

Package leaflet: Information for the user

DELTIUS 10 000 I.U. /ml oral drops, solution Cholecalciferol (vitamin D₃)

Read all of this leaflet carefully before you start using 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, or nurse.
- 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, or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

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

1. What DELTIUS is and what it is used for

DELTIUS oral drops contains cholecalciferol (vitamin D₃). Vitamin D₃ can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D₃ helps the kidneys and intestine absorb calcium and it helps build bones. Vitamin D₃ deficiency is the predominant cause of rickets (defective mineralization of bones in children) and osteomalacia (inadequate mineralization of bones in adults).

DELTIUS oral drops are used:

- to prevent rickets in children (defective mineralization of bones predominantly due to vitamin D₃ deficiency) and osteomalacia in adults (inadequate mineralization of bones predominantly due to vitamin D₃ deficiency).
- to prevent rickets in preterm newborns.
- to prevent vitamin D₃ deficiency in children and adults when a risk of deficiency is identified.
- to prevent vitamin D₃ deficiency in children and adults with problems in absorbing food (malabsorption) defined by doctor.
- to treat rickets in children and osteomalacia in adults.

2. What you need to know before you use DELTIUS

Do not use DELTIUS:

- if you are allergic to vitamin D₃ or any of the other ingredients of this medicine (listed in section 6);
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria);
- if you have kidney stones (renal calculi);

- if you have high levels of vitamin D₃ in your blood (hypervitaminosis D).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using DELTIUS if you:

- are undergoing treatment with certain medicines used to treat heart disorders (eg, cardiac glycosides, such as digoxin);
- have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D₃ in the body);
- are taking medicines containing vitamin D₃ or eating foods or milk enriched with vitamin D₃;
- are likely to be exposed to a lot of sunshine whilst using DELTIUS;
- take additional supplements containing calcium. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using DELTIUS;
- have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.
- take a daily dose of vitamin D₃ exceeding 1,000 I.U. over a long period of time, your doctor should monitor the level of calcium in your blood by lab test.

Other medicines and DELTIUS

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines. This is especially important if you are taking:

- medicines that act on the heart or kidneys, such as cardiac glycosides (eg, digoxin) or diuretics (eg, bendroflumethazide). When used at the same time as vitamin D₃, these medicines may cause a large increase in the level of calcium in the blood and urine;
- medicines containing vitamin D₃ or eating food rich in vitamin D₃, such as some types of vitamin D₃-enriched milk;
- actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (eg, clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body processes vitamin D₃;
- the following medicines because they can interfere with the effect or the absorption of vitamin D₃;
 - antiepileptic medicines (anticonvulsants), barbiturates,
 - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D₃,
 - medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol),
 - certain medicines for weight loss that reduce the amount of fat your body absorbs (eg, orlistat),
 - certain laxatives (such as liquid paraffin).

DELTIUS with food, drink and alcohol

You should take this medicine preferably together with a large meal to help your body absorb the vitamin D₃. You can also mix the drops with cold or lukewarm food, to help you take this medicine. For detailed information see section 3 “How to use DELTIUS”.

Pregnancy, breast-feeding and fertility

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. DELTIUS should be used during pregnancy and breast-feeding only if recommended by your doctor.

Driving and using machines

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or to operate machinery.

3. How to use DELTIUS

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

1 drop contains 200 IU vitamin D₃.

Shake before use.

You should take DELTIUS preferably together with a large meal.

This medicine has a delicate taste of olive oil. It can be taken on its own or you can mix the prescribed number of drops with a spoonful or a small amount of cold or lukewarm food immediately before use. Make sure the entire dose is taken.

Use in children and adolescents

The recommended dose for:

- **Prevention of deficiency 0-1 years:** 400 IU/day (2 drops)
- **Prevention of deficiency 1-18 years:** 600 IU/day (3 drops)
- Higher doses may be required, based on the advice of your doctor.
- **Treatment of deficiency 0-18 years:** 2000 IU/day (10 drops) for 6 weeks, followed by maintenance therapy of 400-1000 IU/day (2-5 drops).

In children, DELTIUS can be mixed with a small amount of children's foods, yogurt, milk, cheese or other dairy products. Do not mix this medicine into a bottle of milk or container of soft food, in case your child does not consume the whole portion, and does not receive the full dose. You should make sure that the entire dose is taken. For children who are no longer breast-feeding you should give the prescribed dose with a substantial meal.

Do not store any product or food mixture that contains DELTIUS for use at a later time or a next meal.

Use in pregnancy and breast-feeding

The recommended dose for:

- **Prevention of deficiency:** 400 IU/day (2 drops)
- Higher doses may be required based on the advice of your doctor.

Use in adults

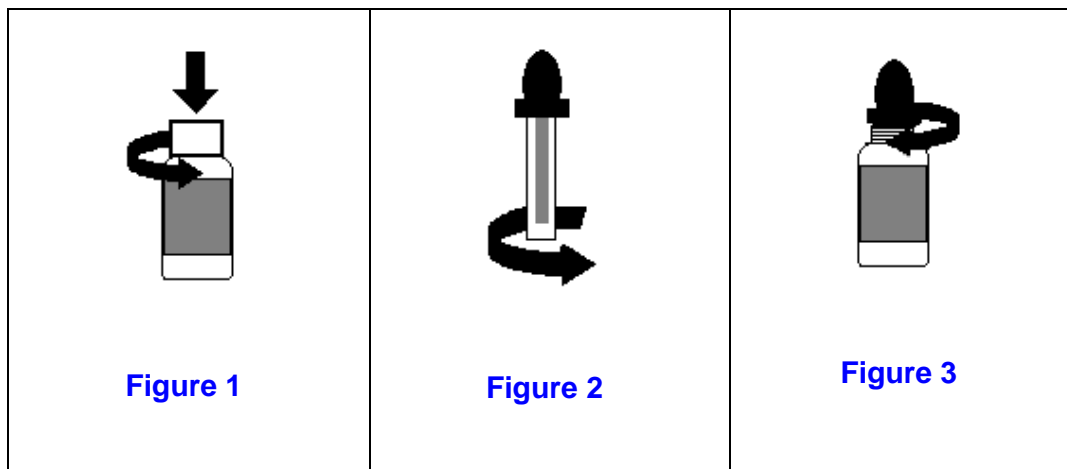
The recommended dose for:

- **Prevention of vitamin D₃ deficiency:** 600 – 800 IU/day (3 – 4 drops). Higher doses may be required based on the advice of your doctor.
- **Addition to specific therapy for osteoporosis:** 800 IU/day (4 drops).

Instructions for use

The pack contains 1 bottle and a dropper applicator cap. The bottle is sealed with a plastic childproof cap. The dropper is protected by a plastic cylinder. Shake the bottle before use and follow the instructions below:

- a. To open the bottle, press down and twist the cap at the same time (see Figure 1);
- b. Before using the dropper applicator cap for the first time, twist off the plastic cylinder by unscrewing the plastic cylinder stem from the dropper applicator cap (see Figure 2);
- c. Insert the dropper applicator cap into the bottle to take up the contents. Collect the prescribed number of drops onto a spoon;
- d. To close the bottle, carefully screw the dropper applicator cap until closed (there is no need to press down) (see Figure 3);
- e. Place the medicine bottle back into the original package.



If you take more DELTIUS than you should

If you or your child take more medicine than prescribed, stop using this medicine and contact your doctor. If it is not possible to talk to a doctor go to the nearest hospital emergency department and take the medicine package with you.

The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood and in urine (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take DELTIUS

If you forget to take a dose of DELTIUS, take the forgotten dose as soon as possible. Then take the next dose at the correct time. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal.

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.

Possible side effects reported with the use of DELTIUS may include:

Uncommon (affects less than 1 in 100 people)

- Too much calcium in your blood (hypercalcaemia)
- Too much calcium in your urine (hypercalciuria)

Rare (affects less than 1 in 1000 people)

- Skin rash
- Itching
- Hives

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DELTIUS

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 bottle after "Exp". The expiry date refers to the last day of that month.

Do not store above 30° C.

Keep the bottle in the outer carton in order to protect from light.

Do not freeze or refrigerate.

After the first opening of the bottle: the product may be stored for a maximum of 6 months.

Do not use this medicine if you notice the solution is cloudy.

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 DELTIUS contains

The active substance is cholecalciferol (vitamin D₃).

1 ml oral solution (50 drops) contains 10 000 I.U. cholecalciferol (vitamin D₃), equivalent to 0.25 mg.

1 drop contains 200 I.U. cholecalciferol (vitamin D₃).

The other ingredient is refined olive oil.

What DELTIUS looks like and contents of pack

DELTIUS 10 000 I.U./ml oral drops is a clear and colourless to greenish-yellow oily solution without visible solid particles and/or precipitate. It is supplied in a 10 ml amber glass bottle sealed with a plastic childproof cap.

Each pack contains 1 amber glass bottle containing 10 ml solution (corresponding to 500 drops), and 1 dropper applicator cap.

Marketing authorisation holder

Italfarmaco S.p.A.
Viale Fulvio Testi, 330
20126 – Milano, Italy

Manufacturer

Abiogen Pharma S.p.A.
Via Meucci, 36 – Pisa (Italy)
info@abiogen.it

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom, France, Greece, Spain and Portugal: DELTIUS 10,000 I.U./ml

This leaflet was last revised in (Date of approval to be inserted in MM/YYYY)