SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TROYCAL 500 (Calcium and Vitamin D3 Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Calcium Carbonate 1250 mg.
(Derived from highly processed oyster shells)
equivalent to elemental Calcium 500 mg.
Cholecalciferol (Vitamin D3) (As stabilized Cholecalciferol) 250 I.U

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film Coated Tablets

Light pink coloured, oblong shaped, biconvex film coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tablets should be used only as a therapeutic and not as a food supplement when the diet is deficient or when normal requirement of both components is increased.
Tablets may be used as an adjunct to specific therapy for osteoporosis or as a therapeutic supplement in established osteomalacia, pregnant patients at high risk of needing such a therapeutic supplementation or malnutrition when dietary intake is less than that required.

4.2 Posology and method of administration

Oral

Adults and elderly and children over 12 years of age:
Two chewable tablets per day, preferably one tablet each morning and evening.

Children:
Not recommended for children under 12 years.

4.3 Contraindications

Absolute contra-indications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D overdosage. Severe renal failure.

Hypersensitivity to any of the tablet ingredients.

Relative contra-indications are osteoporosis due to prolonged immobilisation, renal stones, and severe hypercalciuria.

4.4 Special warnings and precautions for use

Patients with mild to moderate renal failure or mild hypercalciuria should besupervised carefully including periodic checks of plasma calcium levels and urinarycalcium excretion.

In patients with a history of renal stones urinary calcium excretion should bemeasured to exclude hypercalciuria.

With long-term treatment it is advisable to monitor serum and urinary calcium levelsand kidney function, and reduce or stop treatment temporarily if urinary calciumexceeds 7.5mmol/24 hours (300mg/24 hours).Caution is required in patients receiving treatment for cardiovascular disease (seeSection 4.5 – thiazide diuretics and cardiac glycosides including digitalis).

Calcium Carbonate and Cholecalciferol Tablets should also be used withcaution in other patients with increased risk of hypercalcaemia e.g. patients withsarcoidosis or those suffering from malignancies.

This medicinal product contains Sorbitol and Sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucroseisomaltase insufficiency should not take this medicine.

Allowances should be made for calcium and vitamin D supplements from othersources.

4.5 Interaction with other medicinal products and other forms of interaction

The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion. Hypercalcaemia must be avoided in digitalised patients.

Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium.

Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of vitamin D.

The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium.

Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, quinolone or tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium.

4.6 Fertility, pregnancy and lactation

Pregnancy

During pregnancy treatment with Calcium Carbonate and Cholecalciferol tablets should always be under the direction of a physician and requirements for calcium and vitamin D are increased but in deciding on the required supplementation allowances should be made for availability of these agents from other sources. If Calcium Carbonate and Cholecalciferol tablets and iron supplements are both required to be administered to the patient, they should be taken at different times (see Section 4.5).

Breastfeeding

In humans, long term hypercalcaemia can lead to physical and mental retardation, aortic stenosis and retinopathy in a new born child. Vitamin D and its metabolites pass into the breast milk.

Fertility

Overdoses of vitamin D have shown teratogenic effects in pregnant animals.

However, there have been no studies on the use of this medicinal product in human fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The use of calcium supplements has, rarely, given rise to mild gastro-intestinal disturbances, such as constipation, flatulence, nausea, gastric pain, diarrhoea.

Following administration of vitamin D supplements occasional skin rash has been reported.

Hypercalciuria, and in rare cases, hypercalcaemia have been seen with long term treatment at high dosages.

4.9 Overdose

The most serious consequence of acute or chronic overdose is hypercalcaemia due to vitamin D toxicity. Symptoms may include nausea, vomiting, polyuria, anorexia, weakness, apathy, thirst and constipation. Chronic overdoses can lead to vascular and organ calcification as a result of hypercalcaemia. Treatment should consist ofstopping all intake of calcium and vitamin D and rehydration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Calcium Carbonate and Colecalciferol, **ATC code:**A12AX01

Strong evidence that supplemental calcium and vitamin D3 can reduce the incidenceof hip and other non-vertebral fractures derives from an 18 month randomisedplacebo controlled study in 3270 healthy elderly women living in nursing homes orapartments for elderly people. A positive effect on bone mineral density was alsoobserved.

In patients treated with 1200mg elemental calcium and 800IU vitamin D3 daily, i.e.the same dose delivered by two tablets of Calcium Carbonate and Colecalciferolchewable tablets, the number of hip fractures was 43% lower (p=0.043) and the totalnumber of non vertebral fractures was 32% lower than among those who receivedplacebo. Proximal femur bone mineral density after 18 months of treatment increased2.7% in the calcium/vitamin D3 group and decreased 4.6% in the placebo group (p <0.001). In the calcium/vitamin D3 group, the mean serum PTH concentrationdecreased by 44% from baseline at 18 months and serum 25-hydroxy-vitamin Dconcentration had increased by 162% over baseline.

Analysis of the intention-to-treat results showed a decreased probability of both hipfractures (p = 0.004) and other fractures (p < 0.001) in the calcium/vitamin D3treatment group. Analysis of the other two populations (active treatment and

thosetreated and followed for 18 months) revealed comparable results to the intention-totreatanalysis.

The odds ratio for hip fractures among women in the placebo group compared withthose in the calcium/vitamin D3 group was 1.7 (95% CI 1.0 to 2.8) and that for othernonvertebral fractures was 1.4 (95% Cl 1.4 to 2.1). In the placebo group, there was amarked increase in the incidence of hip fractures over time whereas the incidence inthe calcium/vitamin D3 group was stable. Thus treatment reduced the age-related riskof fracture at 18 months ($p = 0.007$ for hip fractures and $p = 0.009$ for all nonvertebralfractures). At 3 years follow-up, the decrease in fracture risk was maintainedin the calcium/vitamin D3 group.

5.2 Pharmacokinetic properties

The pharmacokinetic profiles of calcium and its salts are well known. Calcium carbonate is converted to calcium chloride by gastric acid. Calcium is absorbed to the extent of about 15-25% from the gastro-intestinal tract while the remainder reverts to insoluble calcium carbonate and calcium stearate, and is excreted in the faeces.

The pharmacokinetics of vitamin D is also well known. Vitamin D is well absorbed from the gastro-intestinal tract in the presence of bile. It is hydroxylated in the liver to form 25-hydroxycolecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycolecalciferol (calcitriol). The metabolites circulate in the blood bound to a specific α-globin. Vitamin D and its metabolites are excreted mainly in the bile and faeces.

5.3 Preclinical safety data

Calcium Carbonate and Vitamin D are well known and widely used materials and have been used in clinical practice for many years.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Micro Crystallline Cellulose
Starch (Maize)
Sodium carboxy methyl cellulose
Sodium Lauryl Sulphate
Purified water

Butylated Hydroxy Anisole
Butylated Hydroxy Toluene
Chloroform
Cros Carmellose Sodium
Magnesium Stearate
Film Coat
Ethyl Cellulose
Hydroxypropylmethylcellulose (E15)
Isopropyl Alcohol
Lake Of Erythrosine (Dye content 12-17%)
Methylene Chloride
Propylene Glycol
Titanium Dioxide

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Alu PVDC blister pack

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

TRO/IND/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

- Date of first authorization : 24 August 2015

- Date of renewal : 24July 2021

10. DATE OF REVISION OF THE TEXT

28 July 2023