ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IDEOS, 500mg/400 IU

Chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium ..... 500 mg

Corresponding to calcium carbonate ..... 1250 mg

Cholecalciferol (vitamin D_3) ..... 400 IU

Corresponding to Cholecalciferol concentrate (powder form) ..... 4 mg

For one tablet.

Excipients with known effect: sorbitol, sucrose, hydrogenated soya bean oil

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet.

Square, white-grey tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Correction of vitamin D and calcium combined deficiency in elderly people.
- Vitamin D and calcium supplementation as an adjunct to specific therapy for osteoporosis treatment 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.
- This product contains partially hydrogenated soybean 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).
- Kidney stones (nephrolithiasis, nephrocalcinosis).
- Hypervitaminosis D.
- Renal failure.

4.4. Special warnings and precautions for use

- In case of prolonged immobilisation in patients with hypercalciuria and/or hypercalceamia, Vitamin D and calcium treatment should only be resumed when the patient becomes mobile. (see section 4.3).

- 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.

- In case of combined treatment with digitalis, biphosphonate, thiazide diuretics, tetracyclines: see section 4.5.

- Take account of the dose of vitamin D by unit dose (400 IU) and any other prescription of vitamin D. 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.

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

- 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 cholecalciferol is not metabolised in the normal way and other forms of vitamin D3 must be used (see section 4.3).

- The product contains sorbitol, patients with rare hereditary problems of fructose intolerance 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.

- The product is not intended for use in children and adolescents.

4.5. Interaction with other medicinal products and other forms of interaction

Combination requiring precautions for use:

Digitalis
Risk of dysrythmia. The oral administration of calcium combined with vitamin D increase the toxicity of digitalis. Strict medical supervision and if necessary monitoring electrocardiographic and calcaemia are necessary.

Biphosphonate
Risk of decrease in the gastrointestinal absorption of biphosphonate. It is advisable to allow a minimum period of two hours before taking the calcium.

Thiazide diuretics
Decrease in the urinary excretion of calcium. Monitoring of calcaemia is recommended.

Tetracyclines per os
Possible reduction in the absorption of tetracycline. It is advisable to delay taking the calcium by at least three hours.

In the event of additional administration of vitamin D, at high dosage, a weekly monitoring of serum and urinary calcium is absolutely necessary.

Ferrous salt, zinc
Risk of reduced gastrointestinal absorption of ferrous salt or zinc. It is advisable to allow a minimum period of two 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 advisable to avoid calcium ingestion immediately before and after taking strontium-containing medications.

Estramustine
Risk of reduction in the gastrointestinal absorption of estramustine. It is advisable to allow a minimum period of two hours before taking the calcium.

Thyroid hormones
Risk of reduction in the gastrointestinal absorption of levothyroxine. It is advisable to allow a minimum period of two hours before taking the calcium.

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

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.). It is therefore recommended that meals containing these foods be taken some time before or after ingestion of the product.

4.6. Pregnancy and lactation

This product may be used during pregnancy and lactation. However, the daily intake should not exceed 1,500 mg calcium and 600 IU vitamin D3.

In pregnancy, an overdose of cholecalciferol must be avoided:

- overdoses of vitamin D during pregnancy have been 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, where normal children were born.

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

4.7. Effects on ability to drive and use machines

Neither known nor expected.

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.

<u>Metabolism and nutrition disorders</u>
Uncommon: hypercalcaemia and hypercalciuria.

<u>Gastrointestinal disorders</u>
Rare: Constipation, flatulence, nausea, abdominal pain, and diarrhoea.

<u>Skin and subcutaneous disorders</u>
Rare: Pruritus, rash and urticaria.

<u>Reporting of suspected adverse reactions</u>

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 the national reporting system listed in Appendix V*.

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**

Vitamin D corrects an insufficient intake of vitamin D.

It increases intestinal absorption of calcium and its fixation on the osteoid tissue.

Calcium intake corrects a lack of calcium in the diet.

The commonly accepted requirement of calcium in the elderly is 1500 mg/day.

The optimal amount of vitamin D in the elderly is 500-1000 IU/day.

Vitamin D and calcium correct secondary senile hyperparathyroidism.

5.2. Pharmacokinetic properties

Calcium carbonate

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.

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_3

Vitamin D3 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 D3 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

No relevant findings.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Xylitol, sorbitol, povidone, lemon flavouring*, magnesium stearate.

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

Composition of vitamin D3: cholecalciferol, alpha-tocopherol, partially hydrogenated soybean oil, gelatin, sucrose, corn starch.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

30 months.

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

Polypropylene tube and polyethylene stopper with silica gel desiccant containing 10 or 15 tablets.
Packs of 2, 5 or 10 tubes of 10 tablets
Packs of 2, 4, 6 or 12 tubes of 15 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

8. MARKETING AUTHORISATION NUMBERS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

December 6th, 2013.

11. DOSIMETRY

Not applicable.

12. PREPARATION INSTRUCTIONS FOR RADIOPHARMACEUTICALS

Not applicable.

Detailed information on this medicinal product is available on the website of:" name of MS/Agency"

CONDITIONS OF PRESCRIPTION AND SUPPLY

Medicinal product without medical prescription.