

IDEOS® 500mg/400IU Chewable Tablets

(Calcium / Vitamin D)

Ref: 078/001/0902151F

Package leaflet: Information for the user

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

This medicine is available without prescription. However, you still need to take Ideos 500 mg/400 IU, chewable tablets 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 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.

The name of this medicine is Ideos 500mg/400IU Chewable tablets and it will be referred to as Ideos throughout this leaflet.

In this leaflet:

- ➊ What Ideos is and what it is used for
- ➋ Before you take Ideos
- ➌ How to take Ideos
- ➍ Possible side effects
- ➎ How to store Ideos
- ➏ Further information

➊ 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.

➋ 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. See composition 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.

Talk to your doctor before taking this product if any of the above apply to you.

Take special care with 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 commonly 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.

Taking or using 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,
- * estramustin (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.

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

Taking Ideos with food and drink

This medicine is likely to interact with some foods.

You must take Ideos before or after meals containing, for examples 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...).

Driving and using machines

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

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 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.

IDEOS® 500mg/400IU Chewable Tablets

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(Calcium / Vitamin D)

Patient Information Leaflet (continued)

Important information about some of the ingredients of Ideos

This medicine contains sorbitol (E420) and sucrose (see "Take special care with Ideos"). 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 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 2 tablets per day. Chew the tablets completely before swallowing. Then drink a glass of water.

If you have taken 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 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 product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Ideos 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 reach and sight of children.

Do not use Ideos 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 original container. Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Futher 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: xylitol (E967), sorbitol (E420), 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, maize starch.

What Ideos looks like and contents of the pack

They are greyish white square, chewable tablets. Ideos chewable tablets are available in packs of 4 tubes of 15 tablets (60 tablets).

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Innothera Chouzy, Rue Rene Chantereau, L'Isle Vert, 41150 Chouzy-Sur-Cisse, France.

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Tel: +44 (0)1527 505414 for help.