Abbreviated Prescribing Information

Fultium®-D_3
Colecalciferol

Fultium-D_3 800 IU, 3,200 IU & 20,000 IU Capsules Abbreviated Prescribing Information

Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing Fultium-D_3. Use care when prescribing in pregnancy, as high doses of colecalciferol may affect the foetus.

Fultium-D_3 capsules: Each Fultium-D_3 800 IU capsule contains colecalciferol 800 IU equivalent to 20 micrograms vitamin D_3. Each Fultium-D_3 3,200 IU capsule contains colecalciferol 3,200 IU equivalent to 80 micrograms vitamin D_3. Each Fultium-D_3 20,000 IU capsule contains colecalciferol 20,000 IU equivalent to 500 micrograms vitamin D_3.

Indication:

Fultium-D_3 800 & 20,000 IU capsules. Prevention and treatment of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Fultium-D_3 3,200 IU capsules only. Treatment of vitamin D deficiency.

Dosage and administration:

Adults and the elderly. Treatment of Vitamin D deficiency (serum levels <25nmol/l (<10ng/ml)). Depending on the severity of the disease and the patient's response to treatment: 1-4 Fultium-D_3 800 IU capsules daily for up to 12 weeks or 1 Fultium-D_3 3,200 IU capsule daily for up to 12 weeks or 2 Fultium-D_3 20,000 IU capsules per week for 7 weeks. Prevention of vitamin D deficiency: 1-2 Fultium-D_3 800 IU capsules (800-1600IU) daily or 1 Fultium-D_3 20,000 IU capsule per month. Long term maintenance therapy following deficiency treatment or vitamin D insufficiency (serum levels 25-50nmol/l (10-20 ng/ml): 1-2 Fultium-D_3 800 IU capsules daily.

During pregnancy and breast-feeding: Treatment of vitamin D deficiency 1 – 5 capsules (800 – 4000 IU) daily.

Children over 12 years: Depending on the severity of the disease and the patient's response to treatment: 1 Fultium-D_3 800 IU capsule daily (for prevention/ treatment), or 1 Fultium-D_3 3,200 IU capsule daily for up to 12 weeks (treatment), or 1 Fultium-D_3 20,000 IU every 6 weeks (prevention), or 1 Fultium-D_3 20,000 IU every 2 weeks for 6 weeks (treatment).

Should only be given under medical supervision.

Not recommended for use in children under 12 years

For oral use. Swallow capsules whole with water.

Contraindications: Hypersensitivity to vitamin D or any of the excipients in the product; hypervitaminosis D; nephrolithiasis; diseases or conditions resulting in hypercalcaemia and/or hypercalciuria; severe renal impairment.

Warnings and Precautions: Use with caution in patients with impaired renal function or sarcoidosis and monitor the effect on calcium and phosphate levels. In patients with severe renal insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used. In cases of long-term daily doses exceeding 1,000 IU, monitor serum calcium levels. Use caution in patients receiving treatment for cardiovascular disease. Consider vitamin D supplementation from other sources.

Interactions: Concomitant treatment with phenytoin, barbiturates and glucocorticoids can decrease the effect of vitamin D. Effects of digitalis and other cardiac glycosides may be accentuated. Absorption of vitamin D may be reduced by ion exchange resins, laxatives, actinomycin and imidazole.

Pregnancy and lactation: Use only under medical supervision. Studies have shown safe use up to 4,000 IU daily but reproductive toxicity has been seen in animal studies. The 20,000 IU dose should not be used during pregnancy. Vitamin D is excreted in breast milk, when prescribing additional vitamin D to a breast-fed child consider the dose of any additional vitamin D given to the mother.

Undesirable effects: Allergic reactions are possible. Uncommon adverse reactions include hypercalcaemia and hypercalciuria. Rare adverse reactions include: pruritus rash and urticaria.

Overdose: Refer to SmPC.

Legal Category: POM

Pack size:

Fultium-D_3 800 IU capsules x 30 – NHS Price £3.60
Fultium-D_3 800 IU capsules x90 – NHS Price £8.85
Fultium-D_3 3,200 IU capsules x30 – NHS Price £13.32
Fultium- D_3 3,200IU capsules x90 – NHS Price £39.96
Fultium-D_3 20,000 capsules x15 – NHS Price £17.04
Fultium-D_3 20,000 capsules x30 – NHS Price £29.00

MA Number:

PL40861/0002 [Fultium-D_3 800 IU capsules]
PL40861/0003 [Fultium-D_3 3,200 IU capsules]
PL40861/0004 [Fultium-D_3 20,000 IU capsules]

MA Holder:

Internis Pharmaceuticals Ltd. Linthwaite Laboratories, Linthwaite, Huddersfield, West Yorkshire HD7 5QH, UK

Full Prescribing Information is available from Internis Pharmaceuticals Ltd.

Date of preparation: January 2023

Unique ID no: FULT-76(1)

Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/ yellowcard. Adverse events should also be reported to Thornton and Ross Limited by emailing thorntonross@ medinformation.co.uk or by calling 01484 848164.

Abbreviated Prescribing Information

Fultium®-D_3
Colecalciferol

Fultium-D_3 Drops Abbreviated Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Fultium-D_3 Drops. Use care when prescribing in pregnancy, as high doses of colecalciferol may affect the foetus.

Fultium-D_3 Drops: 1 ml of oral solution contains 2740 IU (68.5 mcg per ml) colecalciferol; 3 drops contains 200 IU colecalciferol

Indications: Prevention and treatment of vitamin D deficiency in adults and children, and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Dosage and administration: For oral use. Can be taken directly or mixed with a small amount of food.

Adults. Treatment of deficiency: 12 - 60 drops (800-4000 IU) daily; During pregnancy and breast-feeding: 6-60 drops (400-4000 IU) daily; Osteoporosis adjunctive therapy: 12 drops (800 IU) daily. Maintenance or prevention of deficiency: 12 - 24 drops (800-1600 IU) daily; During pregnancy and breast-feeding: 6-30 drops (400-2000 IU) daily.

Children. Treatment of deficiency: 0-2 years: 6-15 drops (400-1000 IU) daily; 2-11 years: 6-30 drops (400-2000 IU) daily; 12-18 years: 6-60 drops (400-4000 IU) daily Maintenance or prevention of deficiency: 0-2 years: 3-15 drops (200-1000 IU) daily; 2-11 years: 6-15 drops (400-1000 IU) daily; 12-18 years: 6-24 drops (400-1600 IU) daily.

Contraindications: Hypersensitivity to vitamin D or any of the excipients; hypervitaminosis D; nephrolithiasis; diseases or conditions resulting in hypercalcaemia and/or hypercalciuria; severe renal impairment.

Warnings and Precautions: Use caution in patients with impaired renal function or sarcoidosis. Monitor effect on calcium and phosphate levels in these patients. Consider risk of soft tissue calcification. Use other forms of vitamin D in cases of severe renal insufficiency. Consider the need for calcium supplementation in individual patients. Where calcium supplementation is necessary, close medical supervision is required. Use caution in patients receiving treatment for cardiovascular disease. Make allowances for vitamin D supplementation from other sources. Monitor to prevent hypercalcaemia.

Interactions: Concomitant phenytoin, barbiturates and glucocorticoids can decrease the effect of vitamin D. Ion exchange resins, laxatives, actinomycin and imidazole may also reduce the effect of vitamin D. Oral calcium and vitamin D potentiates the effect of digitalis and other cardiac glycosides.

Pregnancy and lactation: Limited clinical data in pregnancy. Animal studies have shown reproductive toxicity. RDI in pregnancy is 400 IU. Pregnant women who are vitamin D deficient may need a higher dose. Pregnant women should follow the advice of their GP, as their requirements may vary depending on disease severity and response to treatment. Vitamin D and metabolites are excreted in breast milk. Overdose in nursing infants has not been observed, however, when prescribing additional vitamin D to a breast-fed child, consider the maternal dose of any additional vitamin D.

Undesirable effects: Hypercalcaemia and hypercalciuria. Refer to the SmPC for the full list of side effects.

Legal Category: POM

Pack size: Fultium-D_3 Drops, 1 x 25 ml – NHS Price £10.70

MA Number: PL40861/0005

MA Holder: Internis Pharmaceuticals Ltd. Linthwaite Laboratories, Linthwaite, Huddersfield, West Yorkshire HD7 5QH, UK

Full Prescribing Information available.

Date of preparation: January 2023

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