

**PACKAGE LEAFLET**

**Ideos<sup>®</sup>, chewable tablet, 500mg/400 i.j,**  
Packaging: container for tablets, 2x 15 chewable tablets

Proizvođač: **INNOTHERA CHOUZY**

Adresa: **Rue René Chantereau- L'Isle Vert, 41150 Chouzy-sur-Cisse, France**

Podnosilac

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**Ideos®, 500mg/400 i.j., chewable tablets  
calcium, cholecalciferol**

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to take medicine Ideos carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve .
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet you will read:**

1. What medicine Ideos is and what it is used for
2. What you should know before you take medicine Ideos
3. How to take medicine Ideos
4. Possible side effects
5. How to store medicine Ideos
6. Further information

## **1. WHAT MEDICINE IDEOS IS AND WHAT IT IS USED FOR**

### **VITAMIN D AND CALCIUM SUPPLETION**

This medicine is indicated :

- In case of vitamin D and calcium deficiency in the elderly.
- In association to osteoporosis treatments (brittle bones), when the supply of vitamin D and calcium is insufficient.

## **2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE MEDICINE IDEOS**

### **Do not take medicine Ideos:**

- If you are allergic (hypersensitive) to vitamin D or any of the other ingredients of medicine Ideos.
- If you are allergic (hypersensitive) to peanut or soya, due to the presence of soybean oil.
- If you have abnormal high level of calcium in blood (hypercalcaemia).
- If you have high urinary calcium excretion (hypercalciuria).
- If you have a condition that lead to hypercalcaemia and/or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow (multiple myeloma), a malignant bone tumour (bone metastases)).
- If you are suffering from kidney failure (renal insufficiency).
- If you are suffering from kidney stones (nephrolithiasis) or have calcium deposits in your kidneys (nephrocalcinosis).
- If you are suffering from an excessive supply of vitamin D (hypervitaminosis D).

### **Take special care with medicine Ideos:**

- If you have long term treatment, the quantity of calcium in the blood (calcaemia) must be regularly monitored. This monitoring is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides (e.g. digoxin) or diuretics. Depending upon the result, your doctor may decide to reduce or even stop your treatment.
- If you have simultaneous treatments with calcium and vitamin D at high dosage, it is necessary to take this medicine under medical supervision.
- If you have simultaneous treatments with biphosphonate, estramustine othyroids hormones, at least 2 hours should intervene between taking these medecines and Ideos, and in the event of simultaneous treatment with tetracyclines, Ideos should be taken separately (at intervals of 3 hours).
- If you have simultaneous treatment with iron salts (which is used through mouth), strontium and zinc, at least 2 hours should intervene between taking these medecines and Ideos.
- If you are suffering from sarcoidosis or renal disorders,
- If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.
- If you are immobilized (risk of hypercalcaemia).

### **Taking other medicines with medicine Ideos**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. In particular:

**Thiazide diuretics** (medicines used to treat high blood pressure), as they may increase the amount of calcium in your blood.

**Orlistat** (a medicine used to treat obesity), cholestyramine, laxatives such as paraffin oil, as they may reduce the amount of vitamin D3 you absorb.

**Cardiac glycosides** (medicines used to treat heart problems), as they may cause more side effects if you take too much calcium.

**Tetracycline antibiotics**, as the amount absorbed may be reduced. They should be taken at least 2 hours before, or 4-6 hours after medicine Ideos.

**Estramustin** (a medicine used in chemotherapy), **thyroid hormones or medicines containing iron, zinc or strontium**, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after medicine Ideos.

**Bisphosphonates** (a treatment for bone conditions), as the amount absorbed may be reduced. They should be taken at least 3 hours before or after medicine Ideos.

Other medicines containing calcium or vitamin D while you are taking medicine Ideos. This may increase the level of calcium in your blood.

#### **Taking medicine Ideos with food and drink**

Possible interactions with food, e.g. containing oxalic acid (spinach, rhubarb, sorrel, cocoa, tea...), phosphate (pork meat, ham, sausages, processed cheese, dessert cream, drinks with cola...) or phytic acid (complete cereals, dry vegetables, oleaginous seeds, chocolate...). It is therefore recommended to take it remotely meal containing this type of food.

#### **Using of medicine Ideos during pregnancy and breast-feeding**

In case of pregnancy and breast-feeding, daily dose should not exceed 1500 mg of calcium and 600 IU of vitamin D3 i.e. one tablet a day.

During breast-feeding you can use medicine Ideos. As calcium and vitamin D3 passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D3.

Ask your doctor or pharmacist for advice before taking any medicine.

## **Driving and using machines**

Medicine Ideos should not affect your ability to drive and use machines.

## **Important information about some of the ingredients of medicine Ideos**

Medicine Ideos contains excipients sorbitol and sucrose. In case of intolerance on some sugars, please ask your doctor for advice before taking this medicine.

Medicine Ideos contains excipient partially hydrogenated soybean oil, in case of allergic to peanut or soybean oil, don't take this medicine.

## **3. HOW TO TAKE MEDICINE IDEOS**

### **Dosage**

Always take medicine Ideos exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose, for adult only, is one tablet twice a day.

#### *Dosage at patient with kidney failure*

Patients with severe kidney failure should not use the medicine Ideos, chewable tablets.

#### *Dosage at period of pregnancy*

During pregnancy daily intake must not exceed 1500 mg calcium and 600 IU vitamine D<sub>3</sub>, therefore daily dose should not be higher than one chewable tablet.

### **If you have taken more medicine Ideos than you should**

Following symptoms may occur: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones.

In these cases, stop taking medicine Ideos, chewable tablet and immediately contact your doctor for action (who will undertake the necessary procedures).

In the case of prolonged overdose, calcium deposits may appear in blood vessels or body tissues.

In the case of major overdose, cardiac arrest may occur.

### **If you forget to take medicine Ideos**

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Do not take a double dose to make up for a forgotten dose.

**If you stop taking medicine Ideos**

Not applicable.

In case of any doubt or question concerning the use of medicine Ideos, chewable tablet, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, medicine Ideos, chewable tablets can cause side effects, although not everybody gets them.

Uncommon side effect (affects 1 to 10 users in 1,000): excess calcium levels in the blood or urine.

Rare side effects (affects 1 to 10 users in 10,000): constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea, itching, skin rashes and urticaria.

Cases of serious allergic (hypersensitivity) reactions such as swelling of the face, lips, tongue or throat have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE MEDICINE IDEOS**

Keep out of the reach and sight of children!

**Shelf life**

**30 months**

Do not use medicine Ideos after the expiry date which is listed on the outer packaging. The expiry date refers to the last day of the listed month.

Do not store above 25°C.

Unused medicine should be discarded according to the current regulations.

## 6. FURTHER INFORMATION

### What medicine Ideos contains

One tablet contains:

#### The active substances are :

Calcium .....	500 mg
Corresponding quantity of calcium carbonate .....	1250 mg
Cholecalciferol (vitamin D <sub>3</sub> ) .....	400 IU
Corresponding quantity of Cholecalciferol concentrate (powder form) .....	4 mg

#### The other ingredients are :

Xylitol, sorbitol, povidone, magnesium stearate, lemon flavouring (flavouring preparations, natural flavouring substances, maltodextrin, acacia, sodium citrate, citric acid, butylated hydroxyanisole), alpha-tocopherol, partially hydrogenated soybean oil, gelatin, sucrose, corn starch.

### What medicine IDEOS® looks like and contents of the packaging

Chewable tablets..

Square, white-grey tablets.

Polypropylene tube containing 15 chewable tablets with polyethylene stopper with desiccant (silica gel).

Pack of 2 tubes of 15 chewable tablets.

Pack of 4 tubes of 15 chewable tablets.

### Marketing Authorization Holder

Farmegra d.o.o.

Kritskog odreda 4/1,

81000 Podgorica

**Manufacturer**

Innothera Chouzy  
Rue René Chantereau-L'Isle Vert  
Chouzy-sur-Cisse  
Francuska

**This leaflet was last approved in**

December, 2013

**Legal prescription status:**

The medicine can be dispensed without medical prescription.

**Number and date of MA:**

Ideos®, 500mg/400i.j. container for tablets, 2x 15 chewable tablets: 2030/13/477 – 2144 od 09.12.2013.