Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

IDEOS 500mg/400 IU Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains calcium carbonate equivalent to 500 mg calcium and 400 IU (10 micrograms) colecalciferol (vitamin D_3).

Excipients with known effect
Each chewable tablet contains 475 mg sorbitol, 1.53 mg sucrose and 0.3 mg 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

IDEOS is indicated in adults for:
- 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

Posology

Adults
One tablet twice a day.

Paediatric population
There is no relevant use of IDEOS in the paediatric population.

Method of administration
Oral use.
Chew or suck the tablets.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- This medicinal product contains hydrogenated soya bean oil. Patients should not take this medicinal product if they are allergic to peanut or soya.
- Hypercalcaemia, hypercalciuria and diseases and/or conditions, which lead to hypercalcaemia and/or hypercalciuria (e.g., myeloma, bone metastases, primary hyperparathyroidism).
- Calcium lithiasis, nephrocalcinosis
- Severe renal impairment (glomerular filtration rate < 30 ml/min). In patients with severe renal impairment, vitamin D3 in the form of colecalciferol is not metabolised in the normal way and other forms of vitamin D3 must be used.
- Hypervitaminosis D.
- 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

- The product should be prescribed with caution in patients with sarcoidosis because of possible increased metabolism of vitamin D to its active form. These patients should be monitored for serum and urinary calcium.
- The medicinal product should be used with caution in patients with mild to moderate renal impairment (glomerular filtration rate between 30 ml/min to 90 ml/min). Calcium and phosphate homeostasis should be monitored. The risk of soft tissue calcification must be taken into account.
- Calcium and alkali intake from other sources (foods, dietary supplements or other drugs) should be considered when prescribing IDEOS. If very high doses of calcium are taken in combination with absorbable alkaline agents (such as carbonates), there is a risk of Burnett syndrome (or milk-alkali syndrome) consisting of hypercalcemia, metabolic alkalosis, renal failure, and soft tissue calcification. In this case, frequent monitoring of serum calcium and calciuria may be necessary.
- In case of prolonged immobilisation in patients with hypercalciuria and/or hypercalcaemia, vitamin D and calcium treatment should only be resumed when the patient becomes mobile.
- In case of 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.
- 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. **Excipients:**
- IDEOS contains 475 mg sorbitol (E 420) in each chewable tablet. Patients with hereditary fructose intolerance (HFI), should not take/be given this medicinal product.
- IDEOS contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicinal product. Sucrose may be harmful to the teeth.

IDEOS contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Combination requiring precautions for use

Digoxin: risk of serious dysrhythmia. Clinical surveillance is required. Patients should be monitored with regards to electrocardiography and calcium levels.

Biphosphonates: Risk of reduced gastrointestinal absorption of bisphosphonates. It is recommended to take calcium salts apart from bisphosphonates (30 minutes to 2 hours based on the recommendations for the bisphosphonate used).

Strontium: Risk of reduced gastrointestinal absorption of strontium on concomitant administration of calcium-containing products. It is recommended to take at least two hours apart from strontium-containing medications.

Tetracyclines per os: Risk of reduced gastrointestinal absorption of tetracycline. It is recommended to take calcium salts at least two hours apart from tetracyclines.

Rifampicin: Possible decrease in vitamin D concentrations. Vitamin D concentrations should be measured, and supplementation provided if necessary.

Ciprofloxacin, norfloxacin: Risk of reduced gastrointestinal absorption of these fluoroquinolones. It is recommended to take calcium at least two hours apart from ciprofloxacin or norfloxacin.

Dolutegravir: Risk of reduced gastrointestinal absorption of dolutegravir. It is recommended to take calcium at least 2 hours after or 6 hours before dolutegravir intake.

Ferrous salt: Risk of reduced gastrointestinal absorption of ferrous salt. It is recommended to allow a period of at least two hours between calcium and ferrous salt.

Zinc: Risk of reduced gastrointestinal absorption of ferrous salt. It is recommended to allow a period of at least two hours between calcium and zinc.

Estramustine: Risk of reduced gastrointestinal absorption of estramustine. It is recommended to allow a period of at least two hours between calcium and estramustine.

Thyroid hormones: Risk of reduced gastrointestinal absorption of thyroid hormones. It is recommended to allow a period of at least two hours between calcium and thyroid hormones.

Enzyme-inducing antiepileptic drugs (AEDs) (carbamazepine, fosphenytoin, phenobarbital, phenytoin and primidone): Possible decrease in vitamin D concentrations. Vitamin D concentrations should be measured and supplementation provided if necessary.

Combinations to be taken into account:

Orlistat: treatment with orlistat may potentially impair the absorption of Vitamine D.

Thiazides diuretics*:* Risk of hypercalcemia due to a decrease in the urinary excretion of calcium. It is recommended that the calcium levels in plasma are monitored regularly.

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

Pregnancy:
There are several case reports of administration of very high doses of vitamin D in hypoparathyroidism in the mother, where normal children were born.

In pregnancy, an overdose of colecalciferol must be avoided:

- Overdoses of vitamin D during pregnancy have shown teratogenic effects in animals (see section (5.3),
- 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.

In healthy pregnant women, the daily intake of supplemental calcium and vitamin D should not exceed 1500 mg Calcium and 600 IU vitamin D.

IDEOS is therefore not indicated for routine prophylaxis of calcium and vitamin D deficiency in pregnancy, but can be used in pregnant women who are at high risk of developing hypocalcaemia, or who already suffer from a calcium or vitamin D deficiency

Breast-feeding:
IDEOS can be used during breast-feeding. Calcium and Vitamin d pass into breast milk. This should be considered when giving additional vitamin D to the child.

Fertility:
No data is available on the effects of IDEOS on fertility. However, normal endogenous calcium and vitamin D levels are not expected to have undesired effects on fertility.

4.7 Effects on ability to drive and use machines

IDEOS has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000to 1/100) rare (≥1/10,000 to <1/1,000). very rare (<1/10,000), not known (cannot be estimated from the available data).

Immune system disorders
Not known: Hypersensitivity reactions such as angiooedema or laryngeal oedema have been reported.

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Not known: Milk-alkali syndrome (hypercalcaemia, alkalosis and renal impairment). Seen usually only in overdose (see sections 4.4 and 4.9).

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

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

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

An overdose can lead to hypervitaminosis and hypercalcaemia.

Symptoms
The symptoms of hypercalcaemia can include: anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, hypertension, 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.
The risk of overdose may be increased if other calcium containing products or alkaline agents are taken (Milk-alkali syndrome). See Sections 4.4 and 4.8.

Management
Treatment of hypercalcaemia: all calcium and vitamin D3 treatments must be stopped. The need to continue all other concomitant medicines should be reconsidered by the physician. 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. Peritoneal dialysis should be considered in patients with renal failure or in patients refractory to other therapies.
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: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS,ATC code: A12AX
Vitamin D corrects an insufficient intake of vitamin D. It increases intestinal absorption calcium and its fixation on the osteoid tissue. Vitamin D is involved in calcium-phosphorus metabolism. It allows active absorption of calcium and phosphorus from the intestine and their uptake by bone.

Calcium intake corrects a lack of calcium in the diet.
Vitamin D and calcium correct secondary senile hyperparathyroidism.

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

Non-clinical data for calcium carbonate reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, and genotoxicity.
Effects in non-clinical repeat-dose toxicity studies with vitamin D3 were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.
Vitamin D3 has no potential mutagenic or carcinogenic activity.
At very high doses, vitamin D3 has been found to be teratogenic in animals (at doses 4 to 15 times the recommended human dose).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E 967)
Sorbitol (E 420)
Povidone
Lemon flavouring*
Magnesium stearate
Alpha-tocopherol
Hydrogenated soya bean oil
Gelatin
Sucrose
Silicon dioxide
Maize starch

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

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

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Date of last renewal: 08 January 2006

10 DATE OF REVISION OF THE TEXT

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