Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

IDEOS 500mg/400 IU Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients per tablet:
Calcium carbonate ..... 1250 mg
(equivalent to 500 mg of elemental calcium)
Cholecalciferol (vitamin D_3) ..... 400 IU
(equivalent to 10 µg)

Excipients with known effects: 475mg sorbitol, 1.52mg sucrose, 0.3mg hydrogenated soya bean oil.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable tablets.
Greyish white, square, tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

-Vitamin D and calcium deficiency correction in the elderly.
-Vitamin D and calcium supplementation as an adjunct to specific therapy for osteoporosis in patients with established, or at high risk of vitamin D and calcium combined deficiencies.

4.2 Posology and method of administration

For adults only.
Oral use.
Chew or suck the tablets.
One tablet, twice a day.

4.3 Contraindications

-Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
-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 soybean oil. Patients should not take this medicinal product if they are allergic to peanut or soya.

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.

4.4 Special warnings and precautions for use

Additional administration of vitamin D or calcium should be carried out under strict medical supervision. In such situation, weekly monitoring of serum and urinary calcium is absolutely necessary.

During long-term treatment, it is advisable to monitor serum and urinary calcium levels and kidney function (serum creatinine levels). It is advisable to reduce or interrupt treatment temporarily if urinary calcium exceeds 7.5 mmol/24h (300 mg/ 24h). This monitoring is particularly important in the elderly, in cases of combined treatment with cardiac glycosides or diuretics (see section 4.5) and in patients who are frequently subject to the formation of kidney stones. In the presence of hypercalcaemia or signs of problems with renal function, the dose must be reduced or treatment interrupted.

The product should be used with caution in patients with renal insufficiency and the effects on calcium and phosphate homeostasis should be monitored. The risk of soft tissue calcification must be taken into account. In patients with severe renal insufficiency, vitamin D3 in the form of colecalciferol is not metabolised in the normal way and other forms of vitamin D3 must be used (see section 4.3).

The product should be prescribed with caution in patients with sarcoidosis because of the risk of increased of metabolism of vitamin D to its active form. These patients should be monitored for serum and urinary calcium.

This product contains sorbitol (E420) and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Combination requiring precautions for use

Digitalis glycosides*:* risk of cardiac dysrhythmia. Clinical surveillance is required and possibly electrocardiographic and plasma calcium monitoring are recommended.

Thiazides diuretics*:* risk of hypercalcaemia by decreasing urinary calcium excretion. It is recommended that the calcium levels in plasma are monitored regularly.

Tetracyclines, quinolones and biphosphonate: Idéos may impair the intestinal absorption of oral tetracyclines, quinolones or etidronate, the consumption of Idéos should be spaced as far as possible from them (3 hours).

Ferrous salt, zinc: Risk of reduced gastrointestinal absorption of ferrous salt or zinc. It is advisable to allow a minimum period of 2 hours before taking the calcium.

Strontium: risk of a 60 to 70% reduction in strontium bioavailability on concomitant administration of calcium-containing products. It is recommended to avoid taking calcium immediately before and after taking strontium-containing medications.

Estramustine and thyroid hormones: Calcium may reduce the absorption of estramustine and levothyroxine. It is recommended that these medicines should be taken at least four hours before or after Ideos 500mg/400IU Chewable Tablets.

Orlistat, ion exchange resins or laxatives: treatment with orlistat, ion exchange resins such as cholestyramine or laxatives such as paraffin oil may potentially reduce the absorption of Vitamine D.

Corticosteroids: systemic corticosteroids may potentially decrease calcium absorption.

Food: possible interaction with food, e.g. foods containing oxalic acid (spinach, rhubarb, sorrel, cocoa, tea, etc.), phosphate (pork, ham, sausages, processed cheese, dessert cream, beverages containing cola, etc.) or phytic acid (wholemeal cereals, dry vegetables, oleaginous seeds, chocolate, etc.).

These types of foods may reduce the absorption of calcium. It is therefore recommended that meals containing these foods be taken some time before or after ingestion of the product.

4.6 Fertility, pregnancy and lactation

This product may be used during pregnancy and lactation. However, the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D3.

Pregnancy
In pregnancy, an overdose of colecalciferol must be avoided:
- overdoses of vitamin D during pregnancy have shown teratogenic effects in animals.
- in pregnant woman: overdoses of vitamin D must be avoided as permanent hypercalcaemia can lead to physical and mental retardation, supravalvular aortic stenosis and retinopathy in the child.

There are however several case reports of administration of very high doses in hypoparathyroidism in the mother, with no adverse effect on the infant.

Lactation
Vitamin D and its metabolites pass into the breast milk. This should be considered when giving additional vitamin D to the child

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: uncommon (>1/1,000, <1/100) or rare (>1/10,000, <1/1,000).

Immune system disorders
Cases of Hypersensitivity reactions such as angiooedema or laryngeal oedema have been reported.

Metabolism and nutrition disorders
Uncommon: hypercalcaemia and hypercalciuria.

Gastrointestinal disorders
Rare: Constipation, flatulence, nausea, abdominal pain, and diarrhoea.

Skin and subcutaneous disorders
Rare: Pruritus, rash and urticaria.

Reporting of suspected adverse reactions

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. Healthcare professionals are asked to report any suspected adverse reactions via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.imb.ie/; e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

An overdose can lead to hypervitaminosis and hypercalcaemia. The symptoms of hypercalcaemia can include: anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, skeletal pain, renal calcinosis, kidney stones, and in severe cases, cardiac arrhythmia. Extreme hypercalcaemia may lead to coma and death.

Continuous high calcium levels may lead to irreversible damage to the kidneys and soft tissue calcification.
Treatment of hypercalcaemia: All calcium and vitamin D3 treatments must be stopped. Treatment with thiazide diuretics, lithium, vitamin A and cardiac glycosides must also be stopped. Gastric lavage should be performed on patients with problems affecting consciousness. Rehydrate and, depending on severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, kidney function and diuresis must be monitored. In severe cases, ECG and calcaemia should be monitored.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: VITAMIN D CALCIUM SUPPLEMENT
ATC code: A12AX
Idéos is a fixed combination of calcium and vitamin D. The high calcium and vitamin D concentration in each dose unit facilitates absorption of a sufficient quantity of calcium with a limited number of doses. Vitamin D is involved in calcium-phosphorus metabolism. It allows active absorption of calcium and phosphorus from the intestine and their uptake by bone.

5.2 Pharmacokinetic properties

Calcium carbonate

Absorption:
In the stomach, calcium carbonate releases calcium ion as a function of pH. Calcium is essentially absorbed in the proximal part of the small intestine. The rate of absorption of calcium in the gastrointestinal tract is of the order of 30% of the dose ingested.

Elimination:
Calcium is eliminated in sweat and gastrointestinal secretions.
The urinary calcium excretion depends on the glomerular filtration and rate of tubular resorption of calcium.

Vitamin D:
Vitamin D is absorbed from the intestine and transported by protein binding in the blood to the liver (first hydroxylation) and to the kidney (2nd hydroxylation).
Non hydroxylated vitamin D is stored in reserve compartments such as muscle and adipose tissues. Its plasma half-life is of the order of several days; it is eliminated in faeces and urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)
Sorbitol (E420)
Povidone
Lemon flavouring*
Magnesium stearate

* Composition of the lemon flavouring: Flavouring preparations, natural flavouring substances, maltodextrin, acacia, sodium citrate, citric acid, butylated hydroxyanisole.

Excipients in Vitamin D3 concentrate: alpha-tocopherol, partially hydrogenated soyabean oil, gelatin, sucrose, maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store in the original container.
Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene tubes and polyethylene stopper with sillica gel desiccant containing 15 tablets. Pack sizes: 30 or 60 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 avenue Aristide Briand
94110 ARCUEIL
FRANCE

8 MARKETING AUTHORISATION NUMBER

PA1033/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 January 1996

Date of last renewal: 08 January 2006

10 DATE OF REVISION OF THE TEXT

April 2014