONS:** Phenytoin, phenobarbital, primidone, and other enzyme inducers may reduce plasma concentrations of calcifediol. Increased risk of cardiac arrhythmias with cardiac glycosides. Paraffin and mineral oil may decrease intestinal absorption of Domnisol. Co-administration with thiazide diuretics in patients with hypoparathyroidism may cause hypercalcaemia. Penicillin, neomycin, chloramphenicol may increase calcium absorption. Rifampicin, isoniazid, clotrimazole, ketoconazole may reduce vitamin D levels. Cholesterol-lowering statin drugs (atorvastatin) increase vitamin D levels. Phosphate-binding agents such as a magnesium salts may cause hypermagnesemia. Vitamin D can increase absorption of aluminium with antacids containing aluminium. Potential inhibition of action of verapamil and diltiazem. Avoid other vitamin D analogues and uncontrolled intake of calcium supplements due to risk of hypercalcaemia. Corticosteroids counteract effects of vitamin D analogues. Orlistat, cholestyramine and long-term use of stimulant laxatives may reduce absorption of vitamin D. Additive effects with food supplemented with vitamin D.

**FERTILITY, PREGNANCY, LACTATION:** Not recommended during pregnancy unless the clinical condition of the woman requires treatment. High doses of vitamin D should not be administrated during pregnancy. Calcifediol monohydrate is poorly excreted into breast milk. There are no data on the effect of calcifediol monohydrate on fertility.

**DRIVING AND USE OF MACHINES:** no influence on the ability to drive and use machines.

**UNDESIRABLE EFFECTS:** Adverse reactions to Domnisol are generally uncommon (≥ 1/1 000 to <1/100). The most common adverse reactions are due to hypercalcemia: pancreatitis, elevation of blood urea nitrogen (BUN), albuminuria, hypercholesterolemia, weakness, fatigue, drowsiness, headache, irritability, cardiac arrhythmias, nausea, vomiting, dry mouth, constipation, taste disturbances, abdominal cramps, anorexia (may occur if hypercalcemia progresses), increased transaminase (SGOT and SGPT), bone and muscle pain, calcification in soft tissues, nephrocalcinosis and deterioration of kidney function (with polyuria, polydipsia, nocturia and proteinuria), rhinorrhoea, pruritus, hyperthermia, decreased libido. Rarely (≥1/10 000 to <1/1 000), at very high doses photophobia and conjunctivitis with corneal calcifications may occur. Consult SmPC in relation to other adverse reactions.

**LEGAL CATEGORY:** POM.

**MARKETING AUTHORISATION HOLDER**: Flynn Pharma Ltd, 5th Floor, 40 Mespil Road, Dublin 4, IRELAND, D04 C2N4

| Product | NHS List Price | Pack Size | Marketing Authorisation Number |
|---|---|---|---|
| Domnisol | £ 2.15 | 1 capsule | PL 13621/0089 |
| Domnisol | £ 6.45 | 3 capsules | |

**Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Flynn Pharma Ltd. Medical Information e-mail: medinfo@flynnpharma.com. Medical Information: Tel 01438 727822**

**DATE OF PREPARATION OF PRESCRIBING INFORMATION:** August 2023