

Package leaflet: Information for the patient

Fultium-D₃ 25000 IU Oral Solution cholecalciferol (vitamin D₃)

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

What is in this leaflet

1. What Fultium-D₃ is and what it is used for
2. What you need to know before you take Fultium-D₃
3. How to take Fultium-D₃
4. Possible side effects
5. How to store Fultium-D₃
6. Contents of the pack and other information

1. What Fultium-D₃ is and what it is used for

Fultium-D₃ contains the active ingredient cholecalciferol (vitamin D₃):

Vitamin D₃ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Fultium-D₃ is used for initial treatment of symptomatic vitamin D deficiency in adults.

2. What you need to know before you take Fultium-D₃

Do not take Fultium-D₃

- if you are allergic to vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria)
- if you have kidney stones or serious kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fultium-D₃

- if you have kidney damage or disease. Your doctor will need to measure the levels of calcium in your blood or urine
- if you are being treated for heart disease
- if you have sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- if you are already taking additional doses of calcium or vitamin D. While you are taking Fultium-D₃ your doctor will monitor your blood levels of calcium to make sure they are not too high.
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Other medicines and Fultium-D₃

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular the following medicines may interact with Fultium-D₃

- Heart medicines (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood.
- Medicines to treat epilepsy (such as phenytoin) or medicines to make you sleep (barbiturates such as phenobarbitone) as these medicines can decrease the effect of vitamin D.
- Glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D.
- Laxatives (such as paraffin oil) or a cholesterol lowering drug called colestyramine may reduce the absorption of vitamin D.
- Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (medicines such as clotrimazole and ketoconazole used to treat fungal diseases) as they may interfere with the metabolism of vitamin D.

Children and adolescents

Fultium-D₃ 25000 IU Oral Solution is not recommended in children and adolescents under 18 years of age.

Pregnancy and breast-feeding

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

Fultium-D₃ has no known effects on ability to drive or use machines.

3. How to take Fultium-D₃

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

Fultium-D₃ 25000 IU Oral Solution can be taken as is from the bottle or dispensed onto a spoon. The oral solution can be mixed with a small amount of cold or lukewarm food immediately before taking. The whole portion should be consumed.

The bottle should be shaken before use.

The recommended dose is 1 bottle per week during the first month, your doctor will adjust the dose for you.

Use in children and adolescents

Fultium-D₃ 25000 IU Oral Solution is not recommended in children and adolescents under 18 years of age.

If you take more Fultium-D₃ than you should

If you accidentally take more medicine than prescribed tell your doctor or get other medical advice immediately. If possible, take the bottle, the box and this leaflet with you to show the doctor. If you take too much solution you may feel or be sick, become constipated or have stomach pains, weak muscles, tiredness, lack of appetite, kidney problems and in severe cases irregular heartbeats.

If you forget to take Fultium-D₃

If you forget to take a dose of Fultium-D₃, take the forgotten dose as soon as you can. Do not take a double dose to make up for a forgotten dose. After that, take the next dose in accordance with the instructions given to you by your doctor.

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.

Side effects with Fultium-D₃ may include:

Uncommon side effects (affecting less than 1 in 100 people)

- too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion
- too much calcium in your urine (hypercalciuria).

Rare side effects (affecting less than 1 in 1000 people)

- skin rash
- itching
- hives

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions 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

5. How to store Fultium-D₃

Do not freeze.

Store bottle in the original carton in order to protect from light.

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 after “EXP”. The expiry date refers to the last day of that month.

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 Fultium-D₃ 25000 IU Oral Solution contains

The active substance is cholecalciferol (vitamin D₃). 1 single-dose bottle with 2,5 ml contains 25 000 IU cholecalciferol corresponding to 625 microgram vitamin D₃.

The other ingredient is:

- Refined olive oil

What Fultium-D₃ looks like and contents of the pack

Fultium-D₃ 25000 IU Oral Solution is a pale yellow transparent oil. Do not use this medicine if you notice the solution is cloudy.

It is supplied in an amber glass bottle for single use only.

Each pack contains 1 bottle containing 2.5 ml oral solution.

Marketing Authorisation Holder and Manufacturer**The Marketing Authorisation Holder is:**

STADA Arzneimittel AG,
Stadastraße 2–18,
61118 Bad Vilbel
Germany

The Manufacturer is:

Mipharm S.p.A
Via B. Quaranta, 12
20141 Milano
Italy

Thornton and Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

Distributed by:

Clonmel Healthcare Ltd.
Clonmel, Co. Tipperary, Ireland

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

Denmark:	Fultium
Finland:	Fultium 25 000 IU oraalliuos
Germany:	EUNOVA Vitamin D3 UNO 25.000 I.E. Lösung zum Einnehmen
Ireland:	Fultium-D ₃ 25000 IU Oral Solution
Netherlands:	Vitamine D ₃ STADA 25.000 IE drank
Norway:	Fultium 25000 IU mikstur
Poland:	Fultium-D ₃ , 25 000 IU, roztwór doustny
Sweden:	Fultium 25 000 IE oral lösning

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