

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.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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
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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 D₃ 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 D₃ passes into breast milk, you have to check with your doctor first if your infant receives any other products containing vitamin D₃.

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 listed in [Appendix V](#)**. 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.

Do not store above 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 D₃) 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 or 4 tubes containing 15 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL
FRANCE

Manufacturer

INNOTHERA CHOUZY
RUE RENE CHANTEREAU, CHOUZY-SUR-CISSE
41150 VALLOIRE-SUR-CISSE

This leaflet was last revised in

[To be completed nationally]

Other sources of information

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