Abbreviated Prescribing Information - for full prescribing information, including side effects, precautions and contra-indications, see Summary of Product Characteristics (SmPC)

Product name and Composition: Cadelius 600 mg / 1,000 IU one orodispersible tablet contains: Calcium carbonate 1500 mg (equivalent to 600 mg calcium) & Cholecalciferol (Vitamin D_3) 1000 I.U. (equivalent to 0.025 mg).
INDICATIONS: Prevention and treatment of calcium and vitamin D deficiency in the elderly. Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D or calcium deficiency, when a dietary supplement as large as 600 mg/day of calcium and 1000 IU/day of Vitamin D3 is supposed to be adequate. **Dosage and administration:** Adults and elderly*:* One orodispersible tablet per day. **Special Populations:** Not indicated for Children. In hepatic impairment, no dose adjustment is required. Cadelius should not be used in patients with severe renal impairment. **Contraindications:** Hypersensitivity to calcium, cholecalciferol or to any of the excipients (See Full SmPC) Diseases and/or conditions resulting in hypercalcaemia or hypercalciuria. Nephrolithiasis, nephrocalcinosis, hypervitaminosis D and severe renal impairment or renal failure. Cadelius contains partially hydrogenated soya-bean oil and must not be used by persons allergic to peanuts or soya. **Special warnings and precautions for use:** Cadelius orodispersible tablets should be prescribed with caution to patients suffering from sarcoidosis due to risk of increased metabolism of vitamin D into its active form. These patients should be monitored with regard to the calcium content in serum and urine. During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics (see section 4.5) and in patients with a high tendency to calculus formation. In case of hypercalciuria (exceeding 300 mg (7.5 mmol)/24 hours) or signs of impaired renal function the dose should be reduced or the treatment discontinued. Cadelius should be used cautiously in immobilised patients with osteoporosis due to increased risk of hypercalcaemia. The content of vitamin D (1000 IU) in Cadelius orodispersible tablets should be considered when prescribing other medicinal products containing vitamin D or food supplemented with vitamin D. Co-administration with tetracyclines or quinolones is usually not recommended or must be done with precaution. The product contains aspartame, source of phenylalanine. May be harmful for people with phenylketonuria. The product contains soya bean oil and is contraindicated for patients hypersensitive to peanut or soya. The product contains lactose, therefore patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. The product contains sucrose, therefore patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. May be harmful to the teeth. **Interactions with other medicinal products or other forms of interactions:** Thiazide diuretics reduce the urinary excretion of calcium. Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D_3 since the metabolism increases. Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Cadelius. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D. Efficacy of levothyroxine can be reduced by the concurrent use of calcium. Administration of calcium and levothyroxine should be separated by at least four hours. If a bisphosphonate is used concomitantly, this preparation should be administered at least one hour before the intake of Cadelius since gastrointestinal absorption may be reduced. Calcium salts may decrease the absorption of iron, zinc or strontium ranelate. Consequently, the iron, zinc or strontium ranelate preparation should be taken at a distance of two hours from the calcium preparation. Calcium may also reduce absorption of sodium fluoride, and such preparation should be administered at least three hours before the intake of

Cadelius®. Simultaneous treatment with orlistat, ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D. Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before or four to six hours after oral intake of calcium. The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or six hours after intake of calcium. Oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid. **Pregnancy:** Cadelius should not be used during pregnancy. **Breast-feeding:** Cadelius can be used during breast-feeding. Calcium and vitamin D_3 pass into breast milk. This should be considered when giving additional vitamin D to the child. **Undesirable effects:** Hypersensitivity reactions such as angioedema or laryngeal oedema. Uncommon: Hypercalcaemia and hypercalciuria. Rare: Constipation, flatulence, nausea, abdominal pain, and diarrhoea. Rare: Pruritus, rash and urticaria. Patients with renal impairment: potential risk of hyperphosphatemia, nephrolithiasis and nephrocalcinosis. **Overdose:** Overdose can lead to hypervitaminosis and hypercalcaemia (For full information see SmPC). GMS Price: €10.97 Multipack 60 (30 x 2 single packs) orodispersible tablets. Legal Classification: POM. MA Number: PA 2102/002/001. MA Holder: Italfarmaco S.A. C/ San Rafael, 3 28108 Alcobendas (Madrid) España. Further information is available on request from Consilient Health Ltd. Block 2A, Richview Office Park, Clonskeagh, Dublin 14 Ireland, 01 2057760 or drugsafety@consilienthealth.com. Date of Preparation: April 2022.

- **Healthcare professionals are asked to report any suspected adverse reactions. To report an adverse event or a product complaint about a Consilient Health medicine, please contact Consilient Health at drugsafety@consilienthealth.com or 01 2057766**

- **Adverse events and product complaints may also be reported to the Health Products Regulatory Authority. Reporting forms and information can be found at www.hpra.ie then click on "report an issue".**