

## **Package leaflet: Information for the user**

### **IDEOS 500 mg/400 IU, chewable tablets**

Calcium, cholecalciferol

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What IDEOS is and what it is used for
2. What you need to know before you take IDEOS
3. How to take IDEOS
4. Possible side effects
5. How to store IDEOS
6. Contents of the pack and other information

#### **1. What IDEOS is and what it is used for**

This medicine is indicated in adults.

This medicine provides calcium and vitamin D3 (also called cholecalciferol) to the body.

This medicine is used:

- in case of vitamin D and calcium deficiency in the elderly,
- in association with some treatments of osteoporosis (a condition where bone mass decreases and bone brittleness increases), when there is deficiency or a risk of deficiency in vitamin D and calcium.

#### **2. What you need to know before you take IDEOS**

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Do not take IDEOS:**

- if you are allergic (hypersensitive) to calcium, vitamin D or any of the other ingredients of this medicine (listed in section 6),
- if you are allergic (hypersensitive) to peanut or soya, due to the presence of hydrogenated soya bean oil,
- if you have abnormal high level of calcium in your 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 (myeloma), a malignant bone tumour (bone metastases),
- if you are suffering from severe kidney disease (kidney failure),
- if you are suffering from kidney stones (calcium lithiasis) or have calcium deposits in your kidneys (nephrocalcinosis),

- if you have an excessive supply of vitamin D (hypervitaminosis D).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking IDEOS:

- if you have a long period of immobility and if you have a high concentration of calcium in blood and/or urine. Your doctor will allow you to take this medicine when you walk again,
- if you have long term treatment, regular blood and urine tests are necessary to monitor calcium levels. 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,

High levels of calcium and vitamin D may be harmful to health. Ask your doctor or your pharmacist.

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

You must tell your doctor:

- if you are suffering from sarcoidosis, a disease with most commonly symptoms such as tiredness, increase of nodules size and inflammation of lungs and other organs,
- if you are suffering from kidney disease (kidney insufficiency).

If in doubt, ask your doctor or pharmacist for advice.

### **Other medicines and IDEOS**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must tell your doctor or pharmacist if you take:

- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects,
- Bisphosphonates, or strontium containing medicines (used in osteoporosis),
- Thiazide diuretics (medicines used to treat high blood pressure or oedema), as they may increase the amount of calcium in your blood,
- Tetracycline antibiotics (medicines used to treat infections due to bacteria),
- Other medicines or supplements containing vitamin D,
- Medicines or supplements containing iron or zinc,
- Estramustine (a medicine used to treat some prostate cancers),
- Thyroid hormones, used in cases of thyroid disease,
- Orlistat (a medicine used to treat obesity), as it may reduce the amount of vitamin D<sub>3</sub> you absorb.

You should wait at least:

- 2 hours between taking IDEOS and the following medicines: medicines containing iron or zinc, bisphosphonates, estramustine, thyroid hormones,
- 3 hours in the event of simultaneous treatment with tetracycline antibiotics.

### **IDEOS with food and drink**

Possible interactions with food. You must take IDEOS either before or after meals containing:

- oxalic acid (spinach, rhubarb, sorrel, cocoa, tea...),
- phosphate (pork meat, ham, sausages, processed cheese, dessert cream, drinks with cola...),
- phytic acid (complete cereals, dry vegetables, oleaginous seeds, chocolate...).

### **Pregnancy and breast-feeding**

Women who are pregnant or breast-feeding can take IDEOS providing the daily intake does not exceed one tablet.

During breast-feeding, as calcium and vitamin D<sub>3</sub> passes into breast milk, you have to check with your doctor first if your infant receives any other products containing vitamin D<sub>3</sub>.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Not applicable.

### **IDEOS contains sorbitol and sucrose (see Warnings and precautions).**

This medicine also contains hydrogenated soya bean oil. If you are allergic to peanut or soya, do not take this medicinal product. Talk to your doctor for further advice.

## **3. How to take IDEOS**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose, for adult only, is one tablet twice a day.

### **If you take more IDEOS than you should**

Following symptoms may occur: loss of appetite, 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 IDEOS and immediately contact your doctor for action (who will undertake the necessary procedures).

If you take too many IDEOS during a long time, calcium deposits may appear in blood vessels or body tissues.

### **If you forget to take IDEOS**

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Uncommon side effects (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 may also occur.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store IDEOS**

Keep this medicine out of the sight and reach of children.

The stopper contains small granules of silica gel to keep the tablets dry. Keep the stopper out of the sight and reach of children. Do not swallow the silica gel granules.

Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.

**Store below 30°C.**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What IDEOS 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 mgFor one tablet.
  
- 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 soya bean oil, gelatin, sucrose, corn starch.

### **What IDEOS looks like and contents of the pack**

This medicine is a greyish white, square chewable tablet.

Each box contains 2, 5 or 10 tubes of 10 tablets or 2, 4, 6 or 12 tubes containing 15 tablets.

### **Marketing Authorisation Holder and Manufacturer**

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22, Avenue Aristide Briand  
94110 Arcueil  
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Manufacturer  
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**This leaflet was last revised in {month YYYY}.**

[To be completed nationally]

### **Other sources of information**

Detailed information on this medicine is available on the website of { name of MS Agency (link) }