

**Package leaflet: Information for the user**

**DELTIUS 25 000 I.U. /2.5 ml oral solution**

**Cholecalciferol (vitamin D<sub>3</sub>)**

**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 solution contains cholecalciferol (vitamin D<sub>3</sub>). Vitamin D<sub>3</sub>, can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D<sub>3</sub> helps the kidneys and intestine absorb calcium and it helps build bones. Vitamin D<sub>3</sub> deficiency is the predominant cause of rickets (defective mineralization of bones in children) and osteomalacia (inadequate mineralization of bones in adults).

DELTIUS oral solution is used:

- to prevent rickets in children (defective mineralization of bones predominantly due to vitamin D<sub>3</sub> deficiency) and osteomalacia in adults (inadequate mineralization of bones predominantly due to vitamin D<sub>3</sub> deficiency).
- to prevent rickets in preterm newborns.
- to prevent vitamin D<sub>3</sub> deficiency in children and adults when a risk of deficiency is identified.
- to prevent vitamin D<sub>3</sub> 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 D<sub>3</sub> 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 D<sub>3</sub> in your blood (hypervitaminosis D)

### **Warnings and precautions**

Talk to your doctor, 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 D<sub>3</sub> in the body);
- are taking medicines containing vitamin D<sub>3</sub>, or eating foods or milk enriched with vitamin D<sub>3</sub>;
- 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 D<sub>3</sub> 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, 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 D<sub>3</sub> these medicines may cause a large increase in the level of calcium in the blood and urine;
- medicines containing vitamin D<sub>3</sub> or eating food rich in vitamin D<sub>3</sub>, such as, some types of vitamin D<sub>3</sub>-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 process vitamin D<sub>3</sub>;
- the following medicines because they can interfere with the effect or the absorption of vitamin D<sub>3</sub>:
  - antiepileptic medicines (anticonvulsants), barbiturates;
  - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D<sub>3</sub>;
  - 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 D<sub>3</sub>. You can also mix the solution 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.

This high strength formulation is not recommended for use in pregnant and breastfeeding women.

### **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.

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 from the bottle or to help you take the medicine you can also mix the solution with 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:** 25000 IU (1 bottle) every 8 weeks
- **Prevention of deficiency 1-18 years:** 25000 IU (1 bottle) every 6 weeks
- **Treatment of deficiency 0-18 years:** 25000 IU (1 bottle) once every 2 weeks for 6 weeks (followed by maintenance therapy of 400-1000 IU/day)

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

- This high strength formulation is not recommended

#### Use in adults

The recommended dose for:

- **Prevention of vitamin D<sub>3</sub> deficiency:** 25000 IU/month (1 bottle), higher doses may be required, based on the advice of your doctor.
- **Addition to specific therapy for osteoporosis:** 25000 IU/month (1 bottle)
- **Treatment of vitamin D<sub>3</sub> deficiency:** 50000 IU/week (2 bottles) for 6-8 weeks, followed by maintenance therapy (1400-2000 IU/day may be required), based on the advice of your doctor.

#### 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 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](http://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.

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 D<sub>3</sub>).  
A single-dose bottle of 2.5 ml oral solution contains: 25 000 I.U. cholecalciferol (vitamin D<sub>3</sub>) equivalent to 0.625 mg  
1 ml oral solution contains 10 000 I.U. cholecalciferol (vitamin D<sub>3</sub>), equivalent to 0.25 mg
- The other ingredient is refined olive oil.

**What DELTIUS looks like and contents of pack**

DELTIUS 25 000 I.U./2.5 ml oral solution, is a clear and colourless to greenish-yellow oily solution without visible solid particles and/or precipitate. It is supplied in an amber glass bottle sealed with a plastic cap.

Each pack contains 1 or 4 single dose bottles containing 2.5 ml solution.

Not all pack sizes may be marketed.

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

United Kingdom, France, Greece, Portugal and Spain: DELTIUS 25,000 I.U./2,5 ml

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