

Package leaflet: Information for the patient

IDEOS® 500 mg/400 IU Chewable tablets

calcium / vitamin D₃

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 have 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
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 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.

This medicine is intended for use in adults.

2. What you need to know before you take IDEOS

Do not take IDEOS

- If you are allergic (hypersensitive) to calcium or vitamin D or any of the other ingredients of this medicine. (listed in section 6).
- If you are allergic (hypersensitive) to peanut or soya (this product contains soybean oil)
- If you have high calcium levels in your blood (hypercalcaemia).
- If you have high levels of calcium in your urine (hypercalciuria).
- If you have a condition that leads to hypercalcaemia and/or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow, a malignant bone tumor, bone metastases).
- If you are suffering from kidney disease (kidney failure)
- If you are suffering from kidney stones (calcium lithiasis) or if you have calcium deposits in your kidneys (nephrocalcinosis).
- If you have high levels of vitamin D in your blood (hypervitaminosis D)
- If you are immobile for a great part of the day.

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 can walk again.
- In case of prolonged treatment, regular blood and urine tests are necessary to monitor calcium levels in your blood and urine. This monitoring is particularly important in the elderly and where IDEOS 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). If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

You must tell your doctor:

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

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 drugs containing strontium (used in osteoporosis),
- thiazide diuretics (medicines used to treat high blood pressure or water retention), as they may increase the amount of calcium in your blood,
- tetracycline and quinolone antibiotics (medicines used to treat infections due to bacteria),
- other medicines or supplements containing vitamin D,
- estramustine (a medicine used to treat some prostate cancers) as IDEOS can reduce its effect,
- thyroid hormones used in cases of thyroid disease
- orlistat (a medicine used to treat obesity), ion exchange resins such as cholestyramine or laxatives such as paraffin oil, as they may reduce the amount of vitamin D you absorb
- corticosteroids, as they may decrease the absorption of calcium,

You should wait at least:

- 2 hours between taking IDEOS and medicines containing iron or zinc,
- 3 hours in the event of simultaneous treatment with tetracycline or quinolone antibiotics (medicines used to treat infections due to bacteria) or bisphosphonates (used in osteoporosis)
- 4 hours between taking IDEOS and estramustine or thyroid hormones

IDEOS with food and drink

This medicine is likely to interact with some foods. You must take IDEOS before or after meals containing, for example oxalic acid (spinach, rhubarb, sorrel, cocoa, tea...), phosphates (pork meat, ham, sausages, processed cheese, dessert cream, drinks with cola...), or phytic acid (complete cereals, dry vegetables, oleaginous seeds, chocolate...).

Pregnancy and breast-feeding

This medicine can be used during pregnancy and breast-feeding. However, you should not exceed one tablet daily. During breast-feeding, as calcium and vitamin D₃ passes into your 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 any medicine.

Driving and using machines

Ideos tablets are not expected to affect your ability to drive or use machines.

IDEOS contains sorbitol (E420) and sucrose (see section 2 'Warning and precautions')

Ideos tablets contain soybean oil. If you are allergic (hypersensitive) to peanut or soya, do not take this medicinal product. Talk to your doctor for further advice.

3. How to take IDEOS

Dosage

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 usual dose, for adults only, is 2 tablets per day. Chew the tablets completely before swallowing. Then drink a glass of water.

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.

If such effects occur, contact your doctor immediately.

He/she will undertake the necessary procedures.

If you take too much 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

Cases of serious allergic reactions such as swelling of the face, lips, tongue or throat may occur. If any of these symptoms occur, seek immediate medical attention.

The following side effects are uncommon (affect 1 to 10 users in 1,000):

- excess calcium levels in the blood or urine

The following side effects are rare (affect 1 to 10 users in 10,000):

- constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea
- itching, skin rashes and urticaria (nettle rash)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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.

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

Store in the original container. Do not store above 25 °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 protect the environment.

6. Contents of the pack and other information

What IDEOS contains

- **The active substances are:** calcium and cholecalciferol (vitamin D₃). Each tablet contains 500mg of calcium (as calcium carbonate) and 10 micrograms of cholecalciferol (corresponding to 400 IU of vitamin D₃).

- **The other ingredients are:**

Product imported from Spain: xylitol (E967), sorbitol (E420), povidone, magnesium stearate, lemon flavouring (essential oils of lemon, orange, litsea cubeba, maltodextrin, acacia gum, sodium citrate). The vitamin D₃ concentrate may contain sucrose and soybean oil.

Product imported from Greece: Xylitol (E967), Sorbitol (E420) Povidone, Magnesium stearate Lemon flavouring (flavouring preparations, natural flavouring substances, maltodextrin, acacia, sodium citrate, citric acid, butylated hydroxyanisole) Excipients in Vitamin D₃ concentrate (cholecalciferol): alpha-tocopherol, partially hydrogenated soybean oil, gelatin, sucrose, maize starch.

What IDEOS looks like and contents of the pack

This medicine is a greyish, white, square chewable tablet.

IDEOS chewable tablets are available in packs of 4 tubes of 15 tablets (60 tablets).

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Ideos Tablets are manufactured by Innothera Chouzy, Rue Rene Chantereau – L'Isle Vert, 41150 Chouzy sur Cisse, France.

Parallel Product Authorisation number: PPA 465/128/1

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