Idéos®

500mg/400IU Chewable Tablets
Calcium & Vitamin D_3 Combined

Product Name: IDEOS 500mg/400IU Chewable Tablets
(Please refer to the full Summary of Product Characteristics before Prescribing)
Presentation: Greyish white, square, chewable tablets with lemon flavour. Each Idéos® tablet contains 1250mg of calcium carbonate (i.e. 500mg of elemental calcium) plus 10 µg of cholecalciferol (corresponding to 400 IU of Vitamin D_3). **Indications:** Vitamin D_3 and calcium deficiency correction in the elderly. Vitamin D_3 and calcium supplement as an adjunct to specific therapy for osteoporosis in patients with well-established or at high risk of vitamin D and calcium combined deficiencies. **Dosage and administration:** For adults only. One tablet to be chewed/sucked twice a day. **Contraindications:** Hypersensitivity to one of the actives or excipient constituents. Hypercalcaemia, as a result of hyperparathyroidism (primary or secondary), hypercalciuria, calcium lithiasis, tissue calcifications (nephrocalcinosis), vitamin D overdose, Myeloma and bone metastases, renal insufficiency (creatinine clearance < 20 ml/min) this product contains partially hydrogenated soyabean oil, sorbitol (E420) and sucrose. Patients should not take this product if they are allergic to peanut or soya, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Idéos® tablets are also contra-indicated in patients where prolonged immobilisation is accompanied by hypercalcaemia and/or hypercalciuria. In these cases, treatment should only be resumed when the patient becomes mobile. **Precautions and warnings:** Calculate the total vitamin D intake in case of treatment with another drug containing this vitamin. Plasma calcium and urinary calcium determinations is important in patient monitoring therefore plasma calcium and urinary levels should be monitored regularly. If additional calcium is being administered weekly monitoring of plasma calcium and urinary levels is necessary. In patients with renal impairment/failure, dosage has to be adapted accordingly to the creatinine clearance and they should be monitored. If there are signs of renal problems, kidney stones or presence of hyper calcaemia signs then treatment should be adjusted or stopped. In case of long-term treatment, the urinary calcium excretion must be monitored and treatment must be reduced or suspended if urinary calcium excretion exceeds 7,5 to 9 mmol/24 hours (300 to 360mg/24 hours). This product should be prescribed with caution in patients with sarcoidosis due to the risk of metabolism of Vitamin D to its active form. These patients should be monitored for serum and urinary calcium. **Interactions**: **with digitalis glycosides**: Risk of cardiac arrhythmias. Clinical surveillance is required and possibly electrocardiographic and plasma calcium monitoring recommended. **With thiazides diuretics**: risk of hypercalcaemia by decreasing urinary calcium excretion. **Impairment of the intestinal absorption** of oral tetracyclines, etidronate, fluoride or iron. At least 3 hours should intervene between the consumption of Idéos® and these agents. **Estramustine and thyroid hormones:** calcium may reduce the absorption so it is recommended to take Ideos either 4 hours before or after. **Strontium**, it is recommended to avoid taking Idéos immediately before or after strontium containing medicines. **Orlistat, ion exchange resins or laxatives** have the potential to reduce the absorption of Vitamin D. **Ferric Salt, Zinc:** Risk of reduced gastrointestinal absorption of salts, advised to take Idéos® either 2 hours at a minimum before or after taking Ideos. **Foods** containing oxalic acid (e.g rhubarb, spinach, sorrel, cocoa, tea), phosphate (e.g pork, ham, sausages, processed cheese, dessert cream, beverages containing cola etc.) as these foods may reduce the absorption of calcium. Therefore it is recommended that meals containing these foods sometime after or before Ideos. **Pregnancy and Lactation: Pregnancy:** This product can be used during pregnancy and lactation, however the dose should not exceed 1500mg of calcium and 600 IU of vitamin D as overdose can lead to physical and mental retardation supravalvular aortic stenosis and retinopathy in the child. **Lactation:** During lactation the use of additional vitamin D in the child should be considered as Vitamin D and its metabolites pass into breast milk. **Effects on ability to Drive and Use Machines:** None. **Undesirable effects:** Uncommon (>1/1,000 <1/100) or rare (>1/10,000 <1/1000) Cases of hypersensitivity reactions such as angioedema or laryngeal oedema have been reported. **Uncommon:** hypercalcaemia and hypercalciuria. **Rare**: Constipation, flatulence, nauseam abdominal pain, diarrhoea, puritus, rash and urticaria. **Overdose**: Can lead to hypervitaminosis and hypercalcaemia, extreme cases may lead to coma and even death. Please see SmPC for symptoms and treatment in case of overdose. **Pharmacodynamic and pharmacokinetic properties:** Ideos is a fixed combination of calcium and vitamin D. Vitamin D is involved in the calcium- phosphate metabolism and allows active absorption of calcium and phosphorus from the intestine and their uptake by bone, Calcium is absorbed in the small intestine and is eliminated in sweat and gastrointestinal secretions. Urinary calcium excretion depends on glomerular filtration and rate of tubular resorption of calcium. Vitamin D is absorbed from the intestine and transported to the liver and to the kidney. Non-hydroxylated vitamin D is stored in muscle and adipose tissue. There is a half-life of several days and it is eliminated in faeces and urine. **Package Quantities:** Pack size 60 tablets (4 tubes of 15 tablets) **PA number: 1033/1/1 MAH:** LABORATOIRE INNOTECH INTERNATIONAL 22 Avenue Aristide Briand 94110 Arcueil – France. **Legal category: P Pharmacy only**

For a copy of the SmPC or further medical information, please contact medical@dccvital.com
Adverse events should be reported to Fannin Ltd, Pharmacovigilance at 01 2907179 or medical@dccvital.com

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 16764971; Fax: +353 16762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Date of last PI revision: August 2017

IE17/7/SmPC - April 2014.

References:
1. Institute of Medicine (IOM) 2011. Dietary Reference Intakes for Calcium and Vitamin D. Washington: National Academies Press.
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3. Avenell et al. Vitamin D and vitamin D analogues for preventing fractures in post-menopausal women and older men. Cochrane Database Syst Rev. 2014 Apr (14:4)
4. U.S Department of Health and Human Services. *Bone Health and Osteoporosis: A Report of the Surgeon General.* Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General, 2004.
5. Heaney, R. P. (2005). Vitamin D: Role in the Calcium Economy. In Vitamin D (Vol. 1, pp. 773-787).
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7. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC: National Academy Press, 2010.
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9. International Osteoporosis Foundation (2012) Stop at One. www.iofbonehealth.org
10. Diet, nutrition and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation, Geneva, 28 January – 1 February 2002.

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Fannin
Caring for life

Date of preparation: September 2017
IE2017/011/00

Idéos®

500mg/400IU Chewable Tablets
Calcium & Vitamin D_3 Combined

Great Taste…with a hint of Lemon

Fannin
Caring for life

What are the daily nutritional recommendations of Calcium and Vitamin D?

Optimal daily dose of a combined supplementation:
1000mg Calcium + 800IU Vitamin D3 [1,2,3]

2x =

Ideos tablets

contain **BOTH** your daily recommended Calcium and Vitamin D intake

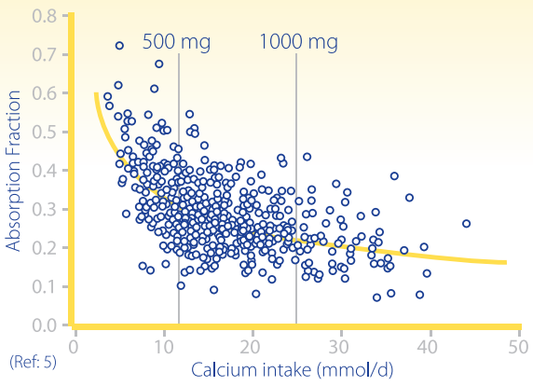
Calcium (1000mg) **Vitamin D (800IU)**

What contains your daily recommeded Calcium/Vitamin D intake? [4]

	Measure		Measure
Cheddar Cheese	1.5 oz.	Milk	2 Cups
Whole Milk	8 fl oz.	Baked Salmon	3 oz.
Canned Salmon	3 oz.	Canned Tuna	3 oz.
Vanilla Ice Cream	1/2 Cup	Sardines	1 oz.
Whole Bread	5 Slices	Pork Sausage	2 oz.
Tortilla	1	Raisin Bran Cereal	3/4 Cup
		Egg Yolk	2

Calcium table = 1000mg Vitamin D table = 800 IU

Maximising your Calcium Intake

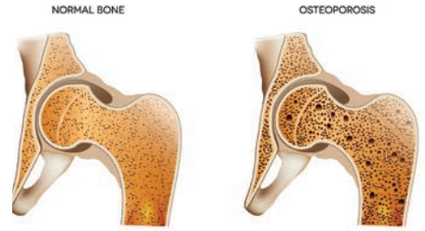


(Ref: 5)

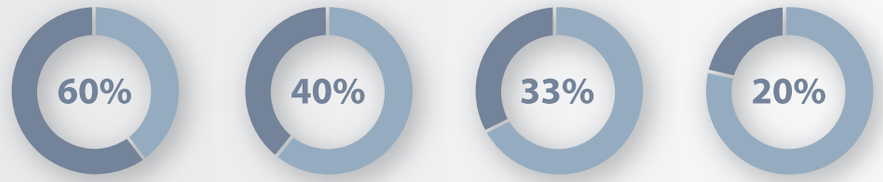
- Supplementation of 1000 mg/day of calcium should be split for better absorption. [5]
- The percentage of calcium absorbed depends on the total amount of elemental calcium consumed at one time; as the amount increases, the percentage absorption decreases. [6]
- Absorption is highest in doses ≤500 mg. [7] Therefore Ideos is recommended to be taken twice daily (2 x 500mg tablets) at different intervals.

[OSTEOPOROSIS = SILENT KILLER]

- **After reaching the age of 50: 1 woman in 3 will have a vertebral fracture, 1 in 5 will have a hip fracture** [8]
- **Unfortunately, the first clinical sign is the bone fracture**



12 MONTHS AFTER A HIP FRACTURE [9]



The Benefits of Ideos

- Lemon Flavour
- One Chewable tablet, twice a day
- Pocket Size Pack
- Suitable for diabetics
- Studies indicate a reduction in the risk of osteoporotic fractures for the older generation with sufficient intakes of Calcium and Vitamin D3 together [10]

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